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**THREE-PART DISHARMONY: THE TRANSFORMATION OF THE FOOD AND
DRUG ADMINISTRATION IN THE 1970s**

BY

BARBARA RESNICK TROETEL

**A dissertation submitted to the Graduate Faculty in History in partial fulfillment
of the requirements for the degree of Doctor of Philosophy, The City University
of New York**

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Abstract

THREE-PART DISHARMONY: THE TRANSFORMATION OF THE FOOD AND
DRUG ADMINISTRATION IN THE 1970s

by

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For most of its history, the FDA had been a relatively unknown cog in the Federal regulatory bureaucracy with a limited staff and budget, restricted duties, and little public interaction. During the 1970s, however, the Food and Drug Administration became a modern regulatory agency with extensive and complex responsibilities, responsive to the demands of Congress, industry, consumer and health groups, and the media. Three forces transformed the FDA: 1) new leadership that sought to reconceptualize the FDA as a modern bureaucracy capable of regulating the changing technology of the food, drug, cosmetic, medical device, and biotechnology industries; 2) demands by the consumer movement for greater accountability and public participation in government decision-making, that resulted in revised and expanded Freedom of Information, Federal Advisory Committee, and Administrative Procedures Acts; and 3) a profound shift in the attitude of the public toward the health, medicine, and diet. A significant and influential segment of middle-class America had begun to lose faith in the miracles of modern medicine, which had made little headway against the chronic killers--heart disease, stroke, and cancer. As

science began to establish strong links between illness and environmental and behavioral factors, consumer groups charged that ordinary foods and consumer products contained substantial health risks. These groups demanded that the FDA ensuring the purity of the food supply, the safety and effectiveness of drugs, and provide consumers with information to make informed decisions about their health. The transformation of the FDA mirrored the changing perceptions of governance, the attitudinal shifts toward health, and the rapidly changing scientific environment in the food and pharmaceutical sciences in the 1970s. Three cases studies illustrate this changing dynamic: 1) efforts to remove Red Dye No. 2; 2) the FDA's decision to ban saccharin, and 3) the development of patient package inserts for prescription drugs (information to be given directly to the patient). They represented complex public policy issues. Deriving answers often produced "three-part disharmony" at the FDA. But by opening the dialogue, FDA's decisions more closely reflected the pluralistic nature of American society.

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CHAPTER 1

"THE PASSING OF THE OLD ORDER"

The beginning of wisdom is the recognition that no one--no matter how wise and objective--has the capacity to state reliably and in a universally acceptable manner what benefits the public truly wants and what costs (and risks) it is willing to bear for the sake of those benefits."¹

The removal of cyclamate from the market in 1969 was the final act of the old order at the Food and Drug Administration. It marked the end of FDA decision-making without public comment, without public hearings, without congressional hearings and investigations, and without extensive media coverage. The end of a time when the FDA, after only a brief in-house review of data linking cyclamate with bladder cancers in rats, could inform the public that it would immediately remove a popular artificial sweetener from the market without further input from the public, Congress or even industry.

By contrast, the 1977 decision to remove saccharin, another artificial sweetener, came after years of study and consultation with outside scientists, produced a blizzard of angry letters and calls to FDA, and a media blitz denouncing FDA's action by soft drink companies, the chief users of saccharin. FDA officials held press conferences to justify and explain their position. Following detailed procedures for public involvement in regulatory decision-making developed in the previous decade, they announced their intention to ban saccharin in the Federal Register, invited comments by all interested parties and held well-publicized hearings at FDA

¹Harold Green, "The Recombinant DNA Controversy: A Model of Public Influence," Bulletin of the Atomic Scientists 34 (November 1978): 13.

headquarters. Responding to demands by its enraged constituents, Congressional committee held extensive hearings, which resulted in the passage of the Saccharin Study and Labeling Act, prohibiting the FDA from taking any action on saccharin for eighteen months.²

In the relatively short period between these two events, the Food and Drug Administration, responding to both internal and external pressures, transformed itself from an obscure cog of the federal bureaucratic machinery into one of its most important and visible components. For most of the 1970s the FDA had been in a process of evolution, trying to adapt its form and function to the new realities of greater public involvement, a more accessible government, and scientifically-based decision-making. The bureaucracy struggled to respond to a greatly increased mandate. The organization that still called itself the Food and Drug Administration also had responsibility for the expanding field of cosmetics, for biologicals, for medical devices from heart implants to foot massage machines, and for the burgeoning field of biotechnology. Furthermore, many of its decisions no longer rested on clear-cut choices. They involved subtle trade-offs of risk vs. benefit or convenience vs. safety.

"Until 1955, 1956, FDA was one of the smallest and most insignificant, from a budgetary standpoint, agency in government," recalled Arthur Checchi, a former FDA official, "No one paid a lot of attention to the FDA, not the Congress, not the White House, not the Secretary [of Health, Education, and Welfare]. Not the public. They had never heard of it. The Agency had a budget in those days of 4 or 5 million

²Saccharin Study and Labeling Act, P.L. 95-203, 91 Stat. 1451, 1977.

dollars [and] it made no waves." For Checchi and many of his generation, the transformation of the FDA began when it went from what they viewed as a "conservative, career organization, totally non-political" agency to one like so many in the federal government, responsive to the party in power, congressional inquiries, and public pressure.³

Until 1966, every Commissioner had risen through FDA ranks, a process that produced an esprit de corps, but also a self-limiting parochialism. Although he had come from outside the agency, FDA Commissioner Herbert Ley, Jr., under whose watch the cyclamate story unfolded, was the last agency head representative of that insularity. He had neither the personal philosophy nor the temperament to lead the agency into a new era in which the media, consumer activists, and grandstanding congressmen made their marks by attacking the FDA for what it did, did not, could not, or would not do.

From 1970 onward, the top two positions at the FDA, Commissioner and General Counsel, would be held by appointees chosen as much for their political savvy as their familiarity with the agency and its mandate. They brought a diversity of professional accomplishments, extensive bureaucratic and management expertise, and experience with Washington's political and scientific establishment. Dr. Charles C. Edwards, a surgeon, appointed Commissioner in 1970, came from the public relations firm Booz, Allen via a top position in the American Medical Association. FDA General Counsel Peter Barton Hutt left the high-powered Washington law firm,

³Arthur Checchi, Assistant Deputy to the Commissioner, Interview, July 24, 1984, transcript, p. 162, Oral History Project, Food and Drug Administration.

Covington and Burling, to become the chief strategist for creating the legal framework that turned the Food and Drug Administration into a modern administrative agency. Although at times with reluctance, the Commissioners and their General Counsels in the 1970s accepted and responded to the new political realities.

Changes within FDA did not result from the action of two strong-willed individuals with their own idiosyncratic vision of a public health agency. Edwards' successors in the 1970s, Dr. Alexander M. Schmidt, a Dean at the University of Illinois Abraham Lincoln School of Medicine, Dr. Donald Kennedy, a Dean at Stanford University, and Dr. Jere Goyan, from the University of California, San Francisco continued the process that Edwards began. They expanded public involvement, increased FDA's scientific capabilities, expanded its responsibilities at the same time that they increased staffing and funding. And like their predecessors they spent a good deal of their time testifying at contentious Congressional proceedings. Richard Merrill, an Associate Dean and Professor of FDA law at the University of Virginia Law School and Richard M. Cooper, who brought experience both in private practice and as one of the architects of a federal energy agency, continued Hutt's efforts to streamline FDA's administrative procedures.

The modernization of the FDA resulted not only from changes orchestrated by its politically sensitive senior officials, but also from the winds of change sweeping through the entire federal government in the aftermath of Vietnam and Watergate. Few areas of American life or government escaped the demands for public accountability and public participation, and the Food and Drug Administration was no exception.

Expansion of the Freedom of Information Act (FOI) opened closely held government documents to public examination. The Administrative Procedures Act, Advisory Committee Act, and Government in the Sunshine Act made public access to, and participation in, governmental meetings and hearings a routine matter. FDA's incorporation of the provisions of these laws into its own regulations allowed the public access to the deliberations of an agency previously as closed and secretive as the FBI or the national security agencies. Prior to 1972, 90% of FDA files had been closed to public examination. After this, only 10% remained off-limits, generally because of proprietary information or personal medical histories. Of course, increased public access did not mean that ordinary Americans routinely filed FOI requests, attended open advisory committee meetings, or filed petitions with the FDA--although, of course, they had the right to do so and occasionally individuals did take advantage of these procedures. These laws and regulations gave interested parties the tools with which to influence the government.

The FDA, as did all other agencies of government, operated in a social environment that had changed remarkably since the early 1960s. The consumer movement had energized a previously complacent public and had inserted itself more forcefully into the political process. Politicians on all levels paid heed to "grass roots" organizations mobilized to support or oppose specific issues. Consumers demanded the right to know about the effectiveness and safety of the products they used. Greater openness and accessibility meant that voices other than the bureaucracy and the industries that it regulated now had some influence on FDA decision-making whether they came in the guise of consumer advocates, women's groups, medical

specialists, congressional staff members, or any other group or person purporting to represent the "public."

Those individuals that had begun to question the safety of foods and drugs amplified their voice by supporting opinion-makers and consumer activist organizations critical of the FDA, such as the Ralph Nader-sponsored Health Research Group and the Center for Science in Public Interest. The media attention garnered by these groups increased their influence on Congress and the FDA. They used changes in FDA rules and regulations not only to passively monitor FDA activities but to actively lobby for or against the agency's policies and regulatory decisions. These changes in federal law in combination with new rules of standing in court cases gave consumer representatives a much greater ability to exert their influence.

Of equal important to these changes were attitudinal shifts in toward medicine and health. The Food and Drug Administration in the 1970s confronted a public that had begun to lose faith in the miracles of modern medicine. Modern medicine had vanquished many traditional infectious diseases, but had made little headway against the chronic killers--heart disease, stroke, and especially cancer. Many people feared the suffering of cancer more than death and supported any effort to minimize their risk of getting the disease. Despite periodic, optimistic proclamations from health organizations and the government that science was on the verge of a cure, in reality, few 'magic bullets' existed. Nor was there evidence that major progress against these diseases would occur in the foreseeable future.

In the 1970s, the focus shifted from curing these diseases to preventing their

onset. Scientists had begun to establish strong links between illness and environmental and behavioral factors. Health professionals began to stress the old adage that an ounce of prevention was worth a pound of cure. By shifting more responsibility to the individual many professionals hoped to counter the rising cost of medical care in the inflationary 1970s. Prevention, with its emphasis on lifestyle changes fostering bodily purity, had a long and illustrious history dating back to the early 19th century in America. The thread of radical hygiene runs from Sylvester Graham in the 1830s through Dr. John Kellogg's work at the Western Health Reform Institute in the 1870s to Adelle Davis' books in the 1960s and 1970s. Not all Americans were willing to make the drastic changes in their lifestyles and eating habits that radical hygiene required but many people tried to improve their health by quitting smoking, losing weight, exercising more, drinking less, eating better, and getting enough sleep. The 1970s fitness craze that filled American streets and roads with huffing and puffing joggers in short pants and expensive footwear was a sign that a number of people took these admonitions seriously. So was the growing number of organic or 'natural' food products that appeared on the market.

This influential subset of the population believed a healthy, "natural" lifestyle to be just as important to longevity as high technology medicine and new "breakthrough" drugs. Heeding critics that contended that the U.S. food industry had foisted on an unknowing public products loaded with dangerous additives and artificial colors and flavors, shoppers scrutinized product labels and consumer groups demanded that government provide more information to the consumer. These organizations charged that some of these additives had been linked to increased

rates of cancer in test animals. Demanding their immediate removal, they asserted that these unsafe additives had been allowed to remain on the market because of industry pressure or lack of concern on the part of the FDA.

Prior to the 1960s, if Americans gave any thought to the major drug companies and their products at all, they marveled at the steady flow of new drugs that promised to cure or ameliorate disease. The public gave scant notice to the dangers inherent in some of these powerful pharmaceutical agents. By 1970, the FDA estimated that doctors wrote over one billion prescriptions per year, and consumer purchased an even greater quantity of over-the-counter medications.

As the decade progressed, the relationship between the pharmaceutical industry, the medical profession, and the American public began to deteriorate. Although few Americans completely deserted the medical profession, disaffection manifested itself in a number of significant ways. The women's movement contended that male doctors patronized women, effectively excluding them from active participation in decisions about their own medical care. In the 1970s, groups such as the Boston Women's Health Book Collective, organized classes and published books, including the best-selling Our Bodies, Ourselves to educate women about their health. Feminists started their own clinics and encouraged the use of midwives instead of obstetricians for childbirth. At approximately the same time, consumer activists pressured hospitals to adopt a Patient Bill of Rights, giving patients far more control and involvement in their own treatment.⁴

⁴Boston Women's Health Book Collective, Our Bodies, Ourselves: A Book By and For Women, (New York: Simon and Schuster, 1971).

During the same period, health books became best-sellers and medical columns became a regular feature of magazines, newspapers, and television news shows, giving individuals another source of information beyond that provided by their family doctor. These sources began to remove the shroud of mystery that surrounded the practice of medicine. Beginning with coverage of the thalidomide tragedy, a steady flow of unfavorable news stories highlighted the risks of drug interactions, the adverse effects of some pharmaceuticals, and ineffectiveness of some of the medications on the market. This convinced consumer and women's groups that patients needed more information about the medicine they took, how these interacted with other medications and foods, and possible side-effects.

Patient advocates maintained that patients had a "right" to active participation in their own medical care and that, by law and tradition, doctors and pharmacists conspired to keep consumers ignorant about the drugs that had been prescribed for them. Prescriptions hastily scrawled in Latin turned into bottles of pills with little or no identification on the label except "take as directed by physician." Turning to the one agency through which all pharmaceutical products must pass--the FDA--a coalition of women's and consumer groups demanded that the interests of the consumer be protected. In 1974 they petitioned FDA to require that patient information be included with all drugs sold on prescription.

Public fears for, and concerns about, its health made actions of the Food and Drug Administration headline news, thus giving it far greater visibility than most agencies in the government. "When I came in 1951," commented FDA historian, Wallace Janssen, "there was very little which was covered by the press, very little.

The press didn't regard FDA as a news source. It was only when something like sulfanilamide happened that you heard from them at all. Nowadays, the FDA has become a major news source. We get more publicity than all the rest of H.E.W. [the Department of Health, Education, and Welfare] put together." Janssen saw more public interest leading to more political interest and the reverse.⁵

Heightened public awareness, led many to question the FDA's decisions, its effectiveness, its attitude toward the industries it monitored, and its regulatory philosophy. These critiques were often played out in the media and in the adversarial arenas of congressional committee rooms. In 1969 Dr. Ley summarized the position of the old guard succinctly when he said, "the real solution [to FDA's problem] is to isolate FDA functions from political pressure, to give the agency the resources to do its job..."⁶

Although many agreed that FDA had been neglected in the past, increasing its funding and manpower provided only a partial solution. More importantly, the agency needed to develop new bureaucratic procedures and refine its regulatory philosophy in response to the expanded mission and mandates that had been thrust upon it. The FDA had seen its limited functions--inspecting manufacturing plants for cleanliness and drug applications for safety information--expand exponentially with the passage of the 1962 Drug Amendments to the Federal Food, Drug, and Cosmetic Act. Moreover, with far greater frequency the decisions that FDA made turned as

⁵Retired FDA scientists, Interviewed by Wallace Janssen, June 29, 1978, transcript, p. 179, Oral History Project, Food and Drug Administration.

⁶F-D-C Reports, December 15, 1969, p. 18.

much on political and philosophical values as on scientific precepts. "The kind of things that we were dealing with then [before 1962] were pretty clear cut," remembered Fred Lofsvold, a retired FDA scientist. "Nobody's in favor of filth in foods, or spray residues on apples, or things of that sort.... But, now, the kinds of things we deal with, there aren't clear cut answers."⁷

The 1962 law, often referred to as the Kefauver-Harris Amendments, had passed in response to a public outcry after the discovery that the sedative, thalidomide, caused catastrophic birth defects when given to pregnant women in their first trimester. The news came out during Judiciary Committee hearings chaired by Senator Estes Kefauver (D-Tenn), who had been investigating the monopolistic actions of the pharmaceutical industry and the high cost of pharmaceuticals for a number of years. However, in the early 1960s, he changed his emphasis to health concerns. Kefauver argued that prescription drugs were advertised in a misleading manner causing irrational and sloppy prescribing by physicians. He also charged that too many prescription drugs on the market offered no advantage over other products and industry spent excessive research resources on 'me-too' drugs (minor modifications of patented drugs intended to circumvent patent protection). Most importantly, drugs were often marketed without much evidence of therapeutic efficacy.⁸

In 1962, Kefauver's FDA reform bill to address these problems was going

⁷Retired FDA scientists, Interviewed by Wallace Janssen, June 29, 1978, transcript, p. 180, Oral History Project, Food and Drug Administration.

⁸Paul J. Quirk, "Food and Drug Administration," in James Q. Wilson, The Politics of Regulation (New York: Basic Books, 1980), 197.

nowhere. In the course of Judiciary Committee hearings, Dr. Helen Taussig expressed her concerns to committee staff members about severe birth defects linked to thalidomide, a drug which was widely available in Europe but had not been approved yet for general use in the United States. However, the William S. Merrill Company, which had U.S. distribution rights for the German pharmaceutical, had already released the drug for experimental purposes to over 1,000 American physicians. These doctors gave it to their patients and collected anecdotal evidence on its effectiveness and safety for the company. In this way, thousands of people had already been exposed to the drug.

Staff members delayed the story until it appeared that a flawed drug bill would reach the Senate floor. They assured media coverage at the hearings by alerting the Washington Post and Washington Star that an important story was about to break. Dr. Taussig testified that the marketing of the drug in the U.S. had been narrowly averted because FDA medical reviewer, Dr. Frances O. Kelsey, concerned about inadequate safety evidence, refused to release it. Morton Mintz, the Post's consumer reporter, gave the story front page coverage. Television brought the story home to every parent with pictures of the unfortunate babies. And President Kennedy gave Dr. Kelsey a gold medal on behalf of a grateful public.⁹

Kefauver used the thalidomide tragedy to push through a tough new drug bill that proponents of stricter drug regulation had long sought. The bill passed unanimously in both houses of Congress. In reality, the new law had little to do with

⁹Robert P. Mayer, The Consumer Movement: Guardian of the Market Place (Boston: G.K. Hall, 1989): 95. In the United States, there were 17 cases of birth defects, 10 of them traced to the purchase of the drug in other countries.

the specific problems associated with thalidomide. The drug was effective for its intended use as a sedative and it would have passed the United States safety requirements then in force. Kefauver used the specter of unsafe drugs to pass legislation that required drug companies to prove the effectiveness of their drugs based on well-controlled, scientifically based clinical trials. Dr. Harry F. Dowling in Medicines For Man described what happened in one sentence: "The headlines screamed, the public was aroused, the drug manufacturers ran scared, and the opponents of a tough bill jumped for cover."¹⁰

Since the Federal Food, Drug, and Cosmetic law had not been substantially changed since 1938, and another occasion for a major overhaul might not arise for another generation, lawmakers used this opportunity to respond to many problems that had arisen in the interim. They gave the Secretary of HEW new powers to suspend a drug on a finding of an imminent hazard to the public health, as well as requiring companies to report promptly any adverse effects attributable to their drugs. The Amendments strengthened FDA's authority governing human testing of new drugs during clinical trials and required informed patient consent for investigational drugs before trials on human subjects.

The new law, which transferred jurisdiction over medical advertising from the Federal Trade Commission to the Food and Drug Administration, required that all copy include full information on adverse effects and contraindications. The law directed manufacturers to include a full disclosure package insert with all drugs. Drug companies had to register with FDA, be inspected at least every two years, and

¹⁰Harry F. Dowling, Medicines For Man (New York: Knopf, 1970).

conform to current good manufacturing practices (GMPs). The FDA's inspection authority now extended to records, files, controls, and facilities.¹¹

The Amendments' most important provisions extended, expanded and strengthened the FDA's regulatory authority over prescription drugs. Under the new law, before manufacturers could market new drugs they had to provide data to the FDA demonstrating not only safety (the requirement of the 1938 law) but effectiveness for the uses indicated. FDA medical reviewers then had 180 days to evaluate the information supplied. If they had no objections, the pharmaceutical company could market the product. Rarely, if ever, did the FDA meet the 180 day limit (The FDA can extend the process to consider the data or request more information by sending out a 'deficiency letter' that temporarily stops the clock). Approvals for some drugs eventually extended to seven or eight years by the mid-1970s.

All companies seeking approval to market new drugs needed to meet the revised standards. However, the law 'grandfathered' drugs on the market before 1938, such as aspirin. Companies could continue to sell them without any further testing because they were generally recognized as safe and effective (provided no evidence to the contrary developed). Furthermore, the law mandated that FDA re-evaluate all drugs approved for marketing between 1938 and 1962 to determine whether they met the new efficacy requirements, a most burdensome responsibility for the already overtaxed agency. The job was mind-boggling: during the period manufacturers had produced almost 4,000 drug products, with over 16,000

¹¹Kefauver-Harris Amendments, P.L. 87-781, 76 Stat. 780, 1962.

therapeutic indications, each of which had to be verified. For several years after 1962, FDA tried different methods to meet the law's requirements of proof based on adequate and well-controlled clinical trials performed by persons qualified to evaluate the effectiveness of the drug. Truckloads of data submitted by manufacturers often proved to be nothing more than glowing testimonials with no basis in valid scientific research obtained from physicians who had often been paid for their endorsements.¹²

In 1966, George Larrick, the last Commissioner to rise through the ranks, retired and President Lyndon Johnson chose Dr. James Goddard, formerly head of the Public Health Service and the Communicable Disease Center, to completely revamp an inefficient agency floundering under an almost impossible mandate. From FDA Deputy Commissioner Winton Rankin's perspective HEW Secretary, John Gardner gave Goddard "a blank check insofar as shaking up the agency." Goddard had the vision for a new FDA but ran into a wall of resistance in trying to move the hidebound agency in new and untried directions. "I believe he saw the need for a complete restructuring of the plan of organization to jolt the old employees out of any complacency they may have had." But his outsider status combined with his lack of managerial skills and the all-encompassing changes he tried to effectuate, doomed much of his tenure to failure. "The consensus among FDA employees to this day is that no other event affected the agency as much as Dr. Goddard's reorganization of 1966." Goddard's stewardship has become legendary in FDA lore as a cautionary

¹²ibid.

tale of how not to reorganize an agency.¹³

Goddard had a lasting effect on one aspect of the agency's functioning. Unable to find an acceptable way to fulfill the Kefauver-Harris mandate for drug re-evaluation, Goddard heeded the advice of United States Senator Hubert H. Humphrey, a former pharmacist. Humphrey had foreseen the massive problems that the new law would pose for the agency, and its ultimate solution. "The scientists in the Bureau of Medicine must be encouraged, enabled, and trained to draw upon the fullest competence of the nation's scientific community. In particular, the New Drug Division must have available the 'cream' of the nation's scientific talent for consultation regularly, or irregularly."¹⁴

Goddard negotiated a unique contract with the National Academy of Sciences and its research arm, the National Research Council (NAS/NRC) in 1966. For \$834,000 NAS/NRC assembled panels of the leading experts in therapeutics to conduct a Drug Efficacy Study Implementation or DESI review of all prescription drugs approved for the United States market between 1938 and 1962.¹⁵

FDA knew that it would have a fight on its hand from both the pharmaceutical industry and the medical profession as it attempted to remove ineffective or

¹³Winton Rankin, Deputy FDA Commissioner, Interview, transcript, pp. 47-49, Oral History Project, Food and Drug Administration. In an innovative move, Dr. Goddard temporarily 'borrowed' personnel from the Public Health Service to help eliminate a backlog of inspections. Recent pharmacy graduates were commissioned as Public Health Service Officers and sent to FDA District Offices for training. One of those officers commissioned in 1966 was the author's husband, William M. Troetel.

¹⁴Congressional Record, 87th Cong. 2d Sess, pp. 16355-6.

¹⁵Judith Axler Turner, "FDA Pursues Historic Role Amid Public, Industry Pressures," National Journal Reports, (February 15, 1975): 250.

misabeled drugs, a number of which had been extremely profitable. Practicing physicians also opposed the withdrawal of drugs they had come to rely upon. Just as importantly, doctors resented the implied denigration of their knowledge and their experience as decisions were taken out of their hands and turned over to university-based medical specialists ensconced in Washington advisory committees.

"Recommendations from the most expert sources are essential if this Administration is to suppress flagrant claims, eliminate worthless products, and at the same time protect the physician's resources," Commissioner Goddard wrote in a 1966 memorandum to Dr. Keith Cannan, Director of the NAS/NRC Division of Medical Science. The FDA sought the assistance of NAS/NRC because of its ability to tap the medical and scientific talent of the nation, its reputation for objective, independent evaluations, and the well-known fact that the FDA did not have medical personnel to carry out a project of this scope.¹⁶

Using NAS/NRC the FDA met the requirements of the Kefauver-Harris Amendments, although the DESI review dragged on for years as pharmaceutical firms negotiated with the FDA for extensions in order to prove the worth of their products. The DESI review eventually resulted in the removal or relabeling of thousands of drugs. Although pharmaceutical manufacturers embarked on extensive litigation to overturn the results of the Kefauver-Harris Amendments, the United States Supreme Court ruled in favor of the FDA, upholding its right to set regulatory standards enforceable in court.

¹⁶Memorandum from James L. Goddard, M.D. Commissioner of Food and Drugs to Dr. Keith Cannan, Division of Medical Science, National Academy of Sciences-National Research Council, March 31, 1966.

This ruling would be extremely important in the 1970s as the FDA began its transition to a modern administrative agency based on rule-making rather than case law. Equally important, the use of non-agency scientific expertise became a permanent part of FDA functioning. Rather than continuing to depend on the National Academy of Sciences, the FDA developed its own system of standing advisory committees during the 1970s.¹⁷

Dr. Herbert L. Ley, Jr.'s stint as Commissioner followed Goddard's tumultuous two years. The bureaucratic organization he attempted to lead was overwhelmed by its new responsibilities and disoriented by its two recent shake-ups. After Goddard's internal reshuffling, a March 1968 HEW Reorganization Order had placed FDA under the Public Consumer Protection and Environmental Health Service (CPEHS), a large, unwieldy umbrella organization. This move, which buried the FDA deep within HEW, added further to the bureaucracy's disarray and plummeting moral. The nation's oldest regulatory agency, proud of its name, its reputation, and its esprit de corps was in danger of losing all three.¹⁸

¹⁷Weinberger v. Hynson, Westcott & Dunning, Inc. 637 F. 2d at 888 (1973).

¹⁸Michael Brannon, "Organizing and Reorganizing FDA," in Food and Drug Law, (Washington, D.C.: Food and Drug Law Institute, 1991), 128-9. CPEHS lasted less than two years. On April 1, 1970, with CPEHS abolished, the FDA was reorganized along product lines with Bureaus of Drugs, Foods, Pesticides, and Product Safety (which was later moved to the Consumer Product Safety Commission). The reorganization of 1970 was the last of significance for more than a decade. From 1970 to 1982 reorganization took the form of expansion as new programs were transferred to FDA. Although divisions have been renamed and functions within them regrouped, the FDA is still organized along product lines with a Center for Drug Evaluation and Research, a Center for Biologics Evaluation and Research, a Center for Devices and Radiological Health, and a Center for Food Safety and Applied Nutrition.

The Food and Drug Administration had reached a critical point in its existence. It clearly could not continue as it had in the past. Unless major reforms were made, its functions would be stripped away and given to one of the newly created consumer agencies whose bureaucracy and leadership understood the concerns of the public and were more responsive to the demands of advocates. For the FDA, it was not just a matter of picking a new Commissioner or re-ordering priorities, but of re-conceptualizing the role of a regulatory agency in era of open government and public accountability.

At various times, Congress has declared very broad objectives and granted enormous authority to executive branch agencies. Those situations in which these mandates have been most successful are those in which the agency administrators had a will to intervene and were willing to make policy for the regulated industry not just with the industry. The training and career experiences of the most successful administrator had given them the sense of what could be done (and could not be done) with available governmental means. They could then target their efforts to building the institutions and bureaucratic channels necessary for the implementation of their policies.

The passage of the Kefauver-Harris Amendments provided just such a scenario. Not only did the law require the FDA to undertake responsibilities that it had never had before, but to make its actions credible it had to base its decisions on a scientific expertise that it did not possess. Moreover, it had to articulate its new objectives not only to the regulated industries, already wary of changes within the agency, but also to the public and Congress. It had made a good beginning in

establishing the DESI review panels, but that was a temporary expedient, it now needed a strong leader or set of leaders with the will to intervene and make policy.

When Dr. Edwards assumed control of the agency, both FDA and HEW officials had had ample opportunity to reflect on the various failures to fit FDA's form to its new functions. With support from his superiors at HEW, Edwards used his extensive managerial skills to reorganize the FDA and begin to establish procedures for implementing a more scientifically based regulatory policy. Drawing upon FDA's previous sporadic use of ad hoc advisory committees, he developed the advisory committee system to supplement FDA's inadequate scientific expertise.

Equally momentous for the ultimate transformation of the FDA was the 1971 appointment of Peter Barton Hutt as FDA General Counsel. Many lawyers in Washington had extensive food and drug law experience that would have served them well in fulfilling the duties of General Counsel, but few combined that knowledge with the self-confidence, or perhaps the arrogance, to believe that they could reinvent the Food and Drug Administration as a modern administrative agency. Hutt not only envisioned the new agency, but sensed the possibilities for change within the parameters available to the agency.

By 1970 the FDA, along with many other government bureaucracies, had to interact not only with its regulated industries but with a newly cognizant and aroused public. Unlike many old-timers in the agency, Edwards understood the changes effecting the agency from a consumer movement powered by professionals familiar with the law, medicine, government, and public relations. These professionals would both shape public perceptions of the FDA and serve as a conduit for public concerns

about FDA's decisions and its commitment to protecting the health and safety of Americans.

The consumer movement had taken to heart the message of Dr. Harvey W. Wiley, the moving force behind the 1906 Pure Food and Drug Law, who warned against the "pernicious threat" of letting industry have a free hand in influencing FDA regulatory decisions. "When we permit business in general to regulate the quality and the character of our food and drug supplies, we are treading upon very dangerous grounds." Government could consult businessmen and take whatever unbiased advice they gave because of the industry's knowledge of the processes involved. But he cautioned, "It is never advisable to surrender entirely food and drug control to business interests." Without any countervailing force from the public, this is exactly what consumers charged had happened at FDA.¹⁹

Edwards justifiably laid at least part of the success of the "widely-based and influential" consumer movement at industry's feet. "It is in large part, the direct result of past injustices to the consumer, inadequate products, and false and misleading promotions," he told the Pharmaceutical Manufacturers Association. "The consumer movement itself is bringing heavy pressure to bear on both industry and government. This, too, is here to stay, make no mistake about it." Alarmed industry leaders may have feared that Edwards had joined the consumer camp. Edwards reassured them that the FDA aimed at constructive regulation that would not wreak havoc on industry

¹⁹Quoted in Morton Mintz, By Prescription Only, 2nd ed., (Boston: Houghton Mifflin, 1967), 130.

nor destroy the relationship that FDA had developed with it over the decades.²⁰

All future commissioners would need to walk this same fine line, responding to the criticisms leveled by Congress and consumer advocates while maintaining a cooperative attitude with the industries FDA regulated. John Trattner, who wrote The Prune Book, a counterpart to The Plum Book of desirable jobs in Washington, grasped the difficulties facing Edwards and those who occupied the Commissioner's office in Rockville, Maryland. "The occupant of this job finds himself in a continual cross fire between business and consumer groups, or liberals and conservatives, or lawyers, judges and scientists. "I was amazed," one former incumbent recalled, "by the scope of the responsibility, the magnitude of the problems, the bitterness of controversies, and the attacks against the commissioner." The same could be said of the agency that he headed.²¹

Dr. Alexander M. Schmidt, Edwards' successor, acknowledged the actual and potential clout behind the consumer movement--which he labeled simply "the public voice"--and its effect on his agency and industry. He admitted that in the past, "many FDA actions were taken with little public participation and less public explanation." He attributed this in part to the complexity and technical nature of the questions facing FDA, but he also admitted that "effective channels for public input were non-existent before the events of the past few years gave focus to the consumer movement. To be perfectly frank, the only strong opinions too often heard

²⁰Dr. Charles C. Edwards, FDA Commissioner. Speech to the Pharmaceutical Manufacturers Association, April 28, 1972.

²¹John H. Trattner, The Prune Book: The 100 Toughest Management and Policy-Making Jobs in Washington, (Lanham, Md: Madison Books, 1988).

by the FDA were its own and those from industry."²²

Restructuring its interactions with industry in an era of open meetings, published calendars, and media exposure was easier than establishing a relationship with the public. The food industry, the drug industry, the medical profession were known quantities with recognized goals. The public, on the other hand was a multi-faceted, illusive, chameleon-like entity that changed from day to day and issue to issue. The politically-sensitive FDA of the 1970s found assessing the position of the public on any particular issue a difficult, complex, and unpredictable process.

As the controversies over food and color additives demonstrate, in certain situations outside pressure forced the FDA to take actions it would not take of its own volition. Health reformers and consumer groups believed that most food and color additives were unnecessary at best and carcinogenic at worst. For four years the Health Research Group and others petitioned the FDA, testified at hearings, made use of its FOI procedures, and took legal action to force FDA to re-evaluate its policy on additives and remove Red Dye No. 2 from the Generally Recognized As Safe (GRAS) list, thereby effectively barring its use in food and drugs. Their success led to the subsequent removal of other colors and food additives.

At other times, political pressures kept the FDA from accomplishing what it felt its mandate and FDA law required it to do, as in the 1977 saccharin controversy. When rats fed saccharin developed bladder tumors, the Delaney Clause to the Federal Food, Drug, and Cosmetic Law required its removal. However, a diet conscious public would not let the FDA banish the last available artificial sweetener

²²F-D-C Reports, September 17, 1973, p. 3.

from the marketplace. Commissioner Kennedy solicited public comments, held hearings, and explained FDA's position both to the public and Congress. It had to remove saccharin from the marketplace. It could not do otherwise within the constraints of the law. Consumers turned to Congress to prevent FDA from acting. Congress heeded the complaints of its constituents, who had begun to question the value of increasing burden of government regulation on the economy and their personal lives. Choosing to make an exception for saccharin rather than repeal the absolutist prohibitions of the Delaney Clause, Congress interceded in what should have been a simple scientific decision by FDA and prevexted the FDA from removing saccharin-containing products from American grocery shelves. In both the case of Red No. 2 and saccharin, because the ambiguity of the scientific evidence, the decision ultimately rested on political questions of risk versus benefit.

However, with the alleged cancer treatment, laetrile, the FDA would not bow to public pressure or compromise its position because to do so would mean abdicating its basic role of protecting the public against ineffective drugs. Although sympathetic to the needs of these desperately ill patients, the FDA reasoned that to acquiesce to their demands would be to concede that it did not have the right to ask any pharmaceutical manufacturer to prove the efficacy of its product through scientifically based, objective criteria. The FDA would have come full circle back to the bad old days of hucksters touting their unsubstantiated claims to the desperate and the gullible.

The Food and Drug Administration was willing, however, to let public concerns shape its concept of patient package inserts. It responded positively to petitions from

a consortium of consumer and women's groups for inserts because the needs of these groups dovetailed with FDA's own position. The agency had already approved the concept of providing information on prescription drugs directly to the patient by requiring inserts for oral contraceptives in 1970. Acknowledging the controversial nature of the inserts and recognizing the difficulties that it presented to industry and the medical profession, nevertheless Schmidt committed the FDA to exploring the issue through the full and equal participation of all concerned. "The patient has an absolute need, not to say right, to know what these problems might be and if, in fact, he's willing to accept the risk."²³

Using its recently instituted procedures for public involvement in FDA decision-making, the FDA announced its intentions in the Federal Register, solicited comments, held symposiums, and slowly worked out the details of patient package inserts. Commissioner Donald Kennedy continued the work started under Schmidt. The FDA worked for five years to gather all parties behind a compromise solution.

Skillfully using changes in federal law, many of which they had helped pass, public advocates made a substantial start toward their goal of participation in FDA decision-making. When FDA actions did not meet expectations, consumer advocates had no qualms about funneling the facts to news organizations or using congressional supporters to put pressure on the agency. The FDA became one of the "hot topics" of the 1970s for Congress. Congressional committees acted as conduits for the grievances of industry, consumers, women's groups, and disgruntled employees of

²³Alexander M. Schmidt, "Dimensions of Change in the FDA," Paper presented at the Pharmaceutical Advertising Seminar, Chicago, Ill., March 3, 1973.

the agency itself. FDA Commissioners, their General Counsels, and senior members of their staff, spent many days on Capital Hill defending their agency against charges of ineptness, inefficiency, foot-dragging, endangering the public health, being partial to industry, and conversely, being hostile to industry. Consumers charged that the FDA approved drugs or food additives without adequate testing or consideration of long-term effects. But industry countered that FDA's painstakingly slow approval process endangered the public's health by keeping safe and necessary drugs off the market. Although the controversies, the committees, and the officials changed over time, the process of intense congressional oversight became a permanent part of FDA functioning. By the end of the decade, the FDA bore little resemblance to the agency that had existed in 1969. The FDA could no longer function effectively within the parameters of its forty year old Federal Food, Drug, and Cosmetic Law. The legislation had been written before pharmaceuticals became the treatment of choice for a vast array of medical conditions, before sophisticated toxicological experiments had revealed the limits of risk assessment, before FDA's mandate had increased exponentially, and before the average citizens realized that risk/benefit decisions were not necessarily scientific calculations but political judgments which they had a right to help make.

A general consensus had developed by 1976 that the time was right to replace the outmoded law with a new legal framework that helped rather than hampered the FDA in its protection of the public health. "Breakthrough" drugs would receive expedited approval, but FDA would get post-marketing surveillance powers and an adverse reaction reporting system. Industry would get an extended patent-life for

their drugs in exchange for an expanded generic drug industry. The law explicitly authorized FDA to establish advisory committees with public representatives, mandated patient package inserts, and released safety and effectiveness data to the public. The omnibus bill would not only provide consistent regulation of all products and incorporate the changes that had been made piecemeal to the old law, but would position the FDA to effectively handle its responsibilities for the last quarter of the twentieth century.

The ultimate fate of the bill is reflective of the realities under which FDA now operated. The FDA, which had in the past dealt primarily with industry, and occasionally with Congress, now found itself refereeing the competing demands generated by a pluralistic society. The old two-way dialogue at the Food and Drug Administration between the regulators and the food and pharmaceutical industry was gone, replaced by the complexity inherent in balancing the agendas of three and at times, four constituencies.

The 1978 omnibus drug bill failed. However, many of its provisions eventually passed in the 1980s as consumer groups, industry, and the FDA hammered out compromises that each side could live with--or benefit from. In an ideal world the three parts--industry, public advocates, government regulators--would work together harmoniously to assure a continuous flow of affordable, safe food and effective, safe drugs. Unfortunately, the FDA is in Rockville, Maryland.

CHAPTER 2

"CYCLAMATE--NOW YOU SEE IT, NOW YOU DON'T"

"If the cyclamate situation results in action by HEW against Ley or FDA--without reference to the outside scientific review on the merits of the problem," warned the F-D-C Reports, "an era of regulation for the drug industry based on public hysteria can be anticipated."¹

Dr. Jacqueline Verrett held up the two fluffy, yellow chicks to the cameras, slowly rotating them to show the perfectly formed wing of one and the deformed shape of the other. As she pointed to a severe deformity in its spine and a foot attached directly to the body at the hip, she explained to NBC News reporter Paul Friedman, "We find that cyclamate causes the same abnormalities that thalidomide does in the chick embryo. But they are occurring in a more severe fashion, and in more frequent numbers." Her sensational findings, which first aired on October 1, 1969, frightened diet-conscious Americans who thought that they had found a way to assuage their sweet tooth and lose weight by merely substituting the artificial sweetener cyclamate, for sugar in their diet.²

Especially troubling to viewers was the fact that she linked the use of cyclamate to thalidomide-like symptoms. Only seven years before, Americans had seen pictures on the evening news of babies born with deformed arms and legs after their mothers had been given the sedative, thalidomide. For many viewers this had been their first realization that drugs could harm as well as heal. And for many it had

¹F-D-C Reports, October 13, 1969, p. 21.

²Dr. Jacqueline Verrett, interview, "NBC Nightly News," October 1, 1969, Archives of the National Broadcasting System.

been their first introduction to the Food and Drug Administration. Breathing a collective sigh of relief, Americans had returned to their private lives reassured that the FDA kept a vigilant eye on the vast number of drugs they took and foods they ate. But here was Dr. Verrett, a research biochemist in the Food and Drug Administration's Toxicological Evaluation Branch, going over the heads of her superiors, to warn the public of the dangers in a food additive that millions of people consumed on a regular basis.

Basing her findings on three years of experiments injecting cyclamate into 10,000 chick embryos, Verrett told Friedman that 15% of the chicks exhibited abnormal development. She also indicated that other experiments similar to hers had been performed by Marvin Legator, chief of the cell biology branch of FDA's Science Bureau's Pharmacology-Toxicology Division. Her statements set off a reaction approaching panic. She advised pregnant women that although the reproductive defects had been demonstrated only in the chicken embryo, "I think the prudent thing is to avoid anything which is unnecessary and which is not given under medical supervision, perhaps until further information has been gained."³

To provide balance, the news show included a film clip of an executive of Abbott Laboratories, the world's largest producer of cyclamate. Scientific Operations Executive Vice-President Charles Brown assured viewers that the chemical had been in use for 25 years and had demonstrated no adverse effects. Friedman ended the interview by mentioning that cyclamate remained on a list of food additives that FDA termed Generally Recognized As Safe (GRAS). "That means that the government's

³Ibid.

official position more closely reflects the views of business interests than it does the serious questions raised by FDA's own scientists."⁴

A week of sensational newspaper and TV coverage followed the revelations by Verrett and Legator. The two, who had staged a "palace revolt," made no attempt to conceal their displeasure with FDA Commissioner Ley and other top officials for not doing enough to warn the public of potential hazards of cyclamate. In a half-page feature in Long Island's Newsday, Verrett claimed that the Food and Drug Administration still listed cyclamate as a safe substance despite the fact that it had known of her research for a year. Realizing the risk to her position but grabbing the moral high ground, she said, 'I am sure this does put me in jeopardy of my job, but I don't give a damn if it does.'⁵

CBS-TV's morning news show also had a report on what was quickly becoming a "hot" story. Reporter George Herman based his report on information that first appeared in a newspaper column titled, "How Safe Are Cyclamates?" co-authored by Jean Carper and Sen. Warren Magnuson (D-Wash), who had an active interest in consumer issues. The column warned pregnant women "to avoid cyclamate artificial sweeteners," again linking the artificial sweetener to thalidomide-like symptoms. The authors charged that "the public is not being told the truth" about cyclamate and called the agency "irresponsible" for not releasing the facts.⁶

⁴Ibid.

⁵Long Island Newsday, October 1, 1969, p. 2.

⁶Senator Warren Magnuson and Jean Carper, "How Safe Is Safe?" Washington Post, October 1, 1969. Carper and Verrett would go on to write a number of books, including Eating Is Dangerous to Your Health.

The following evening, NBC's Huntley-Brinkley Report continued the coverage with a report that FDA Commissioner Herbert L. Ley had asked the National Academy of Sciences to complete a review of cyclamate. The interviewer asked Ley why it had taken the agency's top brass so long to order the NAS review. Ley responded that he had not seen the Bureau of Science data until October 1st, but that he knew the studies were being conducted some time in the spring. More the careful scientist than the politically astute head of a federal agency under pressure, he replied that "one does not move on incomplete work." Within the limits of knowledge and scientific opinion then available to him, Ley considered cyclamate to be safe. "This does not mean that with new data this situation may not change."

The next day Ley, appearing on the CBS Morning News, responded to another question about the NAS review. This time he replied, "If the Academy experts consider the new items of information to be highly significant, I think the appropriate response on the part of FDA would be a banning of the material." Instead of reassuring the public, his ambivalent replies gave evidence of a department in disarray, headed by a commissioner who not only had lost control of his agency, but equivocated on a critical issue of consumer safety.⁷

Indicating his displeasure at FDA for "waffling" on the potential health hazards of the chemical, HEW Secretary, Robert H. Finch, took control of the situation, effectively undercutting the authority of his FDA Commissioner. Consulting with a small number of FDA officials and outside scientists, Finch decided to summarily remove cyclamate from the market.

⁷F-D-C Reports, October, 13, 1969, p. 23.

His actions provide a stunning contrast to the long, acrimonious, and eventually unsuccessful process by which FDA tried to remove saccharin, another artificial sweetener, from supermarket shelves less than a decade later. Unlike saccharin, cyclamate disappeared from a wide range of consumer products without advisory committee meetings, without FDA or congressional hearings, and with little, if any, input from the scientific community, or the public. And perhaps most surprisingly, with little opposition from industry. This would be one of the last times that the FDA could act with such cavalier disregard for the opinions of the public it served.

FDA had known about potential problems with the sweetener for a number of years, in part from the investigative efforts of its own scientists, but also in large measure from research undertaken by the sugar industry to discredit sugar substitutes. Long before consumer advocates discovered the detrimental effects of food additives, the sugar interests and cyclamate manufacturers had been engaged in a behind-the-scenes battle for the multi-billion dollar sweetener business.

Industry organizations such as Sugar Information, Inc. and the International Sugar Research Foundation in Washington, D.C. put almost a half a million dollars into cyclamate research from 1964 to 1969. "We are funding research on cyclamate," John Hickson, Vice President and Research Director of the Foundation argued, "because if someone can undersell you nine cents out of 10, you'd better find some brickbat you can throw at him."⁸

The sugar interests had good reason to be concerned about the growing use

⁸New York Times, June 1, 1969, sec. II, p. 12.

of cyclamate. The food industry and many consumers considered cyclamate to be the ideal sugar substitute. Discovered in 1937 by Michael Sweda, a chemist working for DuPont, it lacked the bitter aftertaste that many people experienced with saccharin, the other major artificial sweetener. DuPont licensed the compound to Abbott, which began producing it in 1953 under the brand-name of Sucaryl and the new product soon dominated the market.⁹

Between 1955 and 1965, the availability of cyclamate led to a host of artificially sweetened products from canned fruit, soft drinks, and chewing gum to toothpastes and mouthwashes. Before cyclamate, the use of artificial sweeteners had been associated with illness and products containing them had been labeled for use by diabetics and others who needed to limit their intake of sugar. In response to the diet craze that developed in the early 1960s, Abbott and other producers quickly reformulated their advertising campaigns to stress the usefulness of artificial sweeteners as dieting aids. This strategy led to skyrocketing sales of these products and the development of a billion dollar industry.¹⁰

Perhaps the chic thinness of John and Jacqueline Kennedy convinced Americans that the time had come to take off those excess pounds. For many, substituting diet soft drinks for sugar-laden soda seemed a painless way to cut calories. Between 1963 and 1967 cyclamate use increased three-fold from six to

⁹William R. Havender, "The Science and Politics of Cyclamates," The Public Interest 71, (Spring 1983): 19.

¹⁰Linda Cummings, "The Political Reality of Artificial Sweeteners," in Consuming Fears: The Politics of Product Risks, ed. Harvey Sapolsky, (New York: Basic Books, 1986), 117.

eighteen million pounds, most of which went into diet soda. In 1963, the beverage industry marketed 2.5 million cases of soft drinks, with only 4% or 100,000 of them 'low calorie.' Five years later, diet beverages made up 15% of the total soft-drink market.¹¹

For the beverage industry, as well as the overweight American, diet sodas became a "magic elixir." Even though cyclamate cost much less than sugar, bottlers charged the same for diet soda as they did for regular soda. As the public reduced its waistline, the manufacturers fattened their profit margins. But continued profitability depended on maintaining the public's belief that diet products made with cyclamate were as safe and "pure" as those made with sugar.

From the beginning there had been nagging doubts about the safety of cyclamate. In 1950, Abbott proposed marketing Sucaryl using test data that FDA dismissively called "an illustration of how an experiment should not be conducted." However, FDA took the unusual step of conducting its own 2-year feeding study in animals because the agency "considered it to be in the public interest that something beside saccharin be available for people who should avoid sugar." The FDA then approved cyclamate with only one restriction--that it contain a label stating "Should be used only by persons who must restrict their intake of ordinary sweets."¹²

Abbott was given further assurance that cyclamate could be used in a wide variety of foods and beverages by the passage of the 1958 Food Additives Amendments to the 1938 Federal Food, Drug, and Cosmetic Act. Although the FDA

¹¹Ibid.

¹²Havender, 18.

had the power to bar dangerous additives under the 1938 law, the burden of proof lay with the FDA to show that the chemical was poisonous or deleterious. The time-consuming process allowed substances to remain on the market while the legal process ground on. The new law provided pre-marketing clearance by the FDA of new chemical additives. Substances already on the market which qualified scientists "generally recognized as safe" under the conditions of their intended use, were not classified as "food additives" and were exempt from these requirements. This GRAS classification could be made either on the basis of scientific data or in the case of substances in use prior to January 1, 1958, on the basis of experience from common and safe use in food. However, if these substances were later found to be hazardous they could be removed from the market. In essence, this "grandfathered" in a number of common substances normally added to food, such as sugar, salt, preservatives--and cyclamate.¹³

According to Winton B. Rankin, who had been Deputy Commissioner of Food and Drugs in the 1960s, the government drew up one list and industry provided another. A large panel of experts culled through both lists, choosing those items that they rated safe. "Only 1 person out of 190 who commented on cyclamate suggested that there was not enough information to include it on the list." Thus cyclamate came to be added to the FDA's GRAS list.¹⁴

¹³Food Additives Amendment of 1958, P.L. 85-929, 72 Stat. 1784 (1958).

¹⁴New York Times, October 26, 1969, IV, p. 9. Nominations to the list of 600 substances generally recognized as safe (GRAS) were made by the National Academy of Sciences/National Research Council, professional societies such as the Institute of Food Technologists, and other interested groups. The combined list of substances, screened on the basis of the criteria of neither adverse experience nor

Most Americans in 1969 remained appallingly ignorant of the number of food additives, both natural and artificial, in their food supply. Besides salt, spices, and seeds, their daily bread contained stabilizers, dough conditioners, preservatives, and other ingredients with complex chemical names. Food manufacturers commonly used 30 types of preservatives, 28 anti-oxidants (to keep oils and fats from turning rancid), 44 sequestrants (to separate trace elements that interfered with food processing), 31 stabilizers (to give food a uniform smooth texture), 85 surfactants (that allow two surfaces to come together, e.g. oil and water), and over 1100 flavorings to produce the American food supply.¹⁵

The increased use of additives reflected the needs of an increasingly urban population, whose food supply often traveled thousands of miles and remained on the grocery shelf for weeks or months before use. It also mirrored a change in eating habits of a more mobile American population which liked to snack and eat on the run, as well as a growing public demand for processed foods.¹⁶

The new food processing complemented a revolution in the American lifestyle--from the industrialization of the work force, to the invention of the automobile, to the escalating number of working women--that made the old eating patterns of three home-cooked meals a day just a memory for most people. Critics decried the

toxicological evidence of lack of safety, was circulated by FDA to approximately 900 outside experts. Some 355 responded with comments. If a supportable objection was registered against any substance, that substance was removed from the list. Those which survived this scrutiny became part of the original GRAS list. FDA Papers, February 1971, p. 33.

¹⁵New York Times, November 9, 1969, p. 74.

¹⁶ibid.

increasing consumption of refined and processed foods, especially snack foods, but perhaps the most marked change in American eating habits was the proliferation of "convenience foods," factory-made dishes or meals that only need warming up or the addition of a final ingredient before eating. But with the TV dinners and instant macaroni and cheese came a steeply increased portion of artificial colors, flavors, stabilizers, and preservatives. In many cases, food producers used additives to put back what their own processing had taken out.¹⁷

Having been granted GRAS status, cyclamate could now be used without restriction in foods and beverages. The spectacular growth of the diet products industry in the 1960s caused both the sugar industry and the FDA to take a greater interest in cyclamate. In 1965, pushed by information supplied by sugar interests, the FDA reviewed conflicting scientific reports, concluding that at present levels of use, cyclamate did not present a danger but recommending continued study. Three years later, the FDA asked the National Academy of Sciences/National Research Council (NAS/NRC) to analyze available data and make a new appraisal of artificial sweeteners. Lacking the expertise and the physical capacity to do any extensive independent scientific testing or evaluation, the Food and Drug Administration had to rely on outside scientific bodies, such as the National Academy of Sciences.

The November 1968 NAS/NRC Interim Report affirmed that up to 5 grams of cyclamate per day posed no hazard to adults. Studies of cyclamate in the diets of animals of several species had shown nothing to justify suspicions of serious ill

¹⁷Joseph D. Beasley, M.D. and Jerry Swift, The Kellogg Report: The Impact of Nutrition, Environment, and Lifestyle on the Health of Americans, (Annandale-on-Hudson, New York: Bard College, 1989), 144.

effects at doses or consumption levels that approximated those used by the general population. However, NAS/NRC cautioned against unrestricted use and called for further studies, noting inadequate information on use in the upper ranges of human intake by the most persistent and avid users.¹⁸

In response to the uncertainty concerning the safety of cyclamate, the Commissioner of the Food and Drug Administration concluded the recommendations of the Interim Report should be implemented through the issuance of a formal regulation. An announcement appeared in the April 4, 1969 Federal Register noting that while cyclamate had been used as a non-nutritive sweetener in a large number of foods, current regulations did not place limits on its uses, and current labeling regulations were insufficient to provide consumers with enough information to enable them to safely use these products. The new regulation required a label declaration of cyclamate content, as well as a statement that "adults should not ingest more than 3,500 milligrams of cyclamate per day and children not ingest more than 1,200 milligrams per day."¹⁹

Commissioner Ley said these changes were intended to make it practical for people to follow the recommendation of the Interim Report. "As for saccharin," Commissioner Ley mentioned in an aside, "there was no evidence or medical observation to show any problems in its use." The regulations were scheduled to go into effect in 30 days barring manufacturers' requests for a hearing. Although the

¹⁸National Academy of Sciences/National Research Council, Ad Hoc Committee on Non-Nutritive Sweeteners, Food Protection Committee, Interim Report (November 1968), 101.

¹⁹34 Federal Register, April 5, 1969, p. 6194.

Federal Register notice stated that "any interested person" might file written comments "preferably in quintuplicate," the FDA and all concerned understood in 1969 that a "public" hearing meant a dialogue between industry and the regulating body. No one expected the public to become involved in the seemingly mundane matter of labeling. Dr. Verrett's cyclamate story would not hit the evening news for another five months. The public sipped its diet soda in blissful ignorance.²⁰

Abbott Laboratories, of course, had grave reservations about the FDA proposed action to the point of questioning FDA authority over cyclamate. Claiming their product was not a food additive as defined by the Food, Drug, and Cosmetic Act, they charged that the Commissioner had no authority to issue a food additive order. The company asserted that the "types of steps taken to effect these [labeling] changes must be examined carefully lest unwarranted confusion result." More than the proposed regulations themselves, Abbott and the other manufacturers feared possible adverse publicity, even though Ley stressed that few consumers exceeded the maximum daily amount.²¹

In order to keep the issue out of the public eye, the artificial sweetener industry chose to maintain a low profile. Industry hoped that this little flurry of excitement would soon be forgotten and sales and profits from cyclamate would continue to soar. Interestingly, the F-D-C Reports, the news service for the pharmaceutical industry, reported to its readers at this time that in contrast to FDA leadership, "FDA staff members prepared a summary of existing work which urged

²⁰Ibid.

²¹F-D-C Reports, April 7, 1969, p. T&G 6.

a stronger stance by FDA restricting the use of cyclamate." Although the article did not name names, this referred to the position taken by FDA scientists Verrett and Legator.²²

By the fall of 1969, the FDA had further cause for concern. In June, scientists at the University of Wisconsin had reported to Abbott significant incidents of bladder tumors in two experiments with white Swiss mice. Abbott, which had experiments in progress at the privately-owned Food and Drug Research Laboratories in New York and the Industrial Bio-Test Laboratories in Illinois, examined its own animals and found bladder lesions in rats fed cyclamate/saccharin in a 10/1 ratio, the same ratio found in many soft drinks. The final test results showed that 12 of the 70 rats that had received the highest dose (5% of diet) had incipient bladder cancer, while none of the control group did. In accordance with the law, Abbott promptly communicated these findings to FDA and the National Cancer Institute. On October 14, it also provided the HEW's Deputy Assistant Secretary for Health, Dr. Jesse Steinfeld, with all experimental data, including slides.²³

Both HEW and FDA dealt with this disturbing news from Abbott behind closed doors. The data were evaluated in-house or by experts chosen by the FDA on October 15 and 16. All those who viewed the data, including a group of pathologists convened by FDA, "concurred that 8 of the slides submitted contained malignant tumors, 3 of which were infiltrating carcinomas of the bladder." At Steinfeld's invitation, Dr. Gilbert Friedell, a well-known authority on bladder tumors,

²²ibid.

²³Havender, p. 19.

examined the slides and concurred with the findings. The evaluations by Abbott, FDA, and NCI were submitted to the NAS/NRC on the morning of Oct. 17. By that afternoon, NAS/NRC recommended removal of cyclamate from the GRAS list, although it did not think the test indicated an immediate threat to public health.²⁴

Officials at FDA and HEW pondered the Abbott results in the wake of Dr. Verrett's highly publicized charges. Although her results had been based on a different type of experiment which had raised questions about birth defects, any other negative reports about cyclamate would further inflame the situation and worry the public. And HEW officials had every reason to believe that someone within FDA's bureaucracy would leak this news to a sympathetic reporter, especially if FDA took no action to remove cyclamate.

Management of the crisis had already moved quickly from FDA offices up the chain of command to HEW Secretary Robert H. Finch. Although FDA Deputy Commissioner Rankin had cleared Verrett's appearance on TV, her charges took FDA officials by surprise. Used to operating in the nether reaches of the government where safety questions could be carefully evaluated, hypotheses tested, results analyzed, or questions could be ignored, the FDA was not prepared to function in the world of instant publicity and sound bite news. Even if Dr. Verrett had presented her findings in the most reserved manner and made no link to thalidomide, many listeners would have been concerned. Yet the agency had not thought through the effect on the public of safety questions about such a widely used product.²⁵

²⁴F-D-C Reports, October 27, 1969, p. 37.

²⁵New York Times, November 22, 1969, p. 40.

Finch, who had not appreciated being taken by surprise over cyclamate, openly criticized the FDA. In particular, he voiced concerns about its varying assessments of the possible health hazards in the continued use of cyclamate. "Dr. Jacqueline Verrett, who conducted the chick experiment, has been quoted as advising pregnant women to exercise care with cyclamates, while Dr. Herbert L. Ley, Jr. the Food and Drug Commissioner, was assuring the public that cyclamates are safe." With clear portents for the future, he said, "I am not satisfied with the present situation there. I think it's just inevitable we're going to have some rather substantial reorganization of procedures and personnel in the Food and Drug Administration."²⁶

In an agency that had prided itself on its esprit de corps, staff scientists simply did not go public with sensational charges to force a decision on the agency. Few people involved in the cyclamate situation doubted the merit, in scientific terms, of Ley's decision to submit the controversy to a NAS/NRC committee for evaluation or his refusal to bow to pressures created by the press and TV reporting of unevaluated and unpublished data. However, to an anxious public, FDA's waffling on the seriousness of the situation undermined public confidence. It also showed that the backward agency was quite innocent of any appreciation for the emerging consumer movement and the new sensitivity on issues touching on public health. FDA top management's inexperience in dealing with a rapidly escalating public relations problem became glaringly evident.

Finch, himself, had just experienced the potential impact of the consumer movement. During the week of September 29th, Ralph Nader disclosed to Finch the

²⁶New York Times, October 8, 1969, p. 32.

substance of his "Nader's Raiders" report on the FDA, which would be released in late December or early January. The "Raiders," volunteer law and graduate students, had descended on various government offices the previous summer to investigate allegations of regulatory laxness. The F-D-C Reports wrote that the college students "had virtually lived in the lab of FDA biochemist Verrett last summer," presumably getting information on FDA negligence that only an insider could provide.²⁷

Nader deplored the FDA's failure to protect the public against hazards from pesticides and food additives. He warned Finch that the report was not a one-shot expose. His organization, Public Citizen, Inc. intended to act as an FDA watchdog through its Health Research Group. Furthermore, his associate, James S. Turner, planned to publish the "Raider's" findings shortly. Turner's popular 1970 book, The Chemical Feast broadcast these charges to a wide audience.²⁸

Much more politically attuned than his FDA colleagues, Secretary Finch held a news conference on the morning of October 19, 1969 to announce plans to remove cyclamate from the GRAS list, thereby removing them from the food supply. Recall of products already on the market was to be carried out in phases--soft drinks to be taken off the market by January 1, 1970 and all other food products using the substance to be removed by February 1. The ruling affected about 250 foods from canned fruits, salad dressings, cakes, and bacon to drugs and mouthwashes.²⁹

²⁷F-D-C Reports, October 13, 1969, p. 19.

²⁸James S. Turner, The Chemical Feast: The Ralph Nader Study Group Report on Food Protection and the Food and Drug Administration, with a Foreward by Ralph Nader (New York: Grossman, 1970).

²⁹34 Federal Register, October 21, 1969, p. 17063-4.

Dr. Jesse L. Steinfeld, HEW Deputy Assistant Secretary for Health and Scientific Affairs, joining Finch at the news conference, offered a hint of the FDA's lack of scientific expertise when he explained that the cancers had not been picked up in the FDA's previous studies "probably because the urinary bladders of the test animals were never examined." Finch ended the discussion on a positive note in an effort to calm the public. "There is no evidence at present to link the artificial sweeteners with cancer in man."³⁰

Steinfeld said bladder tumors had occurred in rats that had been fed cyclamate during their lifetimes in amounts proportionately 50 times as great as the maximum previously proposed for human consumption. The use of extremely high amounts of a chemical to test for carcinogenicity in animals is a standard toxicological method of analysis. FDA officials did not explain nor did reporters covering the story question the rationale of giving huge doses of a chemical to test animals or its relevance to the metabolism of cyclamate in humans.

In response to a question about whether he was satisfied with the FDA "handling" of the matter, Finch replied "by and large, yes....[but] I was unhappy and I expressed my unhappiness about several doctors in FDA who chose to go to the media without consulting their superiors....It was not very ethical." After all the excitement over Verrett's report, it had received no further public response by FDA or HEW officials, having been completely superseded by the carcinogenicity findings.

³⁰Dr. Jesse L. Steinfeld, Deputy Assistant Secretary for Health and Scientific Affairs, Department of Health, Education, and Welfare. Statement at Press Conference, October 18, 1969. The press conference received page one coverage in the October 19, 1969 New York Times, October 19, 1969.

Morton Mintz, medical reporter for the Washington Post and a frequent FDA critic, asked a question that touched on the fundamental relationship between the government and its citizens, "Is there any suggestion here that that kind of data should not be fully disclosed to the public?" Steinfeld responded that while freedom of scientific information is essential, "the problem is that the people to whom [the data] should be communicated are the other scientists.... I think it's unfortunate to publish [such findings] in the general media along with interpretations that are unjustified." [emphasis added] This type of paternalistic attitude was no longer acceptable. Consumer advocates and public interest groups contended that the public not only had a right to see this kind of information and evaluate it, but more importantly a right to have some input into the decisions that the regulatory agency made as a result of it.³¹

In expectation of a ban or restrictions on the use of cyclamate, Canada Dry announced a worldwide removal of its cyclamate-containing products even before Finch's press conference. "The action was being taken in view of public concern over the possible ill effects of artificial sweeteners," said a statement by James D. W. Blyth, president of the company. The statement made page one of The New York Times.³²

"It's been beautiful," said an FDA official. "We haven't had as much as a whimper from either the soft-drink or food industries. It's the best cooperation I've ever seen." Industry felt it had little choice but to comply in order to allay fears of a

³¹F-D-C Reports, October 27, 1969, p. 36.

³²New York Times, October 18, 1969, p. 1.

public not yet used to the "danger-of-the-month" reporting that would become familiar in the next few years. Fred Dickson, president of Coca-Cola USA did tell Newsweek that "you'd have to drink 550 Frescas a day to get as much cyclamate as the rats.... You'd drown before you'd get cancer." But none of the news sources made a point of highlighting the seeming absurdity in his example.

When the FDA made the same claims against saccharin at the end of the decade, industry refused to capitulate. Using the same imagery of people needing to drink hundreds of cans of soda a day, manufacturers capitalized on a growing anti-regulatory mood to ridicule FDA's position. Jokes and cartoons of burping mice helped mobilize public opposition to the ban. Although many industry leaders privately felt the same way as Dickson, according to Newsweek, all they could do for now was "to take their unsweetened lumps."³³

Representatives of Abbott had conferred with high HEW officials all week before Finch's announcement. In light of FDA's decision to end cyclamate' GRAS status, Abbott announced that it would stop manufacturing the chemical. To the public, Abbott indicated its willingness to cooperate in any new regulations. Only 4% of its sales and 3% of its profits came from cyclamate. At this time, it decided not to risk blackening its corporate name by fighting FDA's action (although the company later unsuccessfully spent considerable money and effort trying to reverse FDA's decision on the basis of new data.) Cyclamate users quickly followed suit, reformulating their products with saccharin or saccharin/sugar mixtures.³⁴

³³"The Sweeteners Take Their Lumps," Newsweek, (November 3, 1969): 73.

³⁴New York Times, October 19, 1969, p. 1.

Pepsi-Cola produced full page advertisements that assured users that the "Pepsi-Cola Company cannot in good conscience offer its customers any products about which even the remotest doubt exists. We have immediately formulated a completely new Diet Pepsi which is not only free of cyclamates, but which tastes noticeably better than our previous product." Patting itself, and the industry as a whole on the back, the ad ended "Obviously, we take some satisfaction in our own readiness and technical skill. But, the soft drink industry as a whole has never been reluctant to modify its products for the benefit of its customers."

Coca-Cola advertisements informed readers that "It seems like a good time to tell you a pure and simple story. Coca-Cola is made with 100% natural flavorings. It always has been--since we invented it back in 1886--and it always will be." Coke chose not to mention cyclamate at all! Cumberland Packing Co., makers of the little pink packets of Sweet 'N' Low, used its copy space to indicate that the use of cyclamate in its products had been entirely innocent and with the approval of the Food and Drug Administration. "But we've been concerned over the conflicting scientific reports regarding cyclamates. For that reason, we've been working overtime to perfect a new and improved formula without cyclamates that offers all the advantage of America's favorite sugar substitute."³⁵

Cyclamate represented the first of many food crises that would be reported in the 1970s. With the exception of health food proponents and hippies, who had rejected the output of America's food conglomerates in favor of "natural," organic foods during the 1960s, most Americans piled their supermarket carts high with

³⁵New York Times, October 24, 1969, pp. 22, 25, 28, 36.

anything marked "new," "quick 'n' easy," or "just like homemade." American companies still touted "better living through chemistry" to an accepting public enamored of the American postwar cornucopia of material abundance. Therefore, many saw the cyclamate controversy as an aberration rather than as a symptom of the industry's callous disregard for the public's health. For the most part people expressed relief that a dangerous product had been removed. Of course, the fact that saccharin remained on the shelves made the FDA's decision easier to accept--consumer did not have to weigh safety versus thinness.

Shoppers reacted calmly to the news, in many cases expressing gratitude to the FDA for protecting them from a dangerous product. Georgia resident, Mrs. M. H. Staples, Jr., expecting a baby during the winter, said, "In my condition I'm really worried. It reminds me of the thalidomide thing...." Just as industry had feared, she absolved the FDA of not being vigilant enough and placed blame directly on the manufacturers. "These products should be fully tested before they are put on the market. I guess the soft-drink lobby was able to slip it by the government." Other people, however, exhibited the same defiance that would later be seen in those who wanted to keep saccharin available. Gay Houser said she had lost 25 pounds using diet soft drinks "and I'm going to continue. I smoke, too."³⁶

Soda bottlers had cooperated with the FDA in part because they had the option of quickly developing a new product. The dietetic canned fruit industry, however, did not have an easy alternative. As the National Cannery Association pointed out, canners are not in continual production. In some cases, they had just

³⁶New York Times, October 21, 1969, p. 49.

finished packing the year's fruit crop. The FDA's actions meant heavy losses for the California Cannery and Growers, a 1,100 member cooperative. They estimated that between 4 and 5 million cases of its total pack of 24 million were dietetic, under the Diet-Delight brand.³⁷

FDA responding to industry pressure kept trying to find a way to keep cyclamate on the market but out of soda by extending the deadline for completely banning cyclamate. The week of November 20th, Secretary Finch announced that cyclamate would continue to be barred from beverages because FDA "felt soft drinks were not essential for nutrition." However, they would continue to be allowed to be used in most foods and would be available as a sugar substitute produced in tablet or liquid form. Such foods would now be regarded as over-the-counter non-prescription drugs and would be labeled as such.³⁸

Officials at HEW and FDA also went to these lengths to keep cyclamate available for diabetics and certain hypertensives, whose use of cyclamate-sweetened foods had a stronger medical basis. "I should emphasize that my order does not require the total disappearance from the market place of soft drinks, foods, and non-prescription drugs containing cyclamate," Finch reassured those with health problems. "These products will continue to be available to persons whose health

³⁷34 Federal Register, December 11, 1969, p. 19547. The FDA extended the date by which jams, jellies, and desserts must be phased out from February 1, 1970 to April 1, 1970 and extended the deadline for canned fruits and vegetables to September 1, 1970. In April 1972 a bill was introduced in the House to reimburse growers and canners for their losses. It passed the House, but died in committee in the Senate.

³⁸Ibid.

depends upon them."³⁹

In November, Finch had directed Dr. Roger O. Egeberg, HEW Assistant Secretary for Health Affairs, to establish a Medical Advisory Group on Cyclamates to determine what to do about people who needed cyclamates for medical reasons. In December 1969 the panel issued its report endorsing the prohibition on cyclamate use "in beverages and general purpose foods," but unanimously recommending that cyclamate continue to be available for patients with diabetes or on weight reduction programs, who were under medical supervision. The FDA went along with this recommendation.⁴⁰

In reality, FDA was grasping at straws to circumvent the absolutist provisions of the Delaney Clause, which had been added to the Food Additive Amendments of 1958. The Clause provided, "that no additives shall be deemed to be safe if it is found to induce cancer when ingested by man or animal, or if it is found, after tests which are appropriate for the evaluation of the safety of food additives, to induce

³⁹34 Federal Register, December 31, 1969, p. 20426.

⁴⁰Report of the Medical Advisory Group on Cyclamates to Assistant Secretary for Health and Scientific Affairs, Roger O. Egeberg, December 1969. On August 4, 1970, the Medical Advisory Group reconvened at the request of the FDA to reexamine its previous conclusions in light of all scientific evidence then available. In a report delivered to the FDA on August 13, 1970, it reversed itself, concluding "there is no substantial evidence of the effectiveness of cyclamates at any level for treatment of obese patients and individuals with diabetes." Based on this new report the Commissioner ruled that in "absence of adequate evidence of safety and effectiveness continued sale of cyclamate-containing substances cannot be permitted." 35 Federal Register, August 27, 1970, p. 13615.

cancer in man or animal...."⁴¹

Congressman James J. Delaney (D-NY) had proposed his now-famous clause in the 1950s because he feared that FDA would succumb to industry or public pressure to approve products that caused cancer. In 1955 FDA decided to allow non-zero residues, or some parts per million or billion, of the pesticide Aramite on food crops. As Delaney pointed out, "the significance of FDA's... ruling on Aramite was that for the first time a precedent was set that might give legal sanction to the introduction of so-called 'safe' quantities of cancer-inciting additives into food." He insisted on the inclusion of his absolute ban in the 1958 Food Additives Amendment. Although opposed to the Clause, FDA indicated its willingness to compromise to achieve passage of an additives bill. William "Billy" Goodrich, FDA General Counsel, insisted on the wording "after tests which are appropriate for the evaluation of the safety of food additives, to induce cancer in animals" which made explicit the Secretary's role in evaluating the significance of the animal data.⁴²

By enacting this controversial provision, Congress was saying that no benefits outweighed the risk of human cancer posed by a carcinogen added directly to human

⁴¹Federal Food, Drug, and Cosmetic Act. 21 C.F.R. Section 409(c)(3)(A) 21 USC 348 (c)(3)(A). Essentially the same language covers color additives Sec. 706(b)(5)(B) Federal Food, Drug, and Cosmetic Act; 21 USC 376 (b)(5)(B) and new animal drugs Sec. 512 (d)(1)(H), Federal Food, Drug, and Cosmetic Act; 21 USC 3606(3)(d)(7)(H).

⁴²Phyllis Anderson Meyer, "The Last Per Se: The Delaney Cancer Clause in United States Food Regulation" Ph.D. diss., (University of Wisconsin, Madison, 1983), 137, 200. In spite of Delaney's efforts the original committee bill, H.R. 13254, contained no clause when it was reported from committee on July 28, 1958. However, Delaney's membership on the Rules Committee gave him the ability to block action on the legislation until his clause was included.

food. Nor was it prepared to distinguish between products that contained one part per billion or one part per hundred. (The Clause did not apply to substances 'sanctioned' by FDA or the Department of Agriculture before 1958 or to environmental contaminants of food. Nor did it apply to drugs).⁴³

Congressional assessment of risk may have seemed appropriate in the 1950s. Two decades later, however, the increased sophistication of toxicological testing and the applications of these test methods to more products presented a quandary to both scientists and the lay public. Debates raged over how many parts per trillion presented a danger to humans. Based on this, how many products could or should be banned? Is absolute safety attainable or desirable? What is the cost in trying to reach this goal? What is lost in exchange for the added safety that is gained? Cyclamate demonstrated that these were not just theoretical questions but reflected actual situations that the FDA would continue to face.

Those following the story may have wondered why FDA Commissioner Ley had been so conspicuously absent from the announcements and discussions arising from the decision to remove cyclamate. Nobody interviewed him for the front page of the New York Times nor did he appear on the nightly news shows. The entire public response came from officials in the upper echelon of the Department of Health, Education, and Welfare--Finch, Egeberg, and Steinfeld.

Indeed, Ley would be the last of the invisible commissioners. A former professor of preventive medicine at Harvard University Medical School and a careful

⁴³Richard A. Merrill, "Risk-Benefit Decisionmaking by the Food and Drug Administration," George Washington Law Review, 45 (August 1977): 998.

bureaucratic, he had assumed the duties of Director of FDA's Bureau of Medicine in 1966, replacing Dr. James Goddard as Commissioner in 1968. He inherited an agency virtually in shambles. FDA had seen three commissioners in as many years, had been shunted into a new bureaucratic slot that threatened its very identity, and was still reeling from the responsibilities that the Kefauver-Harris Amendments had thrust upon it.

Ley headed an agency incapable of meeting its own mandate, much less growing consumer demands. "Ley," according to the F-D-C Reports, "knew that, but never really felt secure enough in his job to do anything about it." Security was only part of the problem. Ley was marking time, holding the FDA together as the Johnson Administration turned over the reins of government to the Nixon Administration. As the new administration slowly organized itself and set its domestic agenda, the Republicans looked for someone with the managerial drive and vision to re-conceptualize the FDA as a modern administrative agency.⁴⁴

Nothing was more apparent from HEW Secretary Finch's handling of the cyclamate issue than the fact that Ley's tenure in office was over. By the new year, HEW Secretary Finch had replaced Ley, naming Dr. Charles C. Edwards as his new Commissioner. The patrician-looking Edwards would bring a more forceful personality, a new attitude, and a modern management style to the staid old-line agency. Edwards was not new to government. Recently he had joined the staff of HEW Assistant Secretary Egeberg from the management firm of Booz, Allen, Hamilton.

⁴⁴F-D-C Reports, December 15, 1969, p. 18.

Understandably, Finch wanted a person of his own choosing in this key position. But more importantly, Finch needed someone strong and politically astute to put out fires before they became blazes with which HEW had to contend. Until that point Finch had ignored the advice of former Secretary John Gardner, who had appointed James Goddard as FDA Commissioner. Gardner warned him "to watch out for FDA because it could get a Secretary into trouble."⁴⁵

FDA's recently acquired visibility meant that in the future its functioning would be closely watched, its decisions would be questioned, and its actions challenged. To have some bureaucrat talking off the top of his head or obfuscating had become unacceptable and politically dangerous. Finch wanted an agency head who could stand up to these new inquisitors, a Commissioner who would look and sound authoritative before Congressional investigative committees and correct the image of an agency adrift. Finch's disillusionment with Ley began long before Dr. Verrett and her chicks made the news. In May 1969, Representative Lawrence "Pete" Fountain (D-NC) had held hearings on FDA's failure to remove the combination antibiotic Panalba after it had been found ineffective by a NAS/NRC review committee. Normally, such a ruling would have resulted in the immediate decertification of the antibiotic by the FDA and its removal from the market.

⁴⁵F-D-C Reports, December 15, 1969 p. 21. Dr. Alexander M. Schmidt, who succeeded Edwards as Commissioner remembered that the cyclamate situation was very clearly as a turning point in FDA history. "Charlie [Edwards] was brought in to move the agency into the 20th century ... He was brought in to institute good management in the agency, put in modern people, modern science into the agency." Dr. Alexander M. Schmidt, Interview by James Harvey Young and Robert G. Porter, August 9, 1985, transcript, p. 50. Oral History Project, Food and Drug Administration.

Testimony disclosed that Secretary Finch had met with Upjohn officials at the request of their Congressman Garry Brown (R-Mich). Finch then reversed FDA's decision to decertify over Ley's strenuous objections.

Under provisions of the 1962 Kefauver-Harris Amendments to the Federal Food, Drug, and Cosmetic Act, FDA had been required to review all drugs approved between 1938 and 1962 for efficacy.⁴⁶ For the drug companies, this re-evaluation of currently marketed drugs threatened both their profit margin and their prestige. Panalba became a test of FDA resolve. Ley knew that if drug companies could use their political influence to circumvent NAS/NRC committee decisions it would jeopardize the whole review process and the law. For Finch, headlines that he had intervened politically in a scientific decision cast him and the department in a very unfavorable light.⁴⁷

Finch found further cause to make changes when FDA bureaucrats leaked a report prepared by a committee of FDA officials under Maurice D. Kinslow, in August 1969. The report described the agency as unequipped to protect the public. Members of the committee concluded that FDA worked under crippling limitations and that the increasing complexity of the consumer market had outstripped the agency's ability to reassure the public that the products that it used were safe and effective. From the committee's perspective, the FDA lacked legislation authority, manpower, and funding. As a result it had been unable to develop the concerted and coordinated effort needed to deal "adequately and simultaneously with the problems

⁴⁶Kefauver-Harris Amendments, PL 87-781. October 10, 1962. 76 Stat. 780.

⁴⁷F-D-C Reports, December 15, 1969, p. 21.

of pesticide residues, food sanitation, chemical additives, microbiological contamination, drug and device safety and efficacy, hazardous household products, medicated animal feeds and myriad other problems."⁴⁸

Almost all of its 45 recommendations required a major expansion of FDA activities with a concomitant budget increase. FDA's intent had been to focus attention on its need for more funding and personnel from Congress. The plan backfired. Not only did Congress not increase FDA's appropriation but the Kinslow report placed a public spotlight on FDA inefficiency and inadequacy.⁴⁹

By early October 1969, Finch had made up his mind that changes needed to be made. However, before acting he, too, commissioned a study. He asked HEW Deputy Under Secretary Frederic V. Malek, a management specialist, to evaluate the FDA and draw up plans for its re-organization. The report recommended a total overhaul of FDA citing its lack of an effective organization or formal procedures for pinpointing authority and responsibility. It had inadequate mechanisms for top-management planning and control of FDA activities. This lack of control resulted in large backlogs from the inefficient use of FDA personnel. Lastly, it found that crisis items emerged with little forewarning to top management.⁵⁰

To improve FDA, the report recommended that the FDA be reorganized along product rather than function lines. The Bureaus of Science, Medicine, and

⁴⁸Report From the Study Group on the Food and Drug Administration Consumer Protection Objectives and Programs (Kinslow Report), July 14, 1969.

⁴⁹Kinslow Report, pp. 3-5.

⁵⁰Analysis and Recommendations, The Food and Drug Administration Organizational Review, (Malek Report), December 10, 1969, pp. 6-8.

Compliance would be disbanded and replaced by a Bureau of Drugs, Bureau of Veterinary Medicine and a Bureau of Foods, Pesticides, and Product Safety to achieve better administrative control and functioning. The report had the unqualified support of Finch and his staff. In addition, the Nixon Administration agreed to remove the FDA as of February 1, 1970 from the catch-all Consumer Products and Environmental Health Agency where it had been placed during the Johnson Administration.⁵¹

HEW received the Malek study as it firmed up details of the appointment of Dr. Charles Edwards as the new FDA Commissioner. The report had the tacit approval of Edwards, who would be charged with carrying out its provisions and dovetailed nicely with his ideas about a more efficient and better functioning FDA. But the report was not just a reflection of the thinking of Finch, Edwards, and other HEW insiders. In an unusual move, perhaps indicative of the fact that those at HEW had begun to understand the dynamics of change sweeping American society, the Malek recommendations had been based on input from almost 100 people, including Ralph Nader, representatives of other consumer organizations, government officials, and industry representatives. Despite this, Nader was unhappy with the final report saying, "They seem more interested in neat management structure than they are in the consumer."⁵²

Finch's approval of the Malek report on December 10th set the wheels in motion for change at FDA. Having recently joined HEW, Edwards was somewhat

⁵¹Malek Report.

⁵²"The FDA Shake-Up," Newsweek, (December 29, 1969): 37.

reluctant about moving out of HEW offices to the head one of its subordinate organizations, with far greater potential for aggravation and stress. But Finch refused to take no for an answer--Edwards had too much going for him. Not only was he a physician with American Medical Association administrative experience, but also a top health management consultant. To sweeten the deal, Finch told Edwards that he could pick his own people for the top bureaucratic positions at FDA.

Newsweek reported that Ley had never been officially informed, face-to-face, of his termination. Ley's response to the shake-up at FDA was reflective of the old order's view of regulatory government: "the real solution to FDA's woes is not a new commissioner and another reorganization but to isolate FDA from political pressure, give the agency more money, and provide it with leadership and support to allow it to act solely in the public interest." He did realize that in the new activist climate it was impossible to buffer the FDA from politics. Moreover, regulatory officials could no longer assume to speak ex cathedra for the "public." Clearly, Ley was not the man to grapple with the new complexities facing regulatory government.⁵³

In his letter of resignation Ley declined a proffered position in Assistant Secretary Egeberg's office, complaining about the "biased and inaccurate news coverage" and "clandestine news leaks" that had accompanied his dismissal. He extended his sympathies and best wishes to the new commissioner "because I know from the experience of the past year and a half that the position is one of the most difficult of the non-politically appointed positions in Washington." He declined to remain in an interim capacity, indicating that the change should be prompt and

⁵³F-D-C Reports, December 15, 1969, p. 22.

decisive so that the new commissioner could have the full advantage of new thinking and approaches to the regulatory responsibilities of FDA. Finch accepted Ley's resignation praising him "as a gifted scientist and a dedicated public servant... [who] coped strenuously with an unwieldy organization."⁵⁴

In a statement Ley released on December 11th, he bitterly inveighed against the new and constant pressures on FDA as it had been pushed from national obscurity to national controversy in less than a decade. "Yet Congresses follow Congresses enacting new consumer protection legislation but failing to appropriate the funds to do the job. Congressional committees follow Congressional committees criticizing FDA for not doing what they think it should be doing, but failing to enact stronger legislation." Industrial associations were no better--"prodding, suggesting, and threatening." Legal firms and lobbyists got fat from the FDA controversies they stimulated. The problems were not entirely external in Ley's opinion. Within the agency itself, study groups assessed the agency, wrote reports that were then filed away only to be followed by other reports pointing out deficiencies. "One after another frustrated or otherwise unhappy FDA employees leave the agency to join the adversaries."⁵⁵

In a three-hour interview with the New York Times, that made front page news, the "ousted" Commissioner, on his last day in office, detailed the troubles that swirled around him during his three years with the FDA. He complained that he was under

⁵⁴Robert H. Finch, Secretary, Department of Health, Education, and Welfare, Press release, December 10, 1969, Food and Drug Administration.

⁵⁵F-D-C Reports, December 15, 1969, p. 25.

"constant, tremendous, sometimes unmerciful pressure" from the drug industry. "Some days I spent as many as six hours fending off representatives of the drug industry." This statement would elicit little sympathy from his successors, who had to deal with militant consumer advocates, women's groups angry at their second-class status in drug research, AIDS activists, or grandstanding politicians holding endless congressional hearings, as addition to the continuous industry pressure.⁵⁶

The cyclamate controversy had all the drama and the full cast of characters that would play an ever-increasing role in the dynamics of the FDA during the 1970s. It would not be the first time that reporters trumpeted a disturbing new finding about some food or drug, nor the last time that a congressional committee chaired by a crusading consumer advocate would demand to know what was going on, nor the only time that FDA staffers would go over the heads of their superiors to leak information to friendly sources. Unfortunately, it was not the last time that a product that millions of Americans routinely used, and that they erroneously assumed had been tested by the FDA and found safe, would be found to be hazardous to their health.

The agency that Dr. Edwards had just been chosen to head had received more visibility over cyclamate than at any time since the thalidomide tragedy. However, unlike that 1962 crisis, this time the FDA would remain in the spotlight as consumers continued to worry about their health and safety of the foods and drugs they consumed. The paternalistic attitudes that allowed past FDA officials to assume that

⁵⁶Richard D. Lyons, "Ousted FDA Chief Charges 'Pressure' From Drug Industry," New York Times, December 31, 1969, p. 1.

their expertise gave them the right to speak for the public interest grudgingly retreated before the onslaught of well-organized, well-funded, and knowledgeable public advocates and consumer groups.

While protecting its own turf and perquisites, FDA had to maintain the cooperation of industry and the medical and pharmaceutical professions, at the same time assuring consumers that they also had FDA's ear. All subsequent commissioners have had to allay the suspicions of almost everyone who came in contact with the agency that the FDA was not doing its job, doing it too well, or doing it for the benefit of someone else. FDA had become and would remain one of the "hot seats" in the federal government. Finch hoped that in Dr. Charles C. Edwards he had found a new commissioner who could stand the heat.

CHAPTER 3

"DR. CHARLES EDWARDS TO THE RESCUE"

"We are always alert to the possibility that we are tokens." Martha Robinson, Information Director of the Consumer Federation of America, questioning whether the Food and Drug Administration was sincere in its efforts to involve consumers in its decision-making.¹

At his inaugural press conference on December 10, 1969, a reporter asked Commissioner Charles Edwards what attitudes he would bring to the commissionership that were not already there. Before he could answer, Dr. Roger O. Egeberg, Health, Education, and Welfare Assistant Secretary for Health, and Edwards' former boss muttered that Edwards "is a hard-nosed son-of-a-bitch." When the laughter died down, the new FDA Commissioner continued, "We are going to bring into FDA some hard-nosed management principles and ... where needed some hard-nosed managers, and hopefully ... some capable scientists." In all likelihood, this would be the minimum needed to rejuvenate the Food and Drug Administration, an agency in disarray after the battering it had taken during the 1960s. The press conference signaled that the new boss intended to make serious changes. FDAers, though, had reason to be cynical about this new Commissioner chosen to rescue their embattled agency. After all, in recent years they had seen others try and fail.²

Dr. Edwards had some advantages over those who came before him. For one thing, he had support at both the Department of Health, Education, and Welfare and

¹Judy Gardner, "Consumer Report/Congressional Battle Over FDA Control Focuses on Product-Safety Legislation," National Journal 4, June 10, 1972, 997.

²F-D-C Reports, December 15, 1969, p. 24

the White House. In addition, Edwards, trained as a surgeon at the Mayo Clinic in Rochester, Minnesota, had the varied career experiences that his superiors at HEW hoped would smooth his relations with some of FDA's constituent groups. He had been a consultant to the Surgeon General before taking an administrative post at the American Medical Association. His resume included a stint as Vice President of the Health and Scientific division of Booz, Allen, Hamilton, a management consulting firm before joining HEW.

Edwards also brought to his new position a clear agenda. He believed that FDA decisions had to be based on sophisticated scientific methodology. FDA needed to upgrade its scientific capabilities and draw upon the expertise of the nation's community of scientists and physicians. Secondly, he recognized that the consumer movement was not a temporary phenomenon and that the FDA, as well as the industries that it regulated, needed to accept this fact and adjust its policies and procedures accordingly. Lastly, Edwards knew, based on his professional experience, that FDA needed better management techniques to meet its expanding and increasingly complex mandate. These would provide greater stability and structure to an agency that had seen more than its share of reorganizations, revised mandates, and bureaucratic shuffling. His grasp of the problems facing the FDA in the 1970s and his extensive management experience provided an advantage to a political appointee faced with reorganizing an understaffed, under-financed, and demoralized government agency. But Edwards had one more arrow in his quiver. Edwards started with as clean a slate as anyone taking over a governmental agency could expect to have. HEW Secretary Robert Finch allowed him to fill upper echelon

positions at the Food and Drug Administration with his own appointees--people, untainted by the old policies and insularity of the past, who shared his vision of FDA's direction for the future. Many of them had a background in management, including some associates from Edwards' days at Booz, Allen. Others came from the regulated industries, not unusual in the business-oriented Nixon Administration.

By the end of 1971 many of the old faces were gone. People from outside the agency filled nine of the fourteen major policy-making positions at the agency. Dr. Henry E. Simmons, Director of the Bureau of Drugs, came to the agency in March 1970 from the New York office of Booz, Allen. Deputy Commissioner Sherwin Gardner, another Booz, Allen associate, joined the FDA in October, 1970. Dr. Virgil O. Wodicka, Director of the Bureau of Food, Pesticides, and Safety moved to Washington, D.C. in February, 1970 from Hunt-Wesson Foods, where he had been a technical director. Previous to the Edwards' administration, the agency had brought in outsiders only at lower levels--inspectors, bench chemists, and microbiologists.³

From Edwards' viewpoint these outsiders brought a fresh perspective to their work, greatly expanded the expertise of the agency, and gave it more organizational flexibility. Former Deputy Commissioner Winton Rankin, a long-time FDA employee who had been pushed up and out in the wake of the cyclamate controversy, agreed. He remarked in 1980 that the FDA's biggest mistake was "to insist on advancement to key position from within the Agency [when] we needed the viewpoints, experience, and training that were available only from outside the Agency." By promoting from within, the FDA lost touch with the diversity of viewpoints and abilities that were

³FDA Directory of Officials, (Washington, DC: GPO, 1970).

critical in the rapidly changing medical, scientific, and political climate.⁴

But the staffing of FDA with those who had worked in industry did not sit well with many agency old-timers. Arthur Checchi spoke for many of his generation when he said, "You didn't work for the Food and Drug Administration; you belonged to it."

For them, the FDA that they had known had been irredeemably lost.⁵ Old-line FDAers frequently complained of the "politics" that now influenced agency operations. They used the term "political" to describe two different phenomena: 1] an increase in the number of political appointees in high-level positions, and 2] the continual review of FDA decisions by HEW and by Congress, where the impact on public health was weighed against the political ramifications of FDA's action. Some of this could be dismissed as nostalgia for the "good old days," but other complaints were more pointed. "These short-term, 'political' Commissioners don't have to live with their decisions," said Fred Lofsvold, "They know they're out in three or four years."⁶

Consumer leaders also expressed deep concern about the increasingly political nature of FDA's top management and the close relationship between the regulator and the regulated. As Dr. Michael F. Jacobson of the Center For Science in the Public Interest complained, not only did many of the top executives at the FDA come from major food and drug companies, but frequently FDA employees landed

⁴Winton Rankin, FDA Deputy Commissioner, Interview, September 30, 1980, transcript, pp. 47-48, Oral History Project, Food and Drug Administration.

⁵Arthur Checchi, Assistant Deputy to the Commissioner, Interview, July 24, 1984, transcript, p. 162, Oral History Project, Food and Drug Administration.

⁶Fred Lofsvold, Director, FDA District VIII, Interviewed by James Harvey Young, August 25, 1981, transcript, p. 179, Oral History Project, Food and Drug Administration.

lucrative industry jobs after leaving the government. Jacobson did not deplore the presence of former industry executives in high government position, per se, but rather the lack of a corresponding group of people whose philosophy had developed in a pro-consumer milieu. "Two years ago I looked at the 50 top executives at FDA, and 22 had worked for or with industry, none had worked for or with consumers," Jacobson pointedly observed. "What would the industry response be if 22 of the 50 used to work with Nader and none with industry?"⁷

Edwards had been given a relatively free hand in reshaping the FDA and in establishing patterns and precedents for the foreseeable future. While the stodgy bureaucrats of the past had not provided effective leadership, turning over the agency's directions to those so closely aligned with industry troubled many in the consumer movement. Despite their protestations of impartiality these appointees had been trained and risen to responsible positions in a corporate culture, and consumerists feared, had subconsciously internalized the industry viewpoint. "Their philosophies were molded in the corporate environment which places company interests first, places the burden of responsibility on the public, and deplores governmental restrictions on companies," public advocates charged. "Moreover, if public officials are fishing for jobs with the very companies they are supposed to be regulating, they are unlikely to be too severe in cracking down on those companies if they violated the law."⁸

Of all those joining the FDA from the private sector, none aroused as much

⁷Center for Science in the Public Interest, Newsletter, 3 (Winter 1973): 3.

⁸Nutrition Action, 1 (May 1974): 4.

concern and indignation as Peter Barton Hutt, who became FDA General Counsel in September 1971. The General Counsel was second only to the Commissioner in importance at the FDA and in many instances had as much power to set policy as the Commissioner. The new appointee would have the opportunity to set the future course of the agency, develop new approaches to regulation, and implement new strategies, if he so chose.

Few in Washington doubted that Peter Hutt would do otherwise. One of the luminaries in the food and drug law field, for 11 years he had been a rising star in the high-powered law firm of Covington and Burling, reaching the level of partner. The Washington-based firm had a long track record of successfully representing the nation's largest food and drug companies in their dealings with the FDA. "Covington and Burling lawyers are among the best trained and best paid in the field of defending industry from governmental and consumer intrusions," said consumer advocate Robert D. Choate with the respect given to a worthy adversary. "They are as practiced in the fine art of lobbying as they are polished in courtroom techniques. Peter Hutt is no exception." Consumer groups feared that Hutt could not be trusted to guide the FDA in protecting the public's interest after years of counseling industry.⁹

Hutt had been handpicked by his predecessor, Billy Goodrich. Widely acknowledged for his formative influence on FDA regulatory policy and often deferred to by FDA Commissioners, Goodrich had held the post of General Counsel since

⁹Nicholas Wade, "FDA General Counsel Hutt: A Man Trying to Serve Two Masters," Science, 177 (August 11, 1972): 500.

1952 and had been on the FDA staff for 32 years. He had played a pivotal role in Hutt's career at a number of points. While giving a talk at Harvard Law School, Goodrich met Hutt and urged him to apply for a graduate fellowship to New York University Law School's Food Law Institute. Later, Hutt applied for employment at the FDA, FTC, and Covington and Burling. Accepted by all three, Goodrich advised him to join the law firm, where he would receive the best legal training.¹⁰

The choice of Peter Hutt also had the backing of the new HEW Secretary Elliot Richardson. Technically, Hutt reported to the HEW General Counsel. Richardson, opposed to a strictly political appointment, looked for someone from the relatively small group of bright, young food and drug law specialists in private practice. Richardson realized that this would not go over well with consumer activists, but both the FDA and HEW were not yet ready to give them veto power over appointments. Richardson hoped to quiet the opposition with a candidate whose professional integrity and legal expertise were beyond question.¹¹

Hutt, too, tried to justify his selection. To begin with, any appointee would need the kind of knowledge of food and drug law that he brought to the position. "It would probably take some three or four years of on-the-job training to assimilate not only the technical legal background--that is, the cases, the legislative history, and the statutory provisions--but, perhaps more important, the history and traditions that have shaped this agency's actions." Of course, Richardson could have picked a FDA

¹⁰F-D-C Reports, September 20, 1971, p. 21.

¹¹F-D-C Reports, June 7, 1971, p. 10. Technically, the FDA General Counsel has the title of Assistant General Counsel of the Department of Health, Education, and Welfare, for the Food and Drug Division.

or HEW legal counsel or a law professor with a specialization in food and drug law.

But when Billy Goodrich left, Edwards wanted someone who could get started at once on the major changes that he believed needed to be made at FDA. Hutt had been involved with the FDA for more than 10 years, had a clear idea of what needed to be done, and a philosophical commitment to change.¹²

Soon after leaving FDA, Goodrich became president of the Institute of Shortening and Edible Oils, an industry trade group and one of Peter Hutt's former clients at Covington and Burling. To consumer advocates this raised the issue of an unhealthy relationship between industry and the FDA. Here was a perfect example of the "musical chairs" between industry and government of which they were so skeptical. Ruth Desmond, president of the Federation of Homemakers, called it "an Alphonse and Gaston mutual benefit act performed by protege and benefactor." She wrote to Secretary Richardson that for Hutt to avoid his former clients he would have to run the FDA's General Counsel's office "by remote control, with a ouija board, from a south sea island retreat for an unspecified period of time."¹³

Richardson stood by his nominee. Consumer activists next turned to their allies in Congress to block the nomination. Although the position of General Counsel did not require congressional confirmation and had never been subjected to congressional hearings, Senator Frank E. Moss (D-Utah) announced his intention to

¹²"Behind FDA's Regulations," FDA Consumer, (November 1974): 10.

¹³Congress, Senate, Committee on Commerce, Nomination of Peter B. Hutt to be Assistant General Counsel for Foods, Drugs, and Environmental Health, Department of Health, Education, and Welfare: Hearings before the Committee on Commerce, 92d Cong., 1st Sess., September 17, 1971, 54, 61. [Cited hereafter, Hearings, Nomination of Peter B. Hutt]

hold hearings. The power of the consumer lobby was growing. Moss's office put the Administration on notice that "we are maintaining close scrutiny of all appointees to sensitive positions involving consumer interests."¹⁴

Hutt, who could have refused to appear unless subpoenaed, voluntarily came before the committee in an effort to defuse the situation. However, when Moss requested a list of the clients he had counseled at Covington and Burling during the past ten years, he refused on the basis of lawyer/client confidentiality. In a letter to the committee, Hutt provided a list of cases in which he had been identified on the public record as counsel. Concerning possible conflicts of interest, Hutt promised that "I will disqualify myself from consideration of any case, petition, hearing, or other similar matter in FDA on which Covington & Burling has worked prior to September 1, 1971...."¹⁵

This hardly placated his opponents. While praising Hutt's "incredible legal competence," Representative Benjamin Rosenthal (D-NY), one of the most vocal consumer advocates in Congress raged, "From 203 million Americans, the only one we can find for this job is one who has spent all of his professional life representing the regulated." Reasoning that no one can fully divorce himself from his past, Rosenthal thought it far better to have appointed a reasonably competent law school professor.

Consumer advocate Robert Choate found it "especially peculiar and disheartening" that FDA would choose its new General Counsel from "the very group

¹⁴New York Times, September 12, 1971, p. 59.

¹⁵Hearings, Nomination of Peter B. Hutt, pp. 3-4.

of lawyers most adept at tying up FDA's regulatory processes ... at a time when many of us thought FDA was on the verge of becoming more consumer-oriented." In the end Moss called his appearance "forthright and candid," the hearings adjourned, and Peter Barton Hutt became FDA General Counsel.¹⁶

From his point of view Hutt was making a very significant sacrifice to assume his new position. "What made me leave Covington and Burling for a job at half the salary and twice the vexation?" Hutt asked rhetorically. "Public service." Hutt had every right to be proud of his pro bono work in the field of alcoholism. As attorney of record in two famous lawsuits, known as the Easter and Driver cases, he had secured a legal basis for treating alcoholism as a disease instead of a crime.¹⁷ But Anita Johnson of the Nader-funded Health Research Group ventured another guess at his motivation. "Most of the FDA officials are worried by controversy, but you should see Hutt once a fight gets started--he really loves it. He probably saw more fights going on in the FDA than in defending people like Abbott Laboratories." And they were fights he was sure he could win.¹⁸

If Edwards came to the FDA with an agenda, Hutt brought a missionary's zeal and vision to the task of transforming the Food and Drug Administration into an efficient administrative agency, seeing himself as the 'modern major general' running it. "Somebody had to take the initiative [to change FDA] and it was me," he told

¹⁶Hearings, Nomination of Peter B. Hutt, pp. 28, 33.

¹⁷Easter v. District of Columbia, 209 A.2d. 625 (D.C. Ct. App. 1965) rev'd. 124 U.S. App. DC 33, 361 F.2d (1966). Driver v. Hinnant, 243 F. Supp. 95 (E.D.N.C. 1965) rev'd 356 F. 2d. 761 (4th Cir. 1966).

¹⁸Wade, 499-500.

author Scott Lucas. Never one to doubt his formidable legal skills and prodigious knowledge of food and drug law, Hutt evinced a strong belief in an activist, creative approach to regulation. "It was overdue at FDA," he explained. "We had to change our whole approach to regulation of foods, drugs, cosmetics, and medical devices. We had to make the transition from ad hoc law enforcement to being a modern administrative law agency."¹⁹

Convinced that FDA people, like those in other bureaucracies, lacked imagination, Hutt wanted regulatory decisions to provide the answers to real world situations. 'How can we regulate this or that substance in a rational, sensible way?' If you have a limited amount of funding to regulate all foods and drugs, where do you put your priorities? How do you decide what will be just enough regulation to get the job done but not too much regulation so that it becomes unnecessarily disruptive and burdensome?²⁰

Although he had Billy Goodrich's backing, Hutt's approach stood in stark contrast to that of his predecessor. For most of his career Goodrich served a much smaller FDA that dealt with simpler issues that had been solved by direct court action on a case-by-case basis. Under Goodrich, FDA heard out industry, stated its position and then, if industry did not agree, Goodrich answered, 'We'll see you in court and let the court decide who's right.'" Goodrich used test cases with the worst case companies to produce judicial support for the establishment--or expansion--of FDA's regulatory thrust, knowing the reluctance of courts to counter the expertise of a

¹⁹Scott Lucas, The FDA, (Millbrae, CA: Celestial Arts, 1978), 124.

²⁰Wade, 501.

government regulatory agency.²¹

"For many years we operated with the law and a few basic regulations," remembered Robert C. Brandenburg, who had been FDA Director of Compliance Regulations during Goodrich's time. "Bill [Goodrich] was no great one for the promulgation of regulations. He felt that the law said what had to be done and he wanted, I think, to have the leeway to make decisions himself rather than have each one spelled out for him so that he would have to observe them in detail at each point." By the time Hutt took over the office, outside factors from the courts to the Congress had altered the way the FDA operated. It was no longer an agency whose only responsibilities concerned plant inspections and the proper labeling of products.²²

Like a Model T Ford that wandered onto a California freeway, the FDA had been overwhelmed by the conditions under which it now found itself operating. FDA lacked the personnel, procedures, and philosophy to handle its expanding regulatory responsibilities. Its obligations to assess the safety and efficacy of drugs before marketing or its increased safety standards for food additives and food products were beyond its institutional capacity. Goodrich's horseless carriage, case-by-case legal style no longer fit the high-powered environment in which FDA operated. Edwards and Hutt set out to retool the Food and Drug Administration for the last quarter of the twentieth century.

²¹F-D-C Reports, August 26, 1974, p. T&G 7.

²²Robert C. Brandenburg, Director, Compliance Regulations and Policy Staff, interviewed by Robert G. Porter, December 4, 1982, transcript, pp. 60, 62, Oral History Project, Food and Drug Administration.

Charles Edwards had been chosen by HEW Secretary Finch in December 1969 to turn around an agency still reeling from the unwanted attention it received from cyclamate, and he quickly took command. Professionally successful and financially secure, Edwards explained his interest in one of the most thankless jobs in Federal service as the desire for action and challenges. The FDA in 1970 certainly provided a challenge for a man on the make and Edwards intended to leave his imprint on the agency from the very beginning.

Edwards realized that fundamental questions going well beyond budget and technical proficiency had to be posed: "As the biological and physical worlds probe deeper and learn to measure values ever more minutely, our common concepts of what is ... safe must change." How was the FDA to operate in a world that had redefined risk and safety, or worse, had no widely accepted definition of these concepts? One way to assure support for FDA decisions was to make the process more inclusive. "We must have greater consumer participation in the governmental process so we can be assured that what we are doing is truly in response to consumer desires and expectations." To achieve this goal, Edwards established a broadly representative consumer advisory group.

Edwards also set as a major goal the upgrading of FDA's scientific expertise. "FDA should not only be a full-fledged member of the federal health community but probably its most important member in light of the immediate and direct impact of its mission on the health and well-being of the American people." To do this Edwards proposed increasing the FDA's use of outside scientific experts, at the same time that

the agency upgraded its own woefully inadequate scientific resources.²³

As part of his efforts to update the FDA and strengthen its scientific underpinnings, Edwards established another review committee. Unlike the committee organized by former Commissioner Ley, the new Commissioner went outside FDA to the nation's scientific elite for a fresh appraisal of his agency. Edwards asked Dr. Roy E. Ritts, head of Microbiology at the Mayo Clinic and professor at the Mayo Graduate School of Medicine at the University of Minnesota, to head a panel that included four other scientists from leading U.S. medical schools. This team was asked to review and evaluate the total scientific effort at FDA from research planning to interdepartmental and inter-agency science relationships, from setting priorities to crisis management.

The Ritts Committee turned in a report in May 1971 harshly critical of FDA's overall scientific effort and its substandard conditions, citing laboratories "so poorly managed that scientists seemed to be unable to describe their work coherently...." It found antiquated, crowded and unsafe facilities that "are a disgrace to the agency and the committee can only express alarm that FDA scientists are asked to work under such circumstances."²⁴

The Committee made extensive recommendations including better use of scientific advisory councils, increased science communication with outside communities, improved science planning, and methods to improve the review of

²³Berwin A. Coles, "The Ritts Committee," FDA Papers, (May 1970), 14.

²⁴Report of the Food and Drug Administration Ad Hoc Science Advisory Committee (Ritts Report), May 1971, 24.

applications submitted by manufacturers for the approval of new drugs. The Committee strongly affirmed that science in the FDA is a resource and a means rather than an end unto itself. It stressed that the FDA cannot adequately meet its responsibilities unless its regulatory decisions are based on sound scientific information. "Science is the primary and essential means by which FDA achieves rational decision-making on behalf of consumer protection." Edwards knew that a report prepared by such a prestigious panel would carry weight with his superiors at HEW and could only add to his argument. Indicative of the new public interest in the way FDA operated, the story made the front page of the New York Times.²⁵

In truth, for an organization under attack on as many fronts as the FDA, science provided the strongest defense for its decisions. By the 1970s most of the bastions of authority in American society had been battered by a youth movement that denigrated traditional sources of authority and a war that had more effectively destroyed the trust of the American people in their government than it had ever destroyed the Viet Cong. Ralph Nader's expose, Unsafe At Any Speed and similar books and articles had done an equally effective job of undermining the belief in a business community that balanced a safe, well-made product on the same scales as profits.

Science at least gave the appearance of objective, unbiased truth. An adequately controlled, double-blind clinical trial in which neither the patient nor the doctor knew the recipients of the active drug and the placebo had less possibility for

²⁵Harold M. Schmeck, Jr. "Report Criticizes FDA Over Its Scientific Effort," New York Times, May 28, 1971, p. 1. Ritts Report, 3-4.

subjective interpretation. The FDA could use this scientifically derived evidence to refute the claims of manufacturers that their poorly-tested drugs should remain on the market. Positive results from sophisticated toxicological testing could force the food industry to remove unsafe additives while negative results could be used to convince consumer activists that the foods additives that FDA approved were indeed safe.

But the number of issues on which FDA had to rule had grown so large, so complex, and so diverse that it was unreasonable to assume that FDA's in-house scientists possessed the expertise to evaluate the thousands of foods, drugs, and medical devices that FDA regulated, no matter how much its staff and funding grew. In fact, the FDA had made an effort, albeit unsuccessfully, to recruit an "in-house critical mass" of scientific personnel. During the 1960s it sought to create an environment for scientists comparable to that of the National Institutes of Health. Still, FDA found it hard to attract suitable candidates from private labs and academic institutions. Most scientists preferring to do their own work, rather than review the work of others.²⁶

Edwards attempted to solve this problem by expanding the ad hoc advisory committees, which FDA had used sporadically for the past half-dozen years, into a system of standing committees drawing its members from scientists and physicians at research universities and medical centers. The use of such committees had their own significant history. As early as 1965, FDA had used an ad hoc Obstetrics and Gynecology Advisory Committee to evaluate the safety and efficacy of oral and

²⁶Robert S. Friedman, "Representation in Regulatory Decision Making: Scientific, Industrial, and Consumer Inputs to the FDA," Public Administration Review 38 (May/June 1978): 206.

uterine contraceptives after women's groups charged that the FDA had ignored reports of serious side effects. The FDA used the committee to get additional scientific expertise, as well as to provide backing for its handling of the situation, a practice it would continue in the future.²⁷

In the 1960s, Dr. Joseph Sadusk, Jr., Director of the Bureau of Medicine, envisioned "open advisory committee discussions with industry, scientific, and medical personnel present, along with representatives of the American Medical Association's Council on Drugs, and executive sessions involving only committee members and FDA staff." At this point FDA's intention seemed to be a better understanding of industry's viewpoint and scientific rationale and not a more objective evaluation of the material presented. Clearly no thought was given to providing consumer representation.²⁸

FDA sporadically organized and disbanded ad hoc committees over the next few years, establishing no formal system. Although the DESI review panels established by Dr. Goddard to meet the requirements of the Kefauver-Harris Amendments set a precedent within the FDA of seeking outside expert scientific advice for major decisions, NAS/NRC procedures did not provide a template for future FDA product evaluations. After signing the contract with NAS/NRC, FDA had no further involvement. The panels of experts selected by NAS/NRC met in secret, not

²⁷Richard L. Schmidt, "Public Advisory Committees: Their Role in FDA Decisions," FDA Papers, (September, 1971): 7.

²⁸Institute of Medicine, Food and Drug Administration Advisory Committees, Richard A. Rettig, Laurence E. Earley, Richard A. Merrill, eds. (Washington, D.C.: National Academy Press, 1992, p. 46. [Cited hereafter as IOM, Food and Drug Administration Advisory Committees]

even disclosing the frequency and location of their meetings, and released no public information--even to the FDA--until they reached their final conclusion. The panels had provided for neither industry nor consumer participation. The DESI review process proved unsatisfactory for future FDA actions because it underlined FDA's scientific inadequacy, took control out of FDA hands, and responded to problems on a crisis basis.²⁹

Under Edwards tutelage, the FDA developed a system of advisory committees, covering specific therapeutic categories, which met on a regularly scheduled basis. The FDA sought participants, who served for specific terms, through formalized nominating procedures announced in the Federal Register. However, these advisory committees performed other useful functions for the FDA beside evaluating information and advising the agency on the approvability of specific drugs. According to Dr. J. Richard Crout, then Director of the Bureau of Drugs, Edwards wanted to bring credibility to the drug approval process, as well as generate some protective cover for agency decisions. "Advisory committees served both as consulting groups and as open forums for discussing controversial issues, a function that the agency considered particularly important."³⁰

²⁹Wallace F. Janssen, "Outline of the History of US Drug Regulation and Labeling," Food Drug Cosmetic Law Journal 36 (1981): 437.

³⁰IOM, Food and Drug Administration Advisory Committees, 54. The FDA used internal memoranda to create these committees administratively. Subsequently the FDA promulgated general regulations governing the formation and operation of these committees. "An advisory committee ordinarily has a fixed membership, a defined purpose of providing advice to the agency on a particular subject, regular or periodic meetings, and an organizational structure, for example, a chairman and staff, and serves as a source of independent expertise and advice rather than as a representative or an advocate for any particular interest." 21 CFR, 14.1(b)(5), 1991.

The FDA had 24 public advisory committees in 1972. By 1973 the number had grown to 45, and then to 66 in 1974. Reflecting on changes achieved by the end of 1972, Edwards proudly commented that FDA's expanded budget had allowed it to bring in some top-notch scientists, adding greatly to its scientific capabilities. In addition, the ability to call on leading scientists for advice, when needed, provided immeasurable advantage. "I think this is all terribly important, because the complexity of the decisions, both scientific and technological, that we make everyday are only as strong as the science behind them. A regulatory agency like FDA must have scientific credibility."³¹

For the most part, the advisory committee system gained the support of the pharmaceutical industry because drug executives believed them to be more strongly oriented toward therapeutic innovation than the agency. The committees also provided some opportunity for a fair review of agency decisions that would otherwise escape scrutiny.

Critics of bureaucratic government, on the other hand, charged that industry supported the system because it provided a legitimate way for industry or medical groups to influence policy. Even if those chosen for advisory committees were not

³¹"FDA Today: An Interview with the Commissioner," FDA Consumer, (December 1972/January 1973): 9. In the 1970s, the FDA evaluated hundreds of thousands of over-the-counter medications for efficacy. Instead of examining each product, the FDA developed a system of monographs that determined which ingredients were safe and effective for a specific class of drugs, for instance, antihistamines. Rather than going to the NAS/NRC as they had done with prescription drugs, Peter Hutt organized monograph committees to evaluate each class of drugs. These committees, which were established for a limited period, increased the FDA advisory committees to 66.

industry scientists, their professional associations offered a chance to interact, to develop relationships, and to foster a commonality of interests with industry scientists. At the very least, they certainly did not represent the interests of consumers, despite their protestations of scientific impartiality and detachment.

"Industry officials might prefer not to be regulated, but they assume that regulation is a fact of life. Accordingly, they seek a forum with an opportunity to maximize their case." Industry presentations at advisory committee meetings were designed to make committee members aware of the impact their proposed actions would have on the manufacturer or business.³² "Moving some of the agency-clientele relationship out into the open and formalizing it through advisory committee service, written memoranda during the notice and comment period, and appearances at public hearings," according to Robert Friedman, "is a step on the path from 'interest group pressure' to 'public input.'"³³

Edwards had administratively devised the system that he needed to give FDA credibility and clout, but his was not a unique process. Other regulatory agencies had established ad hoc committees, set their standards by internal memoranda, and effectively closed these committees to public view. An investigation by the Special Studies Subcommittee of the Committee on Government Operations documented over 2600 advisory committee operating with little or no oversight. Over the years, public advocates complained to Congress that they had been excluded from much

³²Friedman, 212.

³³Dennis D. Riley, Controlling the Federal Bureaucracy, (Philadelphia: Temple University Press, 1987), 128.

of the regulatory agencies' work because it occurred behind the closed doors of committee rooms.

Congress passed the Federal Advisory Committee Act in 1972, establishing an agency to set uniform procedural standards for federal advisory committees and to limit their number. However, a secondary objective of the law was to promote a more open process, in line with efforts to foster greater citizen participation in government. The law mandated that 'committee meetings shall be open to the public and fairly balanced in terms of points of view represented and the functions to be performed.' Henceforth, the Federal Register would carry public notices of meetings at which "interested persons shall be permitted to attend, appear before, or file statements." Under the appropriate circumstances the public would have access to the minutes, records, studies and other documents prepared for, or by, each committee.³⁴

The law reflected a Congressional concern that industry-oriented advisory committees, acting in closed meetings, had assumed too large a role in agency decision-making. Congress seemed wary that rogue committees could usurp the functions or prerogatives of government employees. Therefore, Congress stressed the advisory nature of the committee and required that a federal official oversee the

³⁴Federal Advisory Committee Act of 1972, P.L. 92-463, 86 Stat. 770 (1972). In 1962, President John F. Kennedy had issued an Executive Order, which prescribed general guidelines for the formation and uses of advisory committees. However, it had no enforcement provisions. Presidential Papers of John F. Kennedy, Executive Order 11007, February 26, 1962.

functioning of all meetings.³⁵

FDA management itself voiced no such fears. From their perspective, the committees developed as a result of an agency initiative that determined their functional role, the information they were given, and the weight given to their advice. The committee system served its purpose by giving the agency access to the highest levels of scholarship in the scientific community and in other federal agencies. In selected areas where the agency lacked expertise, consultation with technical committees or panels permitted prompt access to those experts able to formulate solutions to regulatory problems.

The rotational nature of committee memberships brought a wide range of individuals into contact with the FDA, exposing them to the agency's deliberations and problems. This could be a double edged sword. On the one hand, it gave participants an insight into the complex problems facing the FDA, its inadequate resources, and the legal restraints under which it operated--factors over which it had little control. On the other hand, it could leave committee members with an unpleasant awareness of bureaucratic in-fighting, industry influence, and less than competent personnel--situations that good internal management techniques could mitigate.³⁶

³⁵Congress, House of Representatives, House Report. No. 91-1731, 91st Cong., 2d sess., 3.

³⁶Later critics worried that committees would lose their independence because of the overbearing presence of agency officials. They argued that agency officials framed the questions, presented the material, and controlled the length and the direction of discussions, so that the committees supported the positions the agency favored.

FDA did not fear the usurpation of its functions by advisory committees. Although Edwards made clear that the FDA needed and welcomed the expertise of the outside scientific community, in the final analysis interpretation and decision-making rested with the FDA. Edwards, a shrewd bureaucrat, signaled his intention not to relinquish control of his organization to outsiders, no matter how qualified or how representative.

He took the same attitude toward the consumer advocates. As he had recognized the need to seek outside scientific expertise, Edwards bowed to the inevitability of dealing with the vocal and visible consumer movement. He promised greater consumer participation in the governmental process "so we can be assured that what we are doing is truly in response to consumer desires and expectations."³⁷

Within his first month in office, Edwards told a meeting of the Consumer Federation of America, with a certain amount of self-dramatization, that at times it had seemed as if nobody cared, including consumers, about the concept of consumer protection. Portraying FDA's role in the past as a 'lonely vigil', he now heard "a whole chorus of voices [that] speak for the consumer." Aware that consumer advocates usually took an adversarial attitude toward FDA, Edwards hoped to win over the group, and others like it, to a more favorable view of the FDA. The message spread by Edwards and his staff was that this transformed FDA understood the consumer perspective and wanted to work with them.³⁸

³⁷Charles C. Edwards, M.D., "We Must Move On," FDA Papers, (March 1970): 10.

³⁸F-D-C Reports, February 1, 1970, p. T&G 5.

Edwards' attitudes were not shared by all. Detractors, who questioned the motives of those who professed to speak for the "public," doubted whether they spoke for anyone but themselves. Although the term has often been abused, exploited, and derided, Paul Shuck, a director of a public interest law firm for Consumers Union, argued that public interest is a useful description of a limited universe of organizations that purport to represent "broad, diffuse, non-commercial interests which traditionally have received little explicit or direct representation in the process by which agencies, courts, and legislature make public policy." Unlike other groups, in which members have professional, occupational, or political ties, the public interest group is organized around "a status or role which virtually all persons in the community are thought to share in common--the status of consumer, citizen, taxpayer, member of the biosphere."³⁹

In 1962, President John F. Kennedy delivered the first consumer message to Congress, proclaiming four "rights of consumers": the right to know, to be safe, to choose, and to be heard. From 1965 onward, consumer protection became a part of the agenda of both political parties. President Lyndon B. Johnson made consumer protection a major part of his program. Mark Nadel in The Politics of Consumer Protection, suggests that by 1966 Johnson, who had already enacted a substantial program of major domestic reform legislation, was facing an increasingly recalcitrant Congress as he tried to push for new programs in the face of inflation and the war in Vietnam. Consumer protection, unlike the Vietnam War, poverty, or civil rights,

³⁹Peter H. Schuck, "Public Interest Groups and the Policy Process," Public Administration Review, 37, (March/April 1977): 133.

was relatively cheap and provided a consensus reform issue that appealed to, and benefitted, the middle class.⁴⁰ By 1969 the legitimacy of a governmental consumer protection role had become so widely accepted that President Richard M. Nixon delivered a "Protection of the Interests of Consumers" message calling for "stronger efforts in the field of food and drug safety, including a thorough reexamination of the Food and Drug Administration." Following the cyclamates controversy, Nixon had asked for a thorough review of all other food additives on the 'generally recognized as safe' (GRAS) list.⁴¹

Why did a public which only a few years before had celebrated American abundance, productivity, and technical expertise suddenly begin to question the quality and safety of its products? Several theories have been put forth to explain the sudden upsurge in the consumer movement in the 1960s.

In Harvey Sapolsky's view mature capitalist societies develop a class of educated dissidents, doctors, lawyers, and policy analysts, who need not gain personally from restrictions on corporate behavior to be concerned about the health consequences of products. Through their shared interest in environmental preservation, physical fitness, and nutrition these professionals are usually most aware of products that pose health threats and the procedures needed to control them. "They heed the product labels that they cause to be written. In essence, they constitute a market for bad news about products, a market that, because of its

⁴⁰Mark Nadel, The Politics of Consumer Protection, (New York: Bobbs-Merrill, 1971), 41.

⁴¹Nadel, 35.

affluence and position, wields influence over both the producers of consumer goods and politicians."⁴²

James Q. Wilson drawing on the research of Douglas Anderson agreed that the strength of consumerism increased with the arrival of a political elite that absorbed the neopopulist outlook fostered by the 1960s: the suspicion of institutions, the criticism of business enterprise, the interest in speaking on behalf of unorganized consumers, and the conviction that such an outlook is not only morally correct but politically useful.⁴³

To transfer a feeling of concern or anxiety into action required an individual who was skilled in what Wilson termed "entrepreneurial politics." For the consumer movement spawned in the 1960s, Ralph Nader was the pre-eminent practitioner of entrepreneurial politics. He and the organizations that he created tapped into, and in turn fed, a groundswell of consumer discontent and unease that had been building for years. Drug efficacy laws were a good example of the methods consumer activists used to focus diffused concerns into action.

Efficacy laws conferred benefits to the general public at a cost to be borne chiefly by a small segment of society, the pharmaceutical industry. Since the incentive to organize was strong for opponents of the policy but weak for the beneficiaries, passage of such legislation required the efforts of a skilled entrepreneur who could mobilize latent public sentiment by 1) revealing a scandal or capitalizing

⁴²Harvey M. Sapolsky, ed., Consuming Fears, (New York: Basic Books, 1986), p. 13.

⁴³James Q. Wilson, "The Politics of Regulation," in James Q. Wilson, The Politics of Regulation, (New York: Basic Books, 1980), 379.

on a crisis, 2) putting opponents on the defensive by accusing them of deforming babies or killing motorists, and 3) associating the legislation with widely shared values, such as health and safety.⁴⁴

Nader practiced entrepreneurial politics at its highest level, but supporters of major legislation affecting the FDA had at one time or another made use of its stratagems. Dr. Harvey Wiley, who was the guiding hand behind passage of the 1906 Food and Drug Act, had his cause aided by the publication of Upton Sinclair's description of filthy meat packing plants in The Jungle. Thirty years later proponents of a stronger FDA used the publicity garnered by two popular books, American Chamber of Horrors: The Truth About Food and Drugs and 100,000,000 Guinea Pigs: Dangers in Everyday Foods, Drugs, and Cosmetics to strengthen public support for their position. The books documented the lack of adequate safety testing by drug manufacturers and the ineffectiveness of FDA law. But the immediate catalyst for the passage of the 1938 Federal, Food, Drug, and Cosmetic Act, with its safety requirements, was the tragic death of over 100 people, mainly children, who had taken an untested drug, Elixir Sulfanilamide. In 1962 after years of trying to pass legislation increasing the powers of the FDA, Senator Estes Kefauver used the thalidomide tragedy to get unanimous backing for a broad bill that transformed the FDA.⁴⁵

⁴⁴Wilson, 370.

⁴⁵Upton Sinclair, The Jungle, with introduction by author, Cambridge, MA: R. Bentley, 1946. Ruth Lamb, American Chamber of Horrors: The Truth About Food and Drugs (Oxford (Toronto), Canada: Farrar, 1936. Frederick J. Schlink and Arthur Kallett, 100,000,000 Guinea Pigs: Danger in Everyday Foods, Drugs, and Cosmetics (New York: Vanguard Press, 1933.

Nader has been compared to a muckraker, but unlike these Progressive Era journalists, he followed expose by action, castigating the regulatory process for the breakdown between legislative promise and effective implementation.⁴⁶ His 1966 book, Unsafe at Any Speed: The Designed-In Danger of the American Automobile, condemning both General Motors for its unsafe Chevrolet Corvair and the federal government for not setting safety standards. However, as opposed to consumer activists in the past, the salient questions for Nader no longer hinged on economic issues, but on 'higher values'--the health and safety of Americans. Nader and other consumer advocates demanded of Congress and the regulatory agencies the highest possible levels of safety for products used by the public--at times, regardless of cost.⁴⁷

With money he received from an out of court settlement with General Motors, Nader bankrolled Public Citizen, Inc., which established a number of subgroups to keep watch on various parts of the government. For the FDA, the most important of these was the Health Research Group, headed since 1972 by Dr. Sidney Wolfe. He and his associates monitored the FDA, initiated lawsuits, petitioned for action on specific subjects, testified before advisory committees, and commented on proposed rules.⁴⁸

⁴⁶Michael Pertschuk, Revolt Against Regulation: The Rise and Pause of the Consumer Movement, (Berkeley: University of California Press, 1982), 31.

⁴⁷Ralph Nader, Unsafe At Any Speed: The Designed-In Danger of the American Automobile, (New York: Grossman, 1965).

⁴⁸Robert P. Mayer, The Consumer Movement: Guardian of the Market Place, (Boston: G.K. Hall, 1989), 42.

Nader and Public Citizen were the most visible embodiment of the consumer movement, but soon other groups and individuals, including the Consumer Federation of America, the Center for Science in the Public Interest, Consumer Reports, the National Women's Health Network added their voices to the demand for better consumer protection.

These groups, often in conjunction with investigative reporters, began to publicize dangers lurking in commonly used products. In the newspapers and on the nightly news, Americans began to hear a seemingly endless stream of horror stories. A partial list of dangers discovered in the 1960s and 1970s include: DDT, cigarettes, flammable children's pajamas, asbestos, tampons that caused toxic shock syndrome, and the DC-10.

As a result of this constant barrage of alleged threats to Americans, the Congress debated and acted on legislation in the areas of environmental and consumer protection in every congressional session from the beginning of the 1960s through the 1970s. Congress created 10 federal regulatory agencies, including the Occupational Health and Safety Administration, the Environmental Protection Agency, and the National Highway Traffic Safety Administration.⁴⁹

⁴⁹David Vogel, "The 'New' Social Regulation in Historical and Comparative Perspective," in Thomas K. McGraw, ed., Regulation in Perspective: Historical Essays, (Cambridge: Harvard University Press, 1981): 161. Vogel has suggested that the United States has experienced three sustained political efforts to transform the structure and dynamics of business-government relations--the Progressive Era, the New Deal, and a third period "rooted in the consumer, civil rights, and antiwar movements of the sixties."

In the latter period, the demands centered on corporate accountability in terms of health and safety. "We are dealing with a level of public consciousness about environmental, consumer, and occupational hazards that appears to be of a different order of magnitude from public outrage over such issues during both the Progressive

These public interest groups could not match industry in terms of resources and lobbying. However, their impact on policy-making came from their access to the media, particularly Washington-based journalists, such as Morton Mintz of the Washington Post, who regularly covered the FDA. They provided a willing ear and an efficient conduit for malcontents, whistleblowers, and concerned scientists motivated by personal pique or ambition, principle, or ideological commitment. FDA's ban on cyclamates resulted from the alliance between an FDA scientist, whose research findings were ignored by the agency, and several sympathetic outsiders, including a Nader attorney. Their watchdog stance created a potential for unfavorable publicity about FDA officials or policies, causing officials to behave with more circumspection.⁵⁰

Edwards had said he welcomed consumer input but he had reservations about some of the consumer advocates for their proclivity for jumping to premature conclusions and demanding immediate regulatory action without full knowledge of the facts. "The very real question is how much protection does the consumer really want," Edwards would chastise, "not how much Ralph Nader wants." The price of absolute safety, even if it were possible, Edwards held, was greater repression and less drug innovation. He did not question consumer advocates' sincerity, but felt that emotional commitment alone did not qualify them to speak for millions of consumers on complex, scientific subjects. In a world in which scientific knowledge was

Era and the New Deal." For the FDA, specifically, the focus of concern changed from cost of medicine and monopoly pricing to the dangers to the health and safety of the citizenry.

⁵⁰Schuck, 140.

constantly evolving, and risks had to be weighed against benefits, few if any absolutes applied.⁵¹

In December of 1970, F-D-C Reports, reviewed Edwards first year in one of the "hottest seats" in Washington. The industry newsletter commented on the emergence of a tough consumerism, "a highly vocal, activist movement--powered by pros who know their way around in law, medicine, government, and public relations." This coalition of citizens interest groups would test Edwards' ability to maintain a delicate balance among the interests that claimed stakes in FDA's regulatory process. The editors concluded that consumerism's ability to generate pressure through legal provisions for public access to governmental proceedings, court cases, and its relationship with the press had placed the movement in the position of a "third force" in the traditional regulatory interaction between FDA and industry.⁵²

No commissioner in the 1970s could afford to disregard this force. In April 1970, Edwards had announced the creation of an Office of Consumer Affairs to provide information to consumers and answer questions from the public. The office was an outgrowth of a program begun in the 1950s when FDA had begun hiring consumer specialists, almost always women, to work at headquarters and in the district offices answering consumer questions and giving speeches to local groups about the FDA and consumer issues. In July 1972, the FDA changed the name of

⁵¹Charles C. Edwards, Speech given at the Western Hemisphere Nutrition Conference in Bal Harbour, Florida, August 31, 1971.

⁵²"Comm. Edwards' Delicate FDA-Industry Balance Confronted with 'Third Force' Consumerism in Drug, Cosmetic, and Device Controls," F-D-C Reports, December 14, 1970, p. 3.

its monthly magazine from FDA Papers to FDA Consumer to indicate its new focus.⁵³ "Our purpose is to educate the American public about the safe use of products regulated by the FDA, and to inform consumers about FDA regulatory actions that affect the public's health and well-being." The new magazine would be illustrated, "easy-to-read," and use non-technical language. The new Office gave consumer issues greater prominence, but was more a public relations organization than a way for consumers to influence action.⁵⁴

Consumer groups, however, did not intend to humbly wait to be asked to join their 'betters' at the table. If anything, they intended to reshape the table at which regulatory policy was decided. Consumer advocates attended the December 1970 Food and Drug Law Institute's (FDLI) meeting, whose main topic was "Consumer, Industry, and Government--Partners for Nutrition, Health and Safety." For years the Institute had functioned as an "old boys" club for high-powered Washington regulatory lawyers, FDA top brass, industry representatives, and drug regulatory professionals. Speaker after speaker discussed the important force that consumerism had assumed in FDA's regulatory framework. Consumerists disrupted one session briefly to make their presence known. As FDLI President-elect Laurance Wood introduced members of the morning panel, Dr Michael Jacobson, a mustachioed young Ph.D. biochemist associated with the Center for the Study of Responsive Law, stood up and demanded

⁵³FDA Consumer, (July/August 1972): 1.

⁵⁴Department of Health, Education, and Welfare, Food and Drug Administration, 1970 Annual Report (Washington, D.C.: Department of Health, Education, and Welfare, 1971), 230.

to know why no consumers were on the panel.⁵⁵

Outgoing FDLI President Frank Depew agreed with the thrust of the challenge. "Over the past year, consumer groups have shown they have the talent, expertise and time to influence key FDA judgments. The housewife, who was active but ineffective in influencing government actions has given way to professionals--consumerist-MDs and public interest lawyers."⁵⁶

During the next few years, FDA made concrete efforts to at least listen to the concerns of consumer organizations. On April 20, 1972, Commissioner Edwards chaired the first meeting of the National Drug Advisory Committee (NDAC). The committee was to advise and consult with the Commissioner on policies, programs, and plans for meeting FDA's drug regulatory problems and responsibilities. The duties of the Committee also included reviewing and evaluating Agency programs.⁵⁷

Rita Ricardo Campbell of the Hoover Institution and a member of the committee recalled that Edwards made it clear that he, as Commissioner was the chairman, "and while there could conceivably be a change in the future, he thought that for the moment, while the Committee was still going through an organizational period, that it would be best to keep the chairmanship in his office." This policy did not change and the importance of controlling the agenda was clearly understood by

⁵⁵F-D-C Reports, December 14, 1970, p. 13.

⁵⁶Ibid.

⁵⁷Department of Health, Education, and Welfare, Food and Drug Administration, National Drug Advisory Committee, Minutes of April 20, 1972 meeting, 2.

Edwards and subsequent commissioners.⁵⁸

The committee was encouraged to evolve primarily as a sounding board for important public questions, such as drug testing on humans, use of normal children and prisoners in new drug trials, the nature of informed consent, oral contraceptives, adverse drug reaction monitoring systems, and revision of the New Drug Application review procedures. The organization and functioning of the NDAC kept evolving in response to committee members' complaints. One of the continuing sources of friction was that the FDA staff used much of the committee's time for extensive briefings, leaving little time for input by members. For the FDA, these were advisory meetings and the FDA usually strove for a consensus on issues, rarely taking a vote.⁵⁹

In 1971, Edwards began meeting informally with a handful of representatives of major consumer organizations. The Commissioner described these meeting as 'extremely productive.' The consumer representatives were less enthusiastic. "I'm not yet decided whether the FDA sincerely wants better consumer protection or just wants to sound and look as though it does," said one participant. "If nothing else, the meetings keep the channels of communication open--like the Paris peace talks," said David A. Swankin, Washington representative of the Consumers Union, alluding to the drawn out, often frustrating negotiations between the United States and Vietnam. "We have seen some movement in the FDA," consumer advocate James Turner

⁵⁸Rita Ricardo Campbell, Drug Lag: Federal Government Decision Making, (Stanford, CA: Hoover Institution Studies, 1976), 3.

⁵⁹Campbell, 25.

cautiously commented. "There has been some tendency to move away from the industry interests. But it has been so far over on that side it must move much more toward the consumer side to arrive in that middle position of referee."⁶⁰

FDA officials liked to think of these meetings as "two-way channels of communications." They hoped to produce the same relationship with consumers that they had developed with members of the technical advisory committees. In establishing the advisory committee system FDA officials envisioned it as a partnership in which the technical expertise of FDA personnel would be complemented and supplemented by the experience and professional knowledge of committee members. The consumerists chose not to play this role, rather maintaining their adversarial stance and pushing their own agenda. James Turner put it bluntly, "We talk about what an awful system it is and tell the Commissioner the things that are troubling us and what we think the FDA should do about them. He tells us what he thinks FDA is doing right."⁶¹

The topics discussed ranged through the full gamut of FDA regulatory responsibilities. The limitations of these types of meetings, as well as the National Drug Advisory Committee are obvious. As Dennis Riley in his critical analysis, Controlling the Federal Bureaucracy, observed, "It is important to remember that while a bureaucrat is legally obligated to read the comments and listen to the testimony, there is and can be no obligation to give any of it the slightest credence.

⁶⁰Judy Gardner, "Congressional Battle Over FDA Control Focuses on Product-Safety Legislation," National Journal 4 (June 10, 1972): 988, 997.

⁶¹Friedman, 208.

The comments of long-time friends, based on shared values and commitments and couched in familiar terms, are almost certain to get a better hearing."⁶²

Consumer representatives recognized this when they began to be appointed to FDA's prescription drug advisory committees. Initially, the representatives found themselves at a scientific disadvantage in discussions with other committee members. The public members often drowned in a sea of insider jargon and incomprehensible reports. At this time, the consumer groups did not have a cadre of experienced, scientifically trained members on which to draw. They had to make use of the limited pool of members who lived in the Washington area and who were available during the day.

In 1974, Robert S. Friedman surveyed FDA advisory committees members. Two-thirds of the respondents agreed with Riley about the impact of consumer representatives. Consumers did get a chance to express their opinions and bring up issues, but many respondents were quick to distinguish between the right to be heard and success in achieving their demands. "In short, many acknowledged receipt of inputs without significant impact of these inputs on final decisions."

In Friedman's opinion it was not just that FDA has a closer relationship with industry, but that consumer representatives were ultimately seen as outsiders. The pharmaceutical, medical device, and biological fields comprised a community of professionals who work on related problems in universities, industry, and government agencies, including FDA, and who interacted with each other at a high level of frequency. Consumer members were treated as outsiders "not because of political

⁶²Riley, 127.

or ideological differences, but because they were not part of the community of professionals." And, this close interaction allowed the interests of industry to be heard even though industry representatives might not be directly involved in the decisions made by the advisory committees.⁶³

Consumer representatives, while conceding a grain of truth in this observation, attributed industry's influence to other causes. "When industry walks into the FDA they don't talk about generalities, they talk about their *specific drug problems*," said Anita Johnson of the Health Research Group. "They bring in their sympathetic experts from Basel and Paris and Rome, they have the money for literature searches, for making up charts, for doing infinite studies.... If you are an FDA medical officer--even if you have never had any industry ties--and every time you make an adverse decision 15 of the world's most famous scientists come in to persuade you are wrong, nobody can stand up under that."⁶⁴

Over time, the consumer organizations became more sophisticated in their lobbying techniques and increased their scientific expertise, which increased their legitimacy. As the FDA expanded its use of consumer representatives and actively solicited nominations, public interest organizations developed a greater pool of technically qualified members to nominate for advisory committees.

At the beginning of the decade the problem of consumer opinions receiving a serious hearing was superseded by the problem of getting any kind of consumer representation on advisory committees. Government agencies found myriad ways

⁶³Friedman, 210-11.

⁶⁴F-D-C Reports, June 18, 1973, p. T&G 2.

to exclude them from the process. The Federal Advisory Committee Act (FACA) mandated that all advisory panel meetings would be open to public scrutiny unless the head of the agency determined the subject matter of a particular session fell under a specific list of nine classes of exemptions including national security matters, trade secrets, and medical records. To close a meeting, the agency head published a public notice citing the particular exemption.⁶⁵

Government agencies used other ruses to avoid greater public involvement. They failed to publish meeting notices in the Federal Register seven days in advance or they cited space limitations as a basis for restricting public access. Although "detailed" minutes were required for every advisory deliberation, the resulting records were, in many cases, inadequate accounts of what transpired.⁶⁶

Due to the continuing pressure of consumer groups, public advocates, and

⁶⁵Federal Advisory Committee Act of 1972, P.L. 92-463, October 6, 1972, 86 Stat. 770. This act used the same exemptions as the Freedom of Information Act. Modifications in the FDA's use of advisory committees occurred with the passage of the 1976 Medical Devices Amendments of 1976, P.L. 94-295 which required the extensive use of public advisory committees in the regulation of devices. The passage of the Government in the Sunshine Act, P.L. 94-409, established new criteria for closing meetings. On July 6, 1976, FDA published new policies sharply limiting agency discretion in closing advisory meetings. Closure can occur only if the Commissioner determines that could result "in a clearly unwarranted invasion of personal privacy, reveal trade secrets, or disclose other specifically exempted material." Under the Sunshine Act, this would include portions of the meeting related to internal personnel rules and practices, persons accused of a crime or investigatory records for law enforcement practices, and would no longer allow the exemption of inter- or intra-agency documents. 41 Federal Register November 26, 1975, pp. 52148-50.

⁶⁶Harold C. Relyea, "Opening Government to Public Scrutiny: A Decade of Federal Efforts," Public Administration Review, (January/February, 1975): 5. In recent years, advisory committee meetings have been videotaped, so that there can be no question of the accuracy and completeness of the reporting.

legal groups the advisory committee system continued to evolve into a more open process during the 1970s. Testifying before the Fountain Committee in 1974, Commissioner Schmidt outlined new FDA policies to correct abuses of the system. Every committee meeting now included an open portion scheduled for at least an hour, during which any interested persons could present relevant data, information, or views, orally or in writing. The Federal Register notice included the subject of the closed session, and the reasons for closure. The committee's executive secretary, a full-time FDA employee, kept minutes of all sessions, both open and closed, which the advisory committee chairman certified for accuracy.⁶⁷

From the outset critics alleged that the system created an advisory elite that favored a relatively few individuals and institutions. Younger scientists, members of minorities, and women were grossly under-represented in the advisory process. In 1972, A National Research Counsel study group produced The Science Committee: A Report by the Committee on the Utilization of Younger Scientists and Engineers in Advisory Service to the Government, a title worthy of any bureaucratic government organization. The NRC study group found that the science committees were dominated by white, middle-aged males whose median age was 50 (the median age of scientists holding the doctorate was 40). Women held 7 percent of all doctorates, but constituted only 1 percent of NRC committee members. In terms of recruitment,

⁶⁷Congress, House of Representatives, Subcommittee on Intergovernmental Relations and Human Resources of the Committee on Government Operations, Use of Advisory Committees by the Food and Drug Administration: Hearings before the Subcommittee on Intergovernmental Relations and Human Resources of the Committee on Government Operations, 94th Cong., 2nd Sess., March 6-8, 12-13, April 30, May 21, 1974, April 23, May 9, 1975, 18. [Hereafter cited as "Hearings. Use of Advisory Committees.]"

the study group recognized that the "telephone method" and the "buddy system" provided the dominant methods of selection and urged that agencies find new ways of identifying well-qualified nominees. The report could have been written about the FDA as much as any government agency.⁶⁸

The composition of the original National Drug Advisory Committee clearly indicated what an illusive and deceptive term 'public representation' could be. Membership included three practicing physicians, the Medical Director of the Ochsner Clinic, the Dean of a school of nursing, a school of medicine, and a college of pharmacy, a Director of pharmaceutical services in a southern university, professors of biostatistics and electrical engineering, an economist, a physician who was president and CEO of large pharmaceutical company, a pharmacist, the president of a small medical device firm, a former social worker, a "specialist" in the New York investment market, and a "consumer." The FDA could claim that the committee demonstrated the "diversity" it desired, but the "consumer" and social worker surely found themselves out-manned and out-gunned by the top-heavy professional and medical representation.⁶⁹

The dependence on elite academicians and physicians sharpened FDA's scientific image, but created problems for the agency. First, it pitted these university-based scientists against practicing physicians. The latter complained bitterly that their knowledge and practical experience was denigrated or ignored. This attitude made

⁶⁸"Science Committees: NRC Report Asks Better Mix in Advisory Groups." Science 176 (June 16, 1972): 1222.

⁶⁹Campbell, 3.

it harder for FDA to convince them to follow its recommendations for appropriate drug usage. Secondly, the use of this small group of highly trained scientists and physicians produced conflict of interest problems.

In testimony before Representative Fountain's committee investigating the FDA's use of advisory committees, Commissioner Schmidt was asked whether the experts used by the pharmaceutical industries were one and the same experts serving on FDA's advisory committees. "Well, if one looks around the country as to where the necessary expertise is, he finds it almost always in conjunction with an academic medical center." Particularly since 1962, both FDA and industry had used experts largely from academia. "The pool of such experts is finite," Schmidt observed.⁷⁰

FDA, of course, required all prospective consultants to submit a financial statement before appointment to an advisory committee. In 1972 the FDA modified its financial disclosure statement to disclose whether a prospective expert had received financial support for participating in research studies. But this raised another more subtle point. If a consultant was disqualified from participating in any action involving firms in which he had a financial interest, was he also disqualified from participating in actions which involved manufacturers of competitive products? From Schmidt's perspective, the basic problem was that most qualified people who served as clinical investigators and consultants had been in the field for a long time. "In most situations, it was this very experience that qualifies them to provide the agency with an expert opinion." It would be a continuing agency problem balancing

⁷⁰Hearings, Use of Advisory Committees, 95.

FDA's need for professional advice against conflicts-of-interest questions.⁷¹

Congress called FDA to task on this point in 1974. Consumer-oriented congressional representatives charged that the agency had abdicated its responsibility by shifting decision-making to its advisory committees. The subcommittee deplored the undue reliance on advisory committees by the agency, recommending that the FDA rely primarily on its own staff to carry out its responsibilities and use the committees only in exceptional circumstances involving issues for which outside expertise was clearly required. The report contained pages of specific suggestions to correct problems in the use or misuse of the committee. A closer reading reveals congressional suspicions that expert committees were being used to reinforce a closed decision-making processes that favored industry views.⁷²

For all its limitations, the advisory committee system more than fulfilled the expectations that Commissioner Edwards had placed on it. It bolstered FDA's sagging scientific reputation by allowing it to draw on the expertise of the nation's top physicians and scientists. These outside experts not only brought an additional non-regulatory perspective to the problem, but they provided 'real world' experience in evaluating clinical trials or potential problems with the use of the drug. In high profile or controversial cases, they lent professional, scientific credibility to FDA's decisions.

⁷¹Hearings, Use of Advisory Committees, 97.

⁷²Congress, House of Representatives, Subcommittee on Intergovernmental Relations and Human Resources of the Committee on Government Operations, Use of Advisory Committees by the Food and Drug Administration, Report No. 94-787, Jan 26, 1976, 94th Congress, 2d Sess., 101.

This system has remained essentially intact to the present, although it has gone through numerous procedural changes over time. What Edwards may not have foreseen was how important the committee system would become to the public as a means of monitoring FDA and industry actions, and as a forum for the public to present its views and participate in FDA deliberations. When Edwards and FDA's top echelon envisioned their interactions with these 'new' consumers, it did so almost entirely in the benign terms of increasing communications from FDA to the public. FDA saw itself shaping consumer values, not being reshaped itself by consumer input. Initially, the FDA took the path of least resistance and minimum change, by assuming that consumers merely wanted more information with which to make informed choices. When the FDA did seek information from the public or the medical community, it was to enable the agency to base its decisions actual experience. For example, it developed a National Electronic Injury Surveillance System connected to emergency wards to provide adverse drug experience reports.

Although FDA had no intention of making consumer groups partners with industry in shaping agency decisions, Edwards did make overtures to consumer groups and in a limited manner began to incorporate their opinions into FDA decision-making. David Swankin of Consumers Union conceded that FDA under Edwards had made efforts to interact with consumer advocates, although its efforts had not kept pace with the "mushrooming" consumer movement. "We want to be treated equally with industry," he said. "The idea of asking for that years ago was unheard of, but

look at the state of the consumer movement now."⁷³

At last the voice of the consumer had begun to be heard, but to have any real influence, consumers or any other advocates needed to know what was happening inside the agency, how things worked, on what information FDA based its decisions. But how could they unlock the secrets of this most guarded of agencies? Help came from the most unlikely of sources--Peter Barton Hutt, former counselor to their nemesis, the food and drug industry.

⁷³Gardner, 988

CHAPTER 4

"PETER HUTT--MASTER BUILDER"

Hutt's Law: Industry is likely to challenge in court any Food and Drug Administration action where the net adverse economic impact exceeds the legal fees involved.¹

"The first thing Commissioner Edwards asked me to do," said newly appointed FDA General Counsel Peter Barton Hutt in 1971, "was to tackle the problems of secrecy." The FDA had a reputation as one of the most secretive agencies in government with over 90% of its files closed to public inspection, despite the Federal Freedom of Information Act provisions. This exclusionary policy prevented consumer advocates or any intrusive members of the public from second-guessing the bureaucrats and protected information submitted by industry. But Edwards and Hutt realized that "the secrecy was self-defeating from the viewpoint of public relations." Sensitive to the changing climate of public opinion and the growth of the consumer movement, they felt that the FDA needed to convince the public and members of Congress that its decisions had been based on scientifically sound principles, had not been unduly influenced by industry, and had taken consumer concerns into consideration.²

Edwards' directive to Hutt was driven in part by a lawsuit brought by Mrs. Carolyn Morgan, a Washington D.C. housewife. Before Hutt took over the office of FDA General Counsel, Mrs. Morgan had written to J. Stewart Hunter, Associate

¹F-D-C Reports, May 21, 1973, p. T&G 9.

²Nicholas Wade, "FDA General Counsel Hutt: A Man Trying to Serve Two Masters," Science, 177 (August 11, 1972): 499.

Director of Information for Public Services of the Department of Health, Education, and Welfare, on April 20, 1970, requesting information on the safety and efficacy of eight brands of oral contraceptives. Mrs. Morgan said that she and her husband wanted no more children, were not using any effective birth control method, and had considered using birth control pills. They did not wish to subject Mrs. Morgan to the risks of using oral contraceptives "without thoroughly studying the clinical and toxicological data on the side effects and efficacy of birth control pills." On May 4th, Hunter issued a denial of her request, which Morgan immediately appealed through the Department of Health, Education, and Welfare.³

Replying on behalf of the FDA, Roger O. Egeberg, the HEW Assistant Secretary for Health and Scientific Affairs, upheld the denial on the grounds that the material requested included trade secrets, inter-agency memoranda, medical files, and information exempted by other statutes. Egeberg then pointed out that the exempt and non-exempt information Morgan had requested was mixed together in over 1900 files, and that to separate the categories would cost \$12,600 in labor! There would be a copying charge of \$.25 per page and Mrs. Morgan would have to pay a fee of \$5000 in advance. Egeberg ventured the opinion that "such a search would be wasteful for both parties."⁴

The Assistant Secretary, however, did provide the plaintiff with a copy of the current printed labeling for each of the eight oral contraceptives and copies of reports

³Roger M. Rodwin, "The Freedom of Information Act: Public Probing into (and) Private Production," Food, Drug, Cosmetic Law Journal 28 (August, 1973): 539.

⁴Constance Holden, "Freedom of Information: Officials Thwart Public Right to Know," Science 175 (February, 4, 1972): 499.

on oral contraceptives furnished to the FDA Commissioner by the Advisory Committee on Obstetrics and Gynecology. In addition, he offered to make available for inspection and reproduction a bibliography of approximately 4,000 citations to the medical and scientific literature concerning oral contraceptives.

Having thus exhausted all administrative remedies, Morgan filed suit on June 29, 1970 in U.S. District Court for the District of Columbia against the FDA, HEW and Assistant Secretary Egeberg "on behalf of herself and all wives, mothers, and consumers similarly situated." While Mrs. Morgan had a genuine interest in the material, as the mother of five daughters, she was also filing the suit with the help of consumer advocate, James S. Turner, to test FDA's Freedom of Information policies.⁵

"A sweeping decision in Mrs. Morgan's favor--not to be discounted in this age of consumerism," F-D-C Reports warned, "could limit the definition of 'trade secret' to manufacturing and chemical controls and financial information." Traditionally the definition of 'trade secret' had been so all-encompassing that FDA did not even have to concede the existence of a New Drug Application (NDA) until the application was approved and had never been required to confirm that an Investigational New Drug (IND) application had been filed. Furthermore, up to that point no outside person or agency, even Congress, had been granted access to IND and NDA information, although Congressional investigators had been allowed to see clinical data after the "trade secrets" information had been purged. In fact, Congress never challenged

⁵F-D-C Report, July 6, 1970, p. 15. Morgan sought information on Lilly's C-Quens, Searle's Enovid and Ovulen, Syntex's Norinyl, Parke-Davis's Norlestrin, Menley-James' Oracon, Ortho's Ortho-Novum, and Upjohn's Provest.

FDA's right to keep secret this information. "Mrs. Morgan's victory would serve as an important and possibly controlling precedent," the paper continued. "If a decision grants Mrs. Morgan access to the information but does not concede the openness of NDAs generally, there could be further court action."⁶

Thus Peter Hutt came to the FDA at a critical juncture in terms of consumer access to the vast amount of information secreted away in FDA file rooms. The Morgan suit required immediate attention, but Hutt also knew that trouble was brewing in Congress over the way bureaucrats had routinely circumvented congressional intent in their handling of the 1967 Freedom of Information Act. Consumer groups, acting in concert with sympathetic legislators, seemed on the verge of making major changes to the obviously flawed law. These changes would affect the way bureaucrats in every government agency handled FOI requests.

Hutt could wait for the 'one size fits all' regulations that would likely come out of Congress and the courts or he could tailor a set of FOI regulations to meet FDA's own specifications. The latter course was more in keeping with Hutt's activist view of the office of General Counsel. However, in initiating such major changes at FDA, Hutt needed to overcome the fears and doubts of wary bureaucrats within his agency, in the process changing decades of FDA bureaucratic culture. Just as importantly, he needed to allay industry fears that opening FDA files would benefit not only consumers but also their industry competitors, who would be able to use FOI procedures for commercial espionage in the future.

Consumer groups, journalists, and public rights advocates asserting that

⁶Ibid.

"information is the currency of power" considered access to federal files an important strategic goal. "If the citizen is to regain command of his political institutions, he must begin at the beginning," instructed John Gardner, of the advocacy group, Common Cause. "And the beginning is 'access.'" By controlling access to information, bureaucrats had shut the public out of the decision-making process.⁷

These modern critics echoed past fears for democracy. "A popular Government without popular information, or the means of acquiring it, is but a Prologue to a Farce or a Tragedy: or perhaps both," James Madison had warned.⁸ Both of the great crises of recent American politics--Vietnam and Watergate--provided evidence of Wilson's assertion that "corruption thrives in secret places" and that "there is no air so wholesome as the air of utter publicity." However, most bureaucrats viewed the efforts of outsiders to open their closely held files more as a destructive gale of disclosure than as a wafting breeze of public enlightenment.⁹

Before the Freedom of Information Act, government agencies operated under the provisions of the 1946 Administrative Procedures Act, which required that executive agencies "keep the public currently informed of their organization, procedures, and rules" but in effect thwarted public disclosure by allowing agencies to remove documents that concerned "any function of the United States requiring

⁷McCann, Michael, Taking Reform Seriously: Perspectives on Public Interest Liberalism (Ithaca, NY: Cornell University Press, 1986), 62.

⁸Harold C. Relyea, "Faithful Execution of the Fol Act: A Legislative Branch Perspective," Public Administration Review 39 (July/August, 1979): 328.

⁹Woodrow Wilson, The New Freedom, with introduction by William E. Leuchtenburg (New York: Prentice-Hall, 1961), p. 76-77.

secrecy in the public interest, or any matter relating solely to the internal management of the agencies"¹⁰

Although FDA did not have a disclosure policy per se, it had a long-standing tradition of safeguarding its files. In the course of drafting the 1938 Federal Food, Drug, and Cosmetic Act, Congress had enhanced FDA's powers to obtain information by giving it broader inspection capability, as well as requiring that manufacturers provide safety and formulation information before marketing their products. However, it also included section 301(j) which made it a crime for government officials to use or disclose information acquired under the Act "concerning any method or process which as a trade secret is entitled to protection." FDA used the law as justification for a blanket refusal to open its files to almost any inquiries.¹¹

Section 301(j) worked to the satisfaction of both the agency and industry. The FDA, which had limited investigational personnel and cumbersome procedures for enforcing the law, promised manufacturers complete secrecy in return for a cooperative attitude on their part in providing the required data. As an added benefit, by sequestering all data, agency personnel did not have to differentiate between classified and non-classified material among the mountain of data the FDA had begun to collect.

When President Lyndon B. Johnson signed the Freedom of Information Act (FOIA) on July 4, 1967, FDA needed to revise its information policies in accordance

¹⁰Administrative Procedures Act, P.L. 79-404, 60 Stat. 237 (1946).

¹¹Federal Food, Drug, and Cosmetic Act of 1938, P.L. 75-717, 52 Stat. 1040 (1938).

with the provisions of the new law. FOIA required each agency to establish and publish its FOI procedures and policies and make identifiable records promptly available--with specific exemptions. As opposed to the previous law which gave bureaucrats broad discretionary powers, the exemptions under FOIA appeared as nine clearly delineated categories intended to be narrowly construed against the substantially broadened scope of required disclosure.¹²

The FDA viewed the prospect of the outsiders rooting around in its files with more than the usual bureaucratic abhorrence. The FDA feared alarming the public by disclosing its tolerances for filth and roach parts in agricultural products, for example, and worried about losing its enforcement advantage by disclosing the contents of its internal manuals for inspectors. In addition, those governing the agency in the quieter years before the 1970s firmly believed that the FDA's system of pre-clearance of drug products, which had developed over the years into a delicate process of negotiation between FDA and the pharmaceutical industry, could not survive public disclosure or a formalization of its procedures.¹³

Despite the clearly stated directives of the new law, resourceful officials found ingenious ways to circumvent the intent of congressional lawmakers. For example, the Information Act authorized agencies to collect a reasonable fee, but left precise

¹²Freedom of Information Act, P.L. 89-487, 80 Stat. 250, (1966). Exempted material included: 1) matters concerning national defense; 2) internal agency rules; 3) statutory exemptions; 4) trade secrets and confidential information; 5) inter- and intra-agency memoranda; 6) personnel and medical files; 7) investigatory files; 8) financial institution reports; and 9) geological and geophysical information concerning wells.

¹³James T. O'Reilly, Food and Drug Administration (New York: Shepard's/McGraw-Hill. 1979), 22-6.

charges to the whim of the agency. Public interest groups frequently complained that agencies set high fees, which acted as an obstacle to the cash-strapped non-profit groups, thus increasing the advantages that deep-pocketed industry groups normally enjoyed. They also believed that government offices attempted to hide non-exempt information by commingling it with records exempt under the law. Although the agencies protested that the commingling was simply the result of their normal filing procedures, they did not deny that a substantial amount of non-exempt information did get removed in this manner.¹⁴

The Act only required agencies to honor requests for "identifiable records." Some agencies did not provide master listings of all documents, but strictly enforced adherence to the identification requirement as a means around the law. In *Wellford v. Hardin*, a plaintiff trying to get information from the Department of Agriculture was denied access when he had failed to identify the specific document being sought. Attempting to comply, Wellford asked to see the master index, but was advised that it was classified!¹⁵

"Along with most other agencies, I am afraid that FDA looked at the new law as an interesting legal curiosity--but nothing to bother about," former FDA Freedom Of Information Chief Robert Brandenburg related in a 1975 speech. "The attitude for most of the next 3 or 4 years continued to be 'ho-hum' or so what?" Past experience had shown that the FDA could outmaneuver the few individuals who tried to get

¹⁴Marshall Patner, "Public Access to Information," Northwestern University Law Review 68 (1973): 198-199.

¹⁵*Wellford v. Hardin*, 315 F. Supp. 768 (D.D.C. 1970).

information. In 1967 public advocates and public interest law firms had not yet become an effective force demanding access. Undoubtedly, Brandenburg and his fellow FOI Chiefs had every reason to minimize the importance and limit the usefulness of the new law. Few bureaucrats wanted to share the inner workings of their departments with "outsiders," viewing the demand for facts, figures, and reports as a "search and destroy" mission by the consumer movement.¹⁶

The Food and Drug Administration used all the stratagems at its disposal when Dale Hattis, a Ph.D student and researcher at the Stanford University School of Medicine, asked the FDA in July 1970 for any data FDA had assessing the safety of various food additives and pesticides. It took the FDA 11 months and 28 days to compose a reply, which informed him that he needed to be more specific.

Hattis then narrowed his request to data on a single food additive, sodium nitrite. Sam D. Fine, FDA Associate Commissioner for Compliance, replied that "toxicological and other scientific information is valuable commercial information," hence, the law exempted the data supplied by the manufacturers from disclosure. However, the FDA did possess some toxicological data on sodium nitrite not supplied by manufacturers which Fine offered to Hattis for a compilation and copying fee of \$99.50. After nearly 18 months of delays, rebuffs, and denials Hattis asked the advice of attorneys at the Environmental Defense Fund (EDF), which helped him bring suit against the FDA in February, 1972.¹⁷

¹⁶Brandenburg, Robert, "How We Got Here," Speech to the Food and Drug Law Institute, March 12, 1975.

¹⁷Holden, 499.

Pushed by suits like Hattis' and Morgan's and with the blessing of Edwards, Hutt began the process of revising FDA's FOI regulations. Hutt knew that the FDA had been cited by a succession of witnesses detailing their dismal experiences under the Act during 1972 hearings by the House Foreign Operations and Government Information Subcommittee. Critics charged that in addition to the interminable delays, exorbitant fees, and poor service, claims by federal agencies that they fairly served the public were inherently false because they "had not kept adequate records of requests for public information under the act to properly evaluate their performance."¹⁸

"We are in the midst of adopting a new policy for releasing information to the public," Hutt explained in a conciliatory letter sent at the end of March to the EDF. "It is regrettable that the lawsuit is necessary, but we can certainly understand your reasons for it." Hutt promised to release the agency's data on sodium nitrite and asked the fund to drop its suit. Replying to Hutt's letter, Thomas J. Graff, counsel for the EDF hailed the new FDA policy as a significant milestone in the battle waged by the public to get access to information hidden by a government bureaucracy unwilling to subject itself to public scrutiny. "Our victory stands as a precedent for any other public groups or citizens who have an interest in overseeing the government's activities with respect to the safety of the nation's food and drug supply."¹⁹

¹⁸Congress, House Committee on Foreign Operations and Government Information, Administration of the Freedom of Information Act, House Report 92-1419, 92nd Cong., 1st sess., 12-19.

¹⁹Constance Holden, "Briefing: FDA to Relax Data Ban," Science, 175, (March, 31, 1972): 1442.

On May 5, 1972, FDA published its proposed FOI regulations in the Federal Register. The regulations, which had been drafted by Hutt, indicated a new FOI philosophy. The notice assured the American people that "public disclosure should be the rule rather than the exception. Accordingly, all information in FDA files will be available for public disclosure unless explicitly exempted under the act or other applicable statutes." Most significantly for FDA relationship with its regulated industries, in the future manufacturers would have to identify and justify all claims for confidentiality of data entitled by law to be protected as 'trade secrets.' Although the regulations would not be finalized until early 1975, FDA began to change its policy in the interim, opening many of its files to the public.²⁰

The FDA pledged to provide safety and effectiveness data for food additives, color additives, and antibiotic drugs, which had previously been treated as confidential. Furthermore, the agency would make available all correspondence with companies, members of Congress, and the public, as well as internal operating manuals, informal enforcement actions, and all completed reports on FDA research. Although just a few years earlier FDA had protested vehemently that it was impossible to release this information, the possibility of congressional action made Hutt's plan the lesser of two evils.²¹

Despite these assurances of openness, neither industry nor consumer advocates heaped praise on the FDA. Industry charged that Hutt had changed the

²⁰37 Federal Register, May 5, 1972, p. 9128.

²¹Department of Health, Education, and Welfare, Food and Drug Administration, Annual Report, 1972, (Washington, DC: GPO, 1973), 151.

thrust of the FOI statute from the agency's performance to the disclosure of information filed by manufacturers, either voluntarily or under requirements of regulatory law. "It can be anticipated," F-D-C Reports informed its readers, "that industry will be much more careful than it has been in the past on the matter of voluntarily providing FDA with information dealing with regulatory problems." The New York Times agreed that "the key difference in policy is that in the future the burden of proof would be on industry to show why some data should be kept confidential. In the past, officers of the agency had generally ruled in favor of confidentiality because that was their safest policy."²²

The highly competitive and extremely profitable pharmaceutical industry voiced special concern about the decision to release information in a New Drug Application (NDA) to the public. Companies feared, with some justification, that this could be extremely useful to their competitors. Using documents contained in the NDA, other drug companies could determine the clinical program used, investigators involved, pharmacological and toxicological data submitted, as well as the rationale behind FDA's decision to approve the drug.²³

Ironically, industry itself quickly became the main user of FOI. While its trade association battled FDA in the courts to prevent the implementation of the new FOI regulations, individual firms took advantage of FDA's new openness to spy on their fellow manufacturers and glean valuable information from their competitors'

²²F-D-C Reports, May 8, 1972, p. 15; New York Times, May 5, 1972, p. 1.

²³Dr. William M. Troetel, Drug Regulatory Consultant, January 22, 1995, personal communication.

submissions. Lawyers also took advantage of the new openness to find pertinent information for suits filed against manufacturers. In 1975 members of the Washington food and drug law firm of Kleinfeld, Kaplan, and Becker set up FOI Services, Inc. in Rockville, Maryland to file "blind requests," (requests that did not disclose the party interested in the information). They were not alone. FDA estimated that 80% of its FOI requests in 1976 came from business entities, private attorneys, and FOI service companies.²⁴

FDA attorney Stuart Pape summed up this situation by saying, "what we have is the taxpayers subsidizing the information-gathering activities of corporations." Deputy Commissioner Sherwin Gardner observed in 1977 that "it is difficult to avoid the conclusion that FOI is substantially being used as a means of corporate intelligence gathering. This certainly is not what the FOI Act was designed to achieve." While some might decry this private use of statutes intended to provide citizens with information about their government, there was no way agencies could limit or control FOI requests.²⁵

²⁴Gina Kolata, "Freedom Of Information Act: Problems at the FDA," Science, 189 (July 4, 1975): 32.

²⁵Russell M. Roberts, "Faithful Execution of the FOI Act: One Executive Branch Experience," Public Administration Review, 39 (July/August 1979): 318. FDA officials testifying before the Senate Administrative Practices Subcommittee, September 15, 1977.

Russell Roberts has defended industry's use of FOI suggesting that many of the requests come from companies who want to see their own complete inspection reports, which they can only get by submitting an FOI request on their own letterhead signed by a company officer. In other situations, companies use of Summary Basis of Approval documents to ascertain the rationale that FDA had used in approving a particular drug. Others have suggested that lawyers combed FDA files for information to use in product liability suits.

Some consumer groups assumed that the disproportionate number of industry FOI requests resulted from the fact that FDA responded positively to industry FOI requests. Anita Johnson, of the Health Research Group, charged that the agency billed her \$100 for safety information on a certain drug. 'That kind of report is in the front of every drug's file folder. It takes only a couple of minutes to locate it.' Whether industry would have been charged the same amount was not clear. Consumer advocates exhibited a highly skeptical view of the new regulations, in general. Yes, the FDA would open 90% of its files, but it would still withhold the safety and efficacy data supporting NDAs. In the view of the consumer advocates, this was precisely the information that FDA should not withhold from the public. As a compromise FDA offered a "summary, vetted for accuracy by FDA officials."²⁶

"Hutt is a master of liberal rhetoric," scoffed Anita Johnson. "The summaries will be perfectly useless. No competent scientists trying to assess the safety or efficacy of a drug would rely on summarized data." James S. Turner, consumer activist, commented, "All [Hutt] has done is eliminate some of the FDA's more outrageous restrictions." Turner did concede that the FDA had a right to keep some information confidential.²⁷

The FDA offered its justification for the new rules in the June issue of its magazine, FDA Papers. In melodramatic tones, Wayne Pines, FDA Papers' editor wrote of the "the soul-searching and thought that went into FDA's decision to break with tradition" and that disclosure of its carefully guarded information entrusted to

²⁶Nutrition Action, 3 (November, 1976): 2.

²⁷Wade, 499.

FDA by companies could affect the originator's competitive position and chip away at the integrity of America's free enterprise system." [emphasis added] In this way, the FDA sought to reassure both its bureaucratic staff and its regulated industries that although times had changed and the FDA had been affected by actions outside its own purview, it sought to maintain the same relationship with industry that it had before the law went into effect.

As the FDA prepared itself for an onslaught of inquiries, Pines cautioned that "the intent of the policy is not to make it possible for citizens to walk into FDA offices and rummage through file cabinets. Nor is it to turn the Agency into a reference library for anyone who wants scientific information, or to bog down government employees in an endless search for documents...."²⁸ The New York Times reiterated this point to those not on the FDA Papers subscriber list. Requesters who did not have a clear idea of the items that they needed would have a tough time getting information. In its proposed policy statement agency officials made it clear that they had neither the staff nor the budget to respond to broadside "tell-me-everything-you-know" queries.²⁹

As the FDA considered the ramifications of its new policy, the Morgan Case made its way through the courts. FDA found itself in a curious legal position. When Morgan filed the action in 1970, FDA had been strongly wedded to the policy that FDA law barred disclosure of all data under the "trade secret" exemption.

Dr. Henry Simmons of FDA had filed an affidavit with the court arguing INDs

²⁸Wayne Pines, "More Information for the Public," FDA Papers, (June, 1972): 12.

²⁹New York Times, May 5, 1972, p. 1.

and NDAs were submitted in confidence and the agency could not divulge the non-published information within those submissions except in enforcement proceedings. He also argued that the American Medical Association and manufacturers had printed and distributed booklets on oral contraceptives containing sufficient information for 'the average wife or mother and other consumers similarly situated' to make this decision. On June 16, 1971, Judge June Green granted the defendant's motion for summary judgment and dismissed the complaint, holding that the test results were exempt from disclosure under subsection (e)(4) of the FOI Act.³⁰

On January 22, 1973, Mrs. Morgan and her husband LeRoy, sat in the District of Columbia Circuit Court to hear oral arguments in their appeal of Judge Green's decision. As if to underline the slowness with which the wheels of justice turn, she held a baby, her sixth daughter born the previous July 24th. By this time, FDA had announced the proposed revision of its FOI regulations. HEW and FDA argued that the proposed regulations would require manufacturers to make available a summary of test results on every "New Drug" cleared through the NDA system, which would then be made public. As the F-D-C Reports noted, "If the DC Circuit panel upholds Green's earlier decision, FDA will be confronted with a judicial opinion that counters its new policy on disclosure of New Drug Application information under certain circumstances."³¹

On May 24, 1974 the Court of Appeals let stand the lower court ruling, affirming on technical grounds the lower federal court's initial decision holding that

³⁰Rodwin, 540, 542.

³¹F-D-C Reports, January 29, 1973, p. 15

safety and efficacy data filed in support of an NDA constituted 'confidential' material. Despite the ruling, within the next few years, FDA instituted broad changes in its FOI regulations that would provide much of the information for which Morgan had gone to court.

While Hutt worked on FDA's own FOI regulations, efforts to update the Freedom of Information Act made their way through Congress. Responding to pressure from reform groups, Congress passed the Freedom of Information Act Amendments of 1974. The passage of the Amendments signaled Congress' intent to restore the strength drained from the 1966 Act by years of agency misuse and foot-dragging. Amongst other provisions, the bill expressly prohibited the use of exorbitant fees "for the purpose of discouraging requests for information or as obstacles to disclosure of requested information." Federal agencies had ten days to decide whether to comply with an original request and 20 days for the determination of appeals. The original Act allowed an agency to deny all requests yet avoid lawsuits merely by procrastinating.³²

The FDA, which had chosen to promulgate its own regulation more than two years before, still had not finalized them. During late 1974 Senator Edward Kennedy's Senate Health Subcommittee heard testimony that FDA had no consistent FOI policy: there were as many rules as there were agency employees, rules were made and then broken, and employees were given inappropriate orders about releasing records.

Prodded by Senator Kennedy, Hutt assured the Senate committee that FDA's

³²Freedom of Information Act Amendments, P.L. 93-502, 88 Stat. 1564 (1974).

Policy Board, consisting of the Commissioner, all Assistant and Associate Commissioners, Bureau Heads and himself had met "interminably" every Friday for the past four months and gone over "every word and comma" of the proposal, with some regulations "battled out word by word." Every Bureau got copies of the draft and funneled their views back to the Board through the Bureau Director. Hutt promised the new regulations before the year was out.³³

On Christmas Eve, 1974 Hutt delivered his magnum opus of FOI regulations. F-D-C Reports described it in its Special Supplement, perhaps with just a touch of sarcasm, as "the bible-dimension, 234-typescript-page Peter's Preamble that explains administrative determinations, FDA Commissioner decisions, and even provides learned judicial pronouncements on legal issues."³⁴

The preamble, which consumed 40 pages of the three-columned Federal Register, covered almost every conceivable issue of public disclosure. The new rules bore little resemblance to the modest proposals offered for public comment in 1972. In promulgating its final rule, the FDA relied on the extensive comments it had received, as well as its experience with FOI requests in the intervening years. The FDA brought its rules and regulations into conformity with provisions of the FOI Amendments, established a Public Records and Documents Center, and adopted the position that, if any record is available to any member of the public, it must be made available to all members of the public, with very few exceptions. It thereby

³³Peter Barton Hutt. Videotape transcript of speech in the Legal Series, Food and Drug Administration.

³⁴"FDA's Freedom of Information (FOI) Regs: Special Supplement," F-D-C-Reports, December 29, 1974, pp. A-1.

guaranteed "equal access to all information."³⁵

In response to consumer complaints, FDA modified its fee schedule and agreed to waive fees for "indigence or where it will benefit the public broadly...." However, consumer and public interest groups contending that the customary definition of indigence ignored the plight of most non-profit and citizens' groups pressed for a broader definition. The FDA turned down this request, ruling that in the past FDA had received a substantial number of open-ended requests, from individuals and organizations purporting to represent the consumer and general public interest. The FDA was not able to commit its limited resources to satisfy these "fishing expeditions."³⁶

On the other hand, FDA also refused to accede to industry demands that companies be notified every time FDA released one of its documents to the public. "If the public is to have prompt access to agency records," said Deputy Commissioner Sherwin Gardner, defending the FDA's position, "the disclosure process cannot be encumbered with elaborate procedures that give private persons, with an interest in confidentiality, an opportunity--in every instance--to attempt to persuade, cajole or negotiate about the disclosure decisions."³⁷

³⁵37 Federal Register, December 24, 1974, p. 44605. The author knows from personal experience that even if the FDA indicates that it will comply with a request this does not mean that all information is forthcoming. Unless the request is extremely specific, the cost of searching can be prohibitive.

³⁶39 Federal Register, December 24, 1974, p. 44608.

³⁷F-D-C Reports, September 19, 1977, p. T&G 8. Although the final rule allowed for implementation thirty days after publication in the Federal Register, the Commission chose to provide sixty days for brief comments on new issues, recognizing that it had been over two years since the original proposal and that the

Although Commissioner Edwards had initiated the project, by the time it came to fruition it was the new FDA Commissioner, Dr. Alexander M. Schmidt, who signed the regulations, hailing them as the "most extensive and specific" ever published by any government agency and a "monument to Peter Hutt's superb draftsmanship."³⁸

FDA experienced a huge increase in its FOI requests. In 1975, it spent more than \$1 million to comply with public requests while receiving only \$78,340 in fees. The number of inquiries rose over the next few years, finally leveling off at about 45,000 per year at a cost exceeding \$6 million. It has been a constant lament at FDA that while Congress passed the FOI laws, they did not provide additional funding to implement and maintain the program, forcing FDA to divert scarce resources from its operating budgets.³⁹

FOI did not present the threat that industry feared or the panacea for which public citizen groups hoped. The cumbersome procedures to request information, the need to know in advance the documents desired, and the fact that intra-agency memoranda and decision documents, trade secrets, and other information had been exempted from disclosure ensured that some information would always be protected.

final regulations incorporated new decisions not specifically dealt with in the proposal. The Pharmaceutical Manufacturers' Association filed a hastily drawn suit in May 1975 seeking to block FDA's implementation of the FOI regulations. District of Columbia District Court Judge Sirica denied PMA's motion for a preliminary injunction on August 1, 1975 and FDA received a summary judgment in April 1976 from Judge John Lewis Smith, affirming FDA's FOI procedures. *Pharmaceutical Manufacturers Association v. Weinberger*, 401 F Supp 44 (DC DC 1975); 411 Supp 576 (DC DC 1976).

³⁸Judith Axler Turner, "FDA Pursues Historic Role Amid Public, Industry Pressure," National Journal Reports, (February 15, 1975): 254.

³⁹FDA Almanac Fiscal Year 1992, (Washington, DC: GPO, 1993), 52-53.

Despite their frequently voiced fears, FDA's regulated industries managed to adapt themselves to its FOI policies. As long as the playing field was level and all firms operated under the same rules, the benefits to be gained from combing FDA's files equaled the losses from other having access to their files.⁴⁰

From the perspective of consumer advocate James S. Turner the changes were important but not revolutionary. "After we managed to get a few things visible, by having people go against regulations and release information surreptitiously," he remembered, "they turned out to be things that would not cause the crumbling of the nation or even the FDA." Although the revised regulations made 90 percent of FDA's files "available to be read," the monumental amount of material to be culled through to find pertinent information ensured that finding the desired material would remain daunting. Turner had been given estimates by librarians that FDA had between one and eight million sheets of paper filed away in warehouses. "I cannot say, in all honesty, that [FOI] ... has solved any problems; but I will say that it offers an opportunity to begin to solve some."⁴¹

Peter Hutt did not limit himself to the revision of the FOI regulations. Not one to avoid controversy or doubt his vision of the FDA, Hutt brought a new philosophy to the regulation of foods and drugs in the United States. In a 1972 speech that Hutt considered his most controversial, he compared the Federal Food, Drug, and

⁴⁰Dr. William M. Troetel, Drug Regulatory Consultant, personal communication, January 22, 1995.

⁴¹National Academy of Sciences. How Safe is Safe? The Design of Policy on Drugs and Food Additives, (Washington, D.C.: National Academy of Sciences, 1974), 132.

Cosmetic Act to the United States Constitution in that it has very broad and general proscriptions and admonitions, which are left to agency implementation. For example, the Act prohibits product adulteration and misbranding or labeling that is false or misleading. But what does that mean? What specific acts should be prohibited and by what means? "One will search in vain through the Federal Food, Drug, and Cosmetic Act to find mention of nutrition labeling... or to find anything dealing with most of what FDA does," Hutt argued.

As an activist General Counsel, Hutt said "the agency could use any reasonable means of enforcement that was not specifically prohibited." Most lawyers took the position that the agency could only use those means that were specifically permitted in the statute. Hutt conceded that there were provisions in the law the Commissioner cannot ignore and powers he did not have, but in terms of administration, it fostered a wide choice of approaches. Hutt posited that the Federal Food, Drug, and Cosmetic Act had great flexibility, if one used "some ingenuity and imagination."⁴²

⁴²Scott Lucas, The FDA, (Millbrae, CA: Celestial Arts, 1978), 128. The Supreme Court supported this thesis in its 1973 opinion *Hynson, Wescott, and Dunning v. Weinberger*. In 1972, The United States Court of Appeals for the 4th Circuit handed down three court opinions that eviscerated FDA's Authority to implement the 1962 Drug Amendments. Hutt appealed these cases and a fourth to the United States Supreme Court. In Hutt's words, the brief said, "Damn it, either give us the authority to be a full-fledged, full-power administrative agency or else tell us we can't do anything and give the job to somebody else." Legally his brief argued that the FDA had primary jurisdiction. FDA had been created by Congress as the expert agency to deal with foods, drugs, medical devices, and cosmetics. To Hutt that meant that FDA had jurisdiction to decide any issue relating to the statute and authority to implement orders, regulations, and guidelines that must be recognized by the courts. The Supreme Court resolved 18 legal issues, including primary jurisdiction unanimously in FDA's favor. "But if we are going to be an administrative agency," concluded Hutt, "then FDA has to act like one and get its house in order."

Hutt set out to change FDA's basic mode of setting policy. He established procedures by which FDA published proposed regulations in the Federal Register, allowed for a comment period, analyzed the response, and then published final regulations, which were enforceable in court. "My feeling was that whereas FDA properly had in the past concentrated on making new law in individual court enforcement cases, the whole future of its enforcement activities had to be in the rulemaking area, where you can issue one regulation and cover the whole field." Seemingly less dramatic and less consequential than the FOI regulations, this would have a more profound effect on FDA functioning.⁴³

The Federal Register stands as a silent testament to the vast expansion of the federal government in modern times and to its involvement in every aspect of the nation's economic life. First appearing on March 14, 1936, the Federal Register reflected the exponential growth of regulatory government during the New Deal. Published daily, it brought together in one place all the rules, laws, orders, directives, promulgations, and regulations issued by the federal government. It has become the major means by which agencies like the FDA keep the public, as well as its own employees, informed of its decisions and policies. Printed in minuscule type on three column pages, it can run to more than 60,000 pages a year, consuming forests

Peter Barton Hutt. Speech. Legal Series: The Evolution of Food Practices and Procedures. n.d. Food and Drug Administration History Office.

⁴³Lucas, 123.

of paper in the process.⁴⁴ Hutt made the publication of FDA's rules and regulations in the Federal Register the key to FDA's transformation into a modern administrative agency. He prefaced these regulations with what came to be called "Peter's Preambles," detailed explanations that delineated FDA's reasoning on the subject and responded to points raised by those who had commented on the proposed regulation. In the past FDA had requested public comment on proposed regulations and had sometimes incorporated these points into its final regulations. However, in many cases the comments were neither summarized nor discussed in the rule. Both industry and consumer advocates objected to the FDA that they did not always understand what had taken place, even though they might agree with the final outcome.⁴⁵

In developing his preambles, Hutt had a number of objectives in mind. On controversial regulatory proposals, the FDA could receive hundreds of comments. Although many would be of a general nature, either supporting or condemning the policy, others cited specific points of disagreement or raised legal questions about the general policy or its components. In a speech given to the FDA staff a number of years after he left the agency, Hutt explained his rationale for instituting the detailed preambles: first, to assure internally within FDA that all comments "would be read and understood," secondly, to assure that final regulation "address[ed] each of those

⁴⁴As the federal government tries to keep pace with the advances in technology, the Federal Register can now be accessed on-line, thereby making it more quickly available, reducing paper and mailing costs, and saving the forests.

⁴⁵Food and Drug Administration, 1972 Annual Report, (Washington, D.C.: GPO, 1973), 151.

comments," thirdly, to guarantee that the policies implemented "at the working level [would] ... be understood all the way up to the Commissioner." Lastly, he wanted to get the regulations, their rationale, the agency's philosophy and intent out to FDA's field offices, to consumer advocates and their organizations, and to all levels of industry.⁴⁶

"These preambles," commented FDA Deputy Commissioner Sherwin Gardner "have become an important part of the regulatory history, similar to the legislative history which describes the background and intent of enacted legislation. Regular readers of the Federal Register have commented that 'Peter's Preambles' often contain more significant material than the regulations themselves."⁴⁷

Behind all Hutt's regulatory actions stood the conviction that FDA's principal goal was "rapid, even-handed law enforcement." The most efficient use of FDA's resources would result from a system where it could enforce voluntary compliance of the regulated industries. This could only be accomplished if industry knew "what is required of it, under the law," and is "held to strict account for any failure to

⁴⁶Peter Barton Hutt. Speech. Legal Series: The Evolution of Food Practices and Procedures. n.d. Food and Drug Administration History Office.

⁴⁷Sherwin Gardner, "Remarks," Food, Drug, Cosmetic Law Journal, 29, (June, 1974): 305. Paper presented at the New York State Bar Association Annual Meeting, New York City, on January 23, 1974. Peter's Preamble became so famous that H. Thomas Austern, one of the Deans of the Food and Drug Law Institute, wrote a jest in ecclesiastical style on the 'legendary' Preambles. It began, "In the beginning was the Word, and the Word was in the Preamble ... And in the temple at Rockville, it was known that only St. Peter could truly divine the meaning of the Word...." H. Thomas Austern, "The Regulatory Gospel According to St. Peter," Food, Drug, Cosmetic Law Journal, 29 (June 1974): 316.

comply."⁴⁸

Having confronted regulatory issues from both sides of the table, Hutt wanted to establish a consistent and knowable set of regulations based on accepted scientific principles that applied to all manufacturers and which limited capricious FDA action. Industry insiders thought that the Hutt approach, if it worked effectively, would produce more evenhanded enforcement. Under the Goodrich approach of case law enforcement, the 'test case' company while in litigation had to cease producing its product. But since no judicial decision had been reached, its competitors had an advantage because they could continue to market their product, at least until the courts passed judgment.⁴⁹

The FDA also assumed that "Peter's Preambles" and "regulation-by-Register" would have the salutary effect of blunting future court challenges to FDA regulations and decreasing court development of FDA authority. Department of Justice lawyer Howard S. Epstein predicted to an American Bar Association Food, Drug and Cosmetic Law Committee that subsequent challenges to agency regulations will be more difficult "because there will be a better administrative record effectively summarized and set forth in the Federal Register. Courts will be more loath to disturb the agency's well documented conclusions."⁵⁰

Hutt admitted as much and more. He readily conceded that as a lawyer he liked to win. By analyzing every issue presented to the FDA and writing FDA

⁴⁸F-D-C Reports, September 9, 1974, p. T&G 5.

⁴⁹"Behind FDA's Regulations," FDA Consumer, (November 1974): 13.

⁵⁰F-D-C Reports, 8/26/74, p. T&G 7.

regulations as a brief in the Federal Register, Hutt doubted that the regulated industry would be likely to challenge its regulations after FDA had "explained it so persuasively." Echoing Epstein's comments, Hutt thought it would be "a very, very, very rare day indeed that a court would over-rule FDA." Later when Hutt returned to Covington and Burling, he would be able to analyze FDA's case by reading the preamble to the final rule in the Federal Register. If he found any flaws in its reasoning, he could use these to challenge FDA in court.⁵¹

Peter Hutt's last major initiative at FDA involved re-organizing the vast number of rules and regulations under which the FDA operated. FDA's extensive regulations took up five volumes in the Code of Federal Regulations. FDA explained in its 1973 Annual Report that the two-year recodification program would make FDA's regulations easier to find, read, and understand.⁵²

The comprehensive document that resulted dealt with the full range of FDA administrative procedures, including the establishment of advisory committees, the filing of citizen petitions, the dissemination of draft regulations. Deputy Commissioner Sherwin Gardner told the annual meeting of the New York State Bar Association, "It will publicly establish our methods of doing business that will be further evidence of Agency commitment to the openness of operation."⁵³

⁵¹Peter Barton Hutt. Speech. Legal Series: The Evolution of Food Practices and Procedures. n.d. Food and Drug Administration History Office. The Preambles have remained a permanent part of FDA rule-making.

⁵²Food and Drug Administration. 1973 Annual Report, (Washington, D.C.: GPO, 1974), 6.

⁵³ Gardner, p. 305.

The new regulations, taking up almost one hundred pages, appeared in the Federal Register on May 27, 1975. Here again Hutt tried to indicate to all concerned, both industry and consumer, exactly what to expect from FDA. Just as importantly, he wanted to bring some semblance of order and control to FDA's intricate legal framework. Agency regulations and practices, many developed over the years on an ad hoc basis to meet immediate needs, were spread haphazardly through numerous sections of the Code of Federal Regulations and agency manuals.

Under normal circumstances, the FDA would propose these regulations, wait for public comment, evaluate the comments received, and then publish a final rule. Hutt decided to shortcut the process, using dire need as a rationale to make the regulations effective 60 days after their publication in the Federal Register. After a successful legal challenge by the American College of Neuropsychopharmacology for not properly observing the provisions of the Administrative Practices Act, FDA re-issued the regulations on September 3, 1975, allowed thirty-days for comments and made its final determination.⁵⁴

The new rules reflected the changes that had opened the federal government to more direct participation by its citizens during the past few years. In light of recent

⁵⁴40 Federal Register May 27, 1975, pp. 22950, 22965. The American College of Neuropsychopharmacology v. Weinberger et al. Civil Action No. 75-1187. On July 23, 1975, the American College of Neuropsychopharmacology brought suit in the United States District Court for the District of Columbia to enjoin the effectiveness of the regulations, contending that Section 553 of the Administrative Procedures Act required that they be proposed for comment prior to publication in the Federal Register as a final rule. On July 31, 1975, the District Court issued an Order permanently enjoining the Commissioner from issuing the regulations. Although the FDA disagreed with the Court's ruling, it complied and reissued the regulations with minor changes in the Preamble.

court rulings, the new regulations broadly defined the terms 'interested persons' and 'adversely affected'. Because of the broad nature of FDA activities, any citizen might have an interest in agency policies. Members of the public could challenge the FDA in court, respond to agency proposals, and participate in administrative proceedings without showing any specific economic or other type of harm. In legal terms, they did not have to exhibit proof of 'standing'.⁵⁵

The change in legal standing would have been an empty victory without a group of public interest lawyers willing to litigate on these broad issues of public participation in regulatory decision-making on behalf of consumers. As had been seen on the advisory committee panels, to be effective, consumers or their representatives needed to have the same expertise as those from industry or the medical profession. Showing up at a hearing or marching around FDA's Parklawn Building was important in attracting media attention, but to have an impact on

⁵⁵40 Federal Register, May 27, 1975, p. 22951. In the 1960s a series of landmark Federal court cases defined a new right of citizens to participate in a wide range of administrative procedures. In the 1966 *United Church of Christ v. FCC* case, the Court questioned whether "the Commission can always effectively represent listener interests in a renewal proceeding without the aid and participation of legitimate listener representatives...." *Office of Communication of the United Church of Christ v. FCC*, 359 F. 2d 994 (D.C. Cir. 1966); 425 F. 2d 543 (D.C. Cir. 1969).

Environmental Defense Fund v. Hardin and *Environmental Defense Fund v. Ruckelshaus* dismantled existing barriers of legal "standing," permitting groups to bring class action suits in federal court even though their interests were not directly involved. These cases asked officials in the Department of Agriculture to restrict the use of DDT. *Environmental Defense Fund v. Hardin*, 325 F. Supp. 1401 (D.C.D.C. 1971); *Environmental Defense Fund v. Ruckelshaus*, 439 F.2d. 584 (D.C.Cir. 1971). According to Charles R. Halpern of the Center for Law and Social Policy, by exposing administrators to a broad range of viewpoint, these decisions contributed to sound decision-making and instilled confidence in agency fairness. Ernest A. Gellhorn, "Panel II: Standing, Participation and Who Pays?" Administrative Law Review, 26 (1974): 439.

regulatory law or FDA actions, participants needed to be both knowledgeable and consistently involved. The groups that have been most effective in fulfilling their agendas, have been those that understand this and acted accordingly. They challenged the validity or legality of bureaucratic actions which fell short of the government's responsibility in any particular situation, often using the Freedom of Information Act to further their case.⁵⁶

Beside the Hattis and Morgan cases, the FDA had already faced its share of public interest lawsuits. For example, in June 1970 the American Public Health Association and the National Council of Senior Citizens filed suit to force the FDA to move more quickly in removing ineffective combination drugs in the wake of the DESI review. The decision on October 11, 1972 by Judge William Bryant blasted the FDA for 'intolerable procrastination' and set strict time limits for completing the implementation program after years of FDA procrastination.⁵⁷

In another instance, Richard Pierce petitioned the FDA in 1971 to promulgate a regulation requiring relative safety and efficacy statements in labeling. He provided FDA with a seven page legal brief explaining why FDA had the authority to require the data under existing statutes. F-D-C Reports commented that Pierce's petition "stands virtually no chance of being incorporated into FDA regulations. Its

⁵⁶David Vogel, "The 'New' Social Regulation in Historical and Comparative Perspective," in Thomas K. McGraw, ed., Regulation in Perspective: Historical Essays, (Cambridge: Harvard University Press, 1981), 188.

⁵⁷F-D-C Reports, 12/14/70, p. 13. Three years after the NAS/NRC panels had completed their reports, some of them had not been made public and published in the Federal Register. As a result of the suit, Judge Bryant continued to monitor FDA's processes for evaluating the effectiveness of drugs under the Kefauver-Harris Amendments for a number of years.

importance stems from the fact that an individual--in addition to organized groups--has become involved in the FDA regulatory process, and has shown a willingness to research law and to urge FDA to re-interpret the statutes with the aim of providing increased consumer protection."⁵⁸

The new procedural regulations reflected the effect of the consumer and public interest law movement and the greater openness in government. For example, the FDA indicated that petitions received by the agency would be considered and furnished with a formal written response, granting or denying the request. "We are prepared to live with the criticism and difficulty that opening our decision making to the public may bring, knowing that the very fact of openness should engender a sense of public trust, and hopefully, an understanding of the complex and difficult issues which surround each regulatory action." There were qualifications, of course, but henceforth FDA would publish petitions that the agency felt had merit in the Federal Register for comment, sometimes with its own version of the proposal.⁵⁹

Nancy Chasen, attorney for Consumers Union, supported FDA's proposed Administrative Practices and Procedures regulations, especially citizen petitions, although she saw several potential problems in view of FDA's record of excessive delay on consumer petitions. She suggested specific time limits be incorporated into the regulations, a suggestion that FDA did not accept.⁶⁰

⁵⁸F-D-C Reports, November 29, 1971, p. T&G 2

⁵⁹40 Federal Register, May 27, 1975, p. 22988.

⁶⁰Letter to Hearing Clerk, Food and Drug Administration, October 3, 1975 from Nancy H.Chasen, attorney for Consumers Union. By permission from the files of Consumers Union, Yonkers, New York. At the point of her submission, more than

In both the Federal Register and later in the FDA Consumer, the FDA made available detailed instructions on how to petition the agency, including appropriate form letters and advice on where and to whom to send them. The individual who wanted to make a simple request or suggestion could even jot it down on a postcard. In this way, the public could ask FDA to reconsider a decision, participate in an open public FDA meeting, or request time to make a presentation.⁶¹

To make things even easier, Jane Q. Public could learn about future meetings through FDA's public weekly calendar of open meetings and conferences. The prospective calendar contained all public meetings, conferences, hearings, advisory committee meetings, congressional hearings, and similar events for the following month. The retrospective calendar listed private meetings of top agency officials for the previous week, not including those with the working press.⁶²

It would be easy to underestimate the importance of the change to administrative rulemaking and the reorganization of FDA's procedural regulations. In part, the new procedures constituted internal housekeeping, a way of establishing a rational set of principles on which to run a large and growing bureaucratic organization. They also aimed to make it easier for industry to operate in the labyrinth of FDA rules and regulation, a way to make clearer FDA's intent and

two and a half years had already elapsed on Consumers Union's petition to have the drained weight of canned fruits and vegetables listed on the label and a year and a half had gone by since Consumers Union's petition to ban the sale of pet turtles because of the danger of salmonella.

⁶¹Ibid.

⁶²40 Federal Register, May 27, 1975, p. 22965.

assumptions to those with whom it had to deal. But for those outside the agency concerned with its philosophy, policy, and rationale for action, the new procedures represented a massive rethinking of FDA's obligations to the public. No longer would it be acceptable to decide in almost complete secrecy the needs and wants of the American public. Federal bureaucrats as well as elected officials were accountable to the American public for their actions.

Few public officials have had the opportunity to effect fundamentally the operation of their agencies as Peter Barton Hutt had--fewer still embraced it as enthusiastically. Hutt had a clear vision of the role of the FDA in a modern administrative state and the complexities that assuming that role entailed. In his three and half years as General Counsel, working in tandem with Edwards, and later with Commissioner Alexander M. Schmidt, Hutt had a powerful effect on the current and future operation of the Food and Drug Administration. From his independent base as chief legal advisor, he initiated policies and procedures that permanently changed the FDA. He and Edwards opened the once isolated agency to other 'voices' that probed, prodded, and questioned from the outside and advised, analyzed, and inquired through advisory committees on the inside.

Ironically, Hutt as FDA General Counsel could accomplish much more for consumers than a Commissioner or General Counsel more closely identified with the consumer movement might have been able to do. Any action taken by such a commissioner would have aroused suspicion and resistance from industry, the medical profession, and FDA's bureaucracy. Hutt, however, had impeccable industry credential, had been hand-picked by Charles Edwards, and had been a past officer

of the American Medical Association. Although industry fought some of his actions and FDA old-timers despaired at the rate and amount of change, Hutt was able to transform the FDA in ways that ultimately benefitted the consumer. In the same way, only Richard Nixon with his unblemished cold warrior credentials could risk opening the door to the People's Republic of China during this same period.

So all encompassing was Hutt's effect on the FDA that Commissioner Alexander M. Schmidt often found himself facing the question, "Who really runs FDA--you or Peter Hutt?" Schmidt asserted that he and Hutt worked closely together as part of his team-approach concept to management. He went on to explain: "If I want to do something and Peter doesn't, his question is: 'Commissioner, you don't expect me to defend that in court, do you?' On the other hand, if Peter wants to do something and I don't, his question--admittedly rhetorical--usually goes like this: 'Whatta ya' mean ask Congress? We already have the authority!'"

Some in FDA bureaucratic ranks, however, rightly questioned Hutt's motives. It was common knowledge that Hutt had not made a permanent career change. At some point, he would return to advising his corporate clients at Covington and Burling. Robert Brandenburg, who administered the revised FOI regulations, felt that they "put unnecessary burdens on the agency.... So I think we could have started with much less stringent requirements being placed upon the agency, than those that Peter Hutt wrote." In a passing aside, Brandenburg commented that although he was casting no aspersions, "these regulations work to his benefit now. Since he had operated on the other side of the fence from an FDA not constrained by these

regulations and felt that they should be."⁶³

Others in industry concurred. H. Edward Dunkelberger, Jr., an industry lawyer said that Hutt is a firm believer in law and order "as long as he writes the laws and gives the orders."⁶⁴

Having permanently put his stamp on the Food and Drug Administration, Peter Barton Hutt prepared to leave in May 1975. Hutt had said on becoming FDA General Counsel that he intended to stay for only three to five years because he felt that government officials should not become 'encrusted' in important positions. "I am afraid that the longer one stays in a job of this type the more one is inclined to defend past decisions rather than to seek out new and innovative programs."⁶⁵

Those who had equated Hutt's extensive ties to industry to a desire to keep the FDA the same closed agency it had been for decades miscalculated his intent. Although the benefit of administrative ruling-making surely redounded to industry, Hutt's regulatory revolution provided benefits to consumerists, public advocates, citizen groups, medical groups, or anyone with a cause, a concern, a demand, or a grievance involving the FDA. Readers of the Federal Register, admittedly a select group, could monitor FDA actions, follow policy changes, and attempt to influence policy by commenting on proposed changes or participating in advisory committee meetings. In essence, the Federal Register offered the public a window into the FDA

⁶³Robert C. Brandenburg, Retired Director, Compliance Regulations and Policy Staff, Interviewed by Robert G. Porter, December 4, 1982, transcript, pp. 60, 62, Oral History Program, Food and Drug Administration.

⁶⁴Turner, "FDA Pursues Historic Role Amid Public, Industry Pressure," 252.

⁶⁵"Behind FDA's Regulations, FDA Consumer, (November 1974): 17.

that it never had before, although these successes should not obscure the fact that the vast majority of decisions and proceedings in all agencies are made and conducted with little, if any, participation, formal or informal, by public interest groups.

Hutt left an agency far different from that which he inherited. At a farewell party, Robert B. Choate, chairman of the Council on Children, presented a mock "Warrant for the Arrest of Peter Barton Hutt, originally reviled, persecuted, and deplored, not for his native skills, which all admitted were exemplary, but for the fact that he hid his corporate background.... And now that the time of his public services are temporarily stopped, the accused is held in bewilderment by the ready-to-rant, rave, and chest-beat crowd, for he actually seems to have done his job. Moreover, he seemeth to have done it well."⁶⁶

The fact that consumer advocates were present at all at a farewell party for the FDA General Counsel is an indication of the changes that had transpired at FDA in the Edwards-Hutt era. Consumerism and public involvement in the FDA had become a fact of life. But it should not be construed that this brief harmonious moment reflected the work-a-day relationship between those inside and outside the agency. Different needs, agendas, and views on the nature of safety, risk, and the proper functioning of a regulatory agency produced a disharmony that would be reflected in battles over red dyes, patient package inserts, saccharin, and numerous other issues.

⁶⁶F-D-C Reports, May 19, 1975, p. 7.

CHAPTER 5

"NO MORE RED M & Ms"

"Regardless of the outcome of the decision, those who disagree with it will continue to pursue the matter through all available channels, while those who agree with it will inevitably remain silent, preparing themselves for the next issue. Graceful acceptance, or even grudging acceptance, by those who have lost any important safety decision is a rare exception."¹

The children poured the contents of their packages of M & Ms into their hands, but all the red ones, the best ones, the ones they ate first (even though they all tasted the same) were gone. Where did they go? The children did not know, but any adult who followed the news in 1970s knew that the red color additive, FD&C Red No. 2, had been under attack for years from consumer advocates who harbored deep suspicions about its safety. When the Food and Drug Administration finally decertified the color in 1976, thereby prohibiting manufacturers from adding it to their products, M & Ms' maker, Mars, Inc., had no choice but to stop using the color. Until they could find a satisfactory replacement, there would be no more red M & Ms.

Mars, Inc. was only one of a large number of companies affected by the FDA's decision. Few outside the food industry realized the color additive's ubiquity. Of course, food manufacturers used Red No. 2 to color candy hearts red, to give cherry soda its characteristic hue, and to change naturally pale strawberry ice cream to a bright pink. But unbeknownst to the general public, companies also used it to color luncheon meats, dry cereals, pickles, pet foods, salad dressings, processed cheese,

¹National Academy of Science, How Safe is Safe: The Design of Policy on Drugs and Food Additives? (Washington, D.C.: National Academy of Sciences, 1974), 125. Statement of Peter Barton Hutt.

cough medicines, and thousands of other products. In fact, Red No. 2, in combination with other dyes, even enhanced the color of white icing and intensified the color of chocolate.

Food manufacturers considered color additives essential in making their products appealing to the consumer. However, for the cosmetics industry, color additives were critical. Color additives supported a billion dollar industry that spent millions in advertising each season to convince women that their happiness depended on choosing the right shade of red or pink lipstick and nail polish. Even the pharmaceutical industry used color additives to differentiate medications to a public that still described highly potent medications as "my little pink heart pills." And millions of children had been convinced to take their medicine, at least the first spoonful, by its pretty pink color and cherry flavor.

The red dye controversy became another salvo in the battle waged between consumer groups and food manufacturers over the question of safety in the American food supply. In the final analysis, the debate came down to the level of risk that was acceptable in exchange for the cornucopia of products available in the average supermarket. Industry adamantly opposed any limitation on the use of the dye. The FDA was exceedingly reluctant to remove a widely used product, such as Red No. 2, without very strong scientific evidence that it constituted a danger to the public. Consumers advocates countered that any evidence suggesting that a product adversely effected the fetus or caused cancer should be cause for removal. Whose standard should prevail, especially if the scientific evidence itself was in dispute?

Although the agency had been involved in a legal battle for years with the

cosmetic industry over the status of color additives, Red No. 2 was a relatively minor issue when Dr. Charles Edwards became Commissioner in early 1970. In line with his efforts to move the FDA into a less confrontational posture with industry, resolve past problems, and base the FDA's decisions on a strong scientific foundation, Edwards moved to defuse the situation.

In a March 1970 speech to the Cosmetic, Toiletry, and Fragrance Association, Edwards gave them the benefit of his advice. "The consumer's voice is being heard in our land as never before and in an ever growing chorus. In my judgment, that voice should not and cannot be long denied. If this is so, then I think time is running short for this Association and for FDA to reach some hard and fast decisions." The consumer movement, Edwards warned, "challenges poor practices of the past and exposes those who refuse to change. Your products are important but not vital to man's survival. Unlike pharmaceuticals you do not enjoy a benefit to risk ratio consideration. The hard fact is that cosmetics must be safe."²

From the point in 1856 when Sir William Henry Perkins first synthesized the color mauve from coal-tar oil, the synthetic dyes had driven the centuries-old vegetable and mineral pigments from the field. By 1900, manufacturers had added hundreds of 'coal tar' or 'aniline' dyes to the American food supply, few of which had been tested for safety. With the passage of the 1906 Pure Food and Drug law, the FDA became involved with the regulation of artificial coloring materials. The new statute included no specific authority for the federal government to regulate colors. Instead the FDA set up a voluntary system of certification for synthetic food colors,

²F-D-C Reports, March 1, 1970, p. 3.

relying upon the Act's prohibition of substances added to food that "may render [the food] injurious to health."³ A year after passage of 1906 Pure Food and Drug Act, all but 7 of these colors had been banned. Amaranth, officially designated FD&C Red No. 2, passed the test.⁴

The FDA's control over coloring material grew in tandem with its increasing powers in other areas of regulation. Cosmetics came under federal regulation with the passage of the 1938 Federal Food, Drug, and Cosmetic Act. The new law made the previous voluntary system mandatory and extended the regulations governing 'coal-tar colors' to all synthetic colors. An additive could be used after the manufacturer had shown that the use of the color in cosmetics was "harmless and suitable."⁵

In the 1950s, cases of acute toxicity attributed to excessive amounts of color in candy and popcorn prompted the FDA to review all certified colors. FDA now interpreted harmless as "harmless per se" that is, safe not only at normal use level, but also at high dosage levels used in animal studies. Under this definition, the FDA removed several colors, including FD&C Red No. 32, the only dye used to color

³Food and Drugs Act of 1906, P.L. 59-384, 34 Stat. 768 (1906).

⁴Michael R. Taylor, "History of Cosmetic Color Additive Regulation: Creative Maneuvering by FDA Bodes Well for the Future," Food, Drug, Cosmetic Law Journal, 37 (April, 1982): 152. Of the original seven approved dyes--Orange 1, Erythosine, Ponceau 3R, Amaranth, Indigotine, Naphthol Yellow and Light Green--only three remained on the market by 1970, Amaranth, FD&C Red No. 2; Erythosine, FD&C Red No. 3; Indigotine, FD&C Blue No. 2. Of the 24 coal-tar colors listed since 1907, 14 have been removed.

⁵Federal Food, Drug, and Cosmetic Act of 1938, P.L. 75-717, 52 Stat. 1040 (1938).

oranges.⁶ Representatives of the Florida Citrus Exchange, fearing that consumers would not buy their naturally splotchy green oranges, took their case to the Supreme Court arguing that "harmless" was a relative term, not an absolute term as FDA contended. The Supreme Court rejected the growers' position, thus allowing FDA to require companies to do animal toxicity testing with dosages substantially exceeding normal human exposure, even when normal use had shown no evidence of harm.⁷

Responding to industry pressure, Congress passed the 1960 Color Additive Amendments to the Federal Food, Drug, and Cosmetic Act, to moderate the stringent requirements of the harmless per se doctrine. Under the new law, the responsibility lay with the manufacturer to submit data to the agency showing that its product had demonstrated safety to a reasonable certainty when put to its intended use [emphasis added]. The Color Additives Amendments carried over the Delaney Clause requirements from the 1958 Food Additives Amendments, outlawing any ingredient that caused cancer in man or animals (although Congress allowed less stringent requirements for cosmetics).⁸

Where was the public in this crucial debate on products that virtually all Americans used or consumed? Few Americans, aside from those directly involved, paid much attention to either the Supreme Court case or Congress' efforts to circumvent the question. Even if they had wanted to involve themselves in the process, channels did not exist for public comment. Americans did not have an

⁶20 Federal Register, November 16, 1955, p. 8492.

⁷Flemming v. Florida Citrus Exchange, 358 U.S. 153 (1958).

⁸Color Additive Amendments of 1960, P.L. 86-618, 74 Stat. 397 (1960).

opportunity to decide whether they thought food coloring important enough to lower safety standards; no way to debate the gains from a pre-approval system for all colors against the loss of FDA's ability to remove a color that caused cancer in animal tests but had not shown any immediate hazard to humans; or for that matter to consider the costs of a zero tolerance system.

The implementation of the law's provisions rested with FDA. With outcomes vitally important to the health of perhaps millions of Americans, FDA negotiated the details of the issue in the anonymity of drab bureaucratic offices in Washington, as nameless staffers hammered out agreements with industry officials without public hearings, minutes, or public notice.

All color additives in use when the law passed on July 12, 1960 received a 'provisional listing'. This did not require any proof of safety, but simply evidence that it had been in use when the law passed. The Amendments gave manufacturers two and a half years to collect data to satisfy the new safety standards, at which time the color received a permanent listing. The Amendments permitted the Secretary to postpone the original closing date "for such periods as he finds necessary to carry out the purpose of this section, if in the Secretary's judgment such action is consistent with the objective of carrying to completion in good faith, as soon as reasonably practicable, the scientific investigations necessary for making a determination as to [permanently] listing such additive." For some colors this process took more than twenty years.⁹

The first color additives list published in October 1960 contained 133

⁹Ibid.

compounds and despite repeated promises to issue a final decision on the provisional listings, from 1960 to 1975 FDA made little progress deciding which colors could be permanently listed. Most of the colors that were removed were those no longer in use. In the beginning, many manufacturers were content to leave the color additives in their provisional status. However, as questions about their safety began to arise, companies realized that permanent listing was to their advantage because under Food and Drug Administration law it would require much more proof of danger to remove a permanently listed color.

FDA used this fact to its advantage in the late 1960s when it was embroiled in a legal battle with the Toilet Goods Association (TGA). The trade group had taken FDA to court over proposed regulations that would have extended color certification provisions from the bulk cosmetic chemicals to the finished cosmetic product, for example, lipsticks. The agency, in essence, kept all pending approvals as hostages pending completion of the litigation.¹⁰

On August 25, 1969, the U.S. Court of Appeals for the Second Circuit ruled that FDA did not have authority to require, in all cases, formulation data for cosmetics but that it could request such data in special situations.¹¹ Edwards and FDA top management wanted to end the cosmetic industry-government battle and indicated a willingness "to be flexible and reasonable in their demands for end-product scientific information." All parties hoped that this would end the stalemate over color additive

¹⁰Taylor, 159.

¹¹Toilet Goods Association vs. Finch 419 F. 2nd 21 (1969).

petitions.¹²

Red No. 2 was one of the colors that had never received permanent listing, in part because it had been part of the TGA court case. However, industry also had to shoulder some of the blame. It had asked for and received numerous postponements of the termination of the color's provisional listing during the 1960s, citing scientific experiments that had not been completed or evaluated. Not until these issues were settled could the color end its provisional listing and receive permanent status.¹³

After the court ruling, settling the matter now seemed in everyone's best interest. FDA had no wish to keep this important color off the market unless serious health or safety issues had been raised. FDA's final evaluation report of March 5, 1969 gave Red No. 2 a clean bill of health for general use in coloring food, dietary supplements, and drugs, but not for use in cosmetics. For the ninth time, the FDA postponed the termination date until December 31, 1970 while it ruled on the

¹²F-D-C Reports, August 30, 1971, pp. 37-8.

¹³Report of the Comptroller General of the United States. Need to Establish the Safety of Color Additive FD&C Red No. 2. Food and Drug Administration, Department of Health, Education, and Welfare, to the Honorable Gaylord Nelson, United States Senate, October 20, 1975, pp. 5-7. [known hereafter as "GAO Report"]

On November 13, 1962, the Toilet Goods Association (TGA) asked for a postponement until August 1964 to evaluate skin tests of the dye. On November 21 and December 14, 1962, the Pharmaceutical Manufacturers Association (PMA) requested a similar postponement. On May 15, 1964 PMA initiated another such request, while the TGA said its testing had been completed but was still being "pharmacologically evaluated." FDA agreed changing the termination dates until July 1, 1965. On June 25, 1965, FDA again agreed to put off taking action on Red No. 2 based on requests from the TGA and the Certified Color Industry Committee that more time was needed to finish scientific work.

cosmetic formulation issue.¹⁴

However, just as the situation seemed ready to quietly resolve itself, questions about FD&C Red No. 2 arose that would not only jeopardize the status of that particular color, but call into question the whole concept of food and color additive safety. In 1970, FDA received reports of Russian studies that raised serious questions about the safety of amaranth, the original name of Red No. 2. M. Andrianova of Moscow's Institute for Nutrition reported finding tumors in 13 of 50 male rats fed a 2% diet of amaranth for 33 months. 50 controls had no tumors. In a study by A. Shtenberg and E. V. Gavrilenko of the Pesticide Toxicology Lab of the Nutrition Institute, USSR Academy of Medical Sciences, female rats fed amaranth had reduced fertility, an increase in stillbirths, a decrease in the number of live births, and deformed fetuses.

For FDA officials, the studies raised as many questions as they answered: had the amaranth been contaminated with other products; was the amaranth used identical to the product called FD&C Red No. 2 in the United States; could the FDA accept the methodology used by the Russians in testing the amaranth? Based on these unanswered questions, the FDA took no regulatory action against Red No. 2. Moreover, suspicions about the Russian scientific experiments could not be extricated

¹⁴GAO Report, pp. 7-8. In 1964, the United Nations' Food and Agriculture/World Health Organization Expert Committee on Food Additives established an Acceptable Daily Intake (ADI) of 1.5 mg/kg/day. In 1969, FDA reviewed the available data and concluded that there was no adverse effect at an intake of 1% of the diet. Taking 1/100 of this value as a safe level of use, for the average 60 kg person this mean ingestion of between 90 and 300 mg. per day. Usage data showed that the maximum daily intake in the United States was approximately 85 mg/person/day.

from the Cold War politics of the era.¹⁵

Having waited ten years to take action against any major coloring agents, the FDA was in no hurry to act, especially against this ubiquitous additive, the banning of which would likely cause major disruptions in the food, drug, and cosmetic industries. Although the FDA took no immediate regulatory action, it could not turn a blind eye and totally ignore the disturbing Russian reports, no matter how flawed. Furthermore, the Russian studies pointed up the abysmal lack of testing, especially reproductive studies, for most of the coloring agents on the market.

In the early 1970s regulatory environment, it was no longer a feasible option to simply ignore the Russian results, even had the FDA wanted to follow such a course. The FDA no longer operated in isolation. Consumer advocates not only monitored FDA actions, they had their own sources of information, some from within the agency, that kept them apprised of problems. They were always ready to comment on, or publicize, any lapse or dereliction of duty as they saw it. Throughout the next four years, as evidence mounted, the FDA was a most reluctant actor in terms of Red No. 2. Taking a reactive role, it responded only when forced to by consumer groups clamoring for its removal, in each case asking for new tests or evaluation by another scientific body before making a decision.

"I would hope that the FDA will reassure the American public," Ralph Nader

¹⁵Andrianova, M. "Carcinogenic Effects of the Red Food Dyes, Amaranth, Ponceaux SX, and Ponceaux 4R. Vop. Pitanya 29:61, 1970.

Shtenberg, A.I. and Ye. V. Gavrilenko. "Effect of Amaranth Food Dye on Reproductive Function and Progeny Development in Experiments with Albino Rats," Vop. Pitanya 29:66, 1970. The fact that the controls had no tumors raised some red flags for FDA as it was a finding totally at variance with scientific experience with this animal.

wrote in a December 29, 1970 letter to Commissioner Edwards, "by either permanently listing or de-listing the provisionally listed color additives as soon as possible, with disclosure of full technical data for each decision."¹⁶

Consumer advocates had begun to publicly question the safety and nutritional value of the vaunted American food supply. Safety had already become a keyword in the American lexicon by 1970--safety in the streets, safety of the environment, drug safety, automobile safety and now, safety of that most personal of commodities, food. The 1969 removal of cyclamate had already signaled that all was not well. At the height of the news coverage over cyclamate, The New York Times ran a multi-part series under the headline, "Food Safety Emerges as a Worry in Era of Additives." Although the public hoped that cyclamate was an aberration, the series made clear that the cost of ready-to-eat, convenience foods was the addition of preservatives, flavorings, colors, stabilizers, and numerous other compounds known only to food chemists.¹⁷

There had been a time when the food processing industry was hailed as postwar American miracle that brought thousand of different food products to the neighborhood grocery. As the technology became more complex "the wizardry of the food chemists rivaled the ancient dreams of alchemists, turning the pedestrian contents of their beakers into substances that looked and tasted like sugar, bacon, cream, and other delights," recounts food historian, Harvey Levenstein. Most American consumers had been impressed by these achievements, and until recently

¹⁶F-D-C Reports, January 11, 1971, p. 24.

¹⁷New York Times, November 9, 1969, p. 74.

showed little concern for the methods and ingredients used.¹⁸

Of course, consumer advocates Ralph Nader and James S. Turner saw this 'alchemy' as more a product of the Sorcerer's Apprentice than the wise Sorcerer himself. In his Foreword to Turner's 1970 expose, The Chemical Feast, Nader wrote that "making food appear what it is not is an integral part of the \$125 billion food industry." From claims for "enriched white bread" made from wheat stripped of most of its nutrients to the heavy promotion of "near-zero nutrition 'snacks,' to chemically doused bakery goods, and soft drinks," the food industry had deceived the consumer. Turner charged that the Food Group, as the food lobby was known in Washington, had almost entirely determined the limits of public dialogue and public policy about food quality. "It is time for consumers to have information that will provide them with an effective understanding of the secrecy-clouded situation."¹⁹

The Chemical Feast was based on a 202 page report compiled by Turner, and a team of 16 law and graduate students, Nader's Raiders, working with his Center for the Study of Responsive Law. The report, released to the press on April 8, 1970, portrayed the Food and Drug Administration as an agency whose food standards and regulations read "like a catalog of favors to special industrial interests." Turner judged the FDA's "faith in industrial self-regulation," to be misguided since industry's sole motivation, he was persuaded, was profit.

¹⁸Harvey Levenstein, Revolution at the Table, (New York: Oxford University Press, 1995), 202.

¹⁹James S. Turner, The Chemical Feast: The Ralph Nader Study Group Report on Food Protection and the Food and Drug Administration, with a Foreword by Ralph Nader, (New York: Grossman Publishers, 1970), v, vi.

The book opened with a charged paragraph designed to shock readers. "For too long Americans have rested secure in the belief that their health surpasses that of all other peoples of the world, that they live longer, suffer less, and eat better than people in any other nation. They are mistaken." In a chapter entitled "Hidden Ingredients," Turner documented the fact that manufacturers could add caffeine to soda or monosodium glutamate (MSG) to mayonnaise or call something orange drink when it had only 10% orange juice without indicating the fact on the label. Turner laid responsibility squarely with government regulators. "The diminishing quality of a number of American food items can be traced directly to the ineffectiveness of the FDA food standards program." While consumers blithely assumed that the FDA protected their interests, "in fact, it is unscrupulous businesses that are being protected in their fraud." How could the public protect itself when FDA, the very agency meant to protect its food supply, caved in to the demands of business?²⁰

Turner and his co-investigators recommended that the Agency should: 1] require that all food additives be listed on all food packages and that all food be labeled by grade; 2] require the government to take off the market not only additives that had been linked with cancer, but also those that had been associated with possible birth defects or genetic damage until their safety had been established; 3] establish its own testing laboratory or set up an outside referral board so that manufacturers could not select their own testing labs; and 4] appoint a special Assistant for Consumer Affairs or set up a consumer council.²¹

²⁰Turner, 64.

²¹Turner, 233.

Others joined Turner in questioning the safety and quality of American food. In 1972, Michael F. Jacobson, a co-founder of the Center For Science in the Public Interest, published Eater's Digest: The Consumer's Factbook of Food Additives. Jacobson, who had recently earned a doctorate in microbiology from M.I.T, was one of a new breed of scientifically-trained consumer advocates. Starting with acetic acid and ending with yellow prussiate of soda, Eater's Digest familiarized readers with the arcane ingredients commonly found in foods. Although he did not want to be put in the same camp as those who shrilly warned about 'poisons in the pantry,' Jacobson clearly believed that most companies used food and color additives to bolster the bottom line rather than the taste or the nutritional value of the food they put on the shelf. Jacobson counseled that these colorings had risks and added nothing to food but an improved appearance.²²

His general philosophy could be distilled to: when in doubt, leave it out. Because a chemical's effect on the human fetus could not be reliably estimated on the basis of animal studies, Jacobson believed, "if animal studies indicate any chance of birth defects, a chemical as unnecessary as an artificial coloring should be banned without further discussion." Both Jacobson and Turner faulted the FDA for not using the power that it already had. However, if those powers proved to be inadequate, then FDA's only recourse was to demand greater powers from Congress to better police the supermarket. Turner, in particular, blamed an entrenched bureaucracy overly sympathetic to industry for lack of consumer protection. He assumed that only

²²Michael F. Jacobson, Eater's Digest: The Consumer's Factbook of Food Additives, (New York: Doubleday, 1972), 18.

a greatly enhanced consumer presence working in combination with new leadership and pro-consumer members of Congress could force needed changes upon the FDA. Both books sold well, attracting the attention of the press and the mainstream American consumer.²³

Questions about food additives, and the food supply in general, had arisen during the 1960s youth rebellion and "counter-culture," which extolled the natural and denigrated the mass-produced and artificial. Living small, walking lightly on the earth, eating lower down the food chain meant rejecting the over-processed, materialistic culture that so represented America's contribution to the world. Unlike sporadic antiwar protests, dietary righteousness could be lived 365 days a year, three times a day. The New Left had always insisted that the personal was political. What could be more personal than food? And what could be more political than challenging agribusiness, one of America's most important industries, that sold \$100 billion worth of food in 1969?²⁴

"The turbulent cultural climate of the late 1960s was unusually favorable to the growth of interest and belief in radical hygiene," wrote James P. Whorten in Crusaders For Fitness. "Long-building uneasiness about the untoward effects of scientific and technological advance (particularly environmental pollution and food contamination) was joined by the social idealism and hatred of entrenched authority bred by civil rights and Vietnam protests." Charges of contamination of the food

²³Jacobson, 66.

²⁴Warren Belasco, Appetite For Change: How the Counterculture Took on the Food Industry, 1966-1988, (New York: Pantheon Books, 1989), 32.

supply by corporations and dereliction of duty by the FDA would find a receptive audience in the aquarian generation.²⁵

Health through personal regeneration has a long and venerable history in the United States. Radical schemes of hygiene have been a feature of American life since the early 1800s, especially in periods of general reformist ferment. Mark Twain wrote in 1906, "one of the classic characters bred by American culture of the past century and a half is the health fanatic, the man who eats what he doesn't want, drinks what he doesn't like, and does what he'd druther not, all the while smugly announcing himself to be energetic, joyful, and certain of long life, and exhorting his errant neighbors to reform."²⁶

In the early 19th century, Sylvester Graham, remembered today for the cracker that bears his name, tirelessly lectured on the value of natural foods and a regimen of exercise, cold baths, fresh air, water, and control over the appetite. In 1876, Mother Ellen Harmon White of the Seventh Day Adventist Church hired a young physician, John H. Kellogg to run her Western Health Reform Institute in Battle Creek, Michigan. The sanatorium treated thousands of patients a year, including Theodore Roosevelt and John D. Rockefeller, with a physically purifying regime that included the corn flakes his brother had created.²⁷

A belief in the principles of radical hygiene transcended simple changes in

²⁵James C. Whorten, Crusaders for Fitness: the History of American Health Reformers. Princeton: Princeton University Press, 1982, p. 335

²⁶Samuel Clemens, Following the Equator, 2 vols. (New York: 1906), II, 151.

²⁷Michael S. Goldstein, The Health Movement: Promoting Fitness in America, (New York: Twayne Publishers, 1992), 43.

eating patterns or exercise regimens. Those who espoused this ideology identified correct personal hygiene as the necessary foundation for most, even all, human progress. To radical hygienists the value of preventing ill health far exceeds the value of curing or ameliorating illness. An ounce of prevention is better than any amount of cure. One of the movement's guiding principle was that each individual--not the medical care system, nor society--must assume responsibility for the development and maintenance of his or her health by maintaining self-control and restraint in the face of worldly enticements.²⁸ Writing in The Health Movement: Promoting Fitness in America, Michael Goldstein found the unifying force in this highly visible 1970s social movement to be "a shared set of grievances focusing on the cost and availability of preventive medical care, the rising tide of chronic illness, the poor quality of our eating habits, our exercise habits and substance abuse, including tobacco, caffeine, and alcohol." In an atmosphere that venerated expensive, high technology medicine, medical professionals gave lip-service to prevention, government funded it with pennies on the dollar, and Americans as individuals lost sight of the fact that how well they felt depended on how well they lived.²⁹

The new converts began to swell the ranks of those, such as Adelle Davis, Carlton Frederick, and Gary Null, who had been preaching the gospel of health for years. Often referred to as 'health food nuts,' they had been alternately ignored and ridiculed by the vast majority of Americans enamored of their burgers, fries, and

²⁸Whorten, 4.

²⁹Goldstein, 4.

Cheez-Whiz, whose major physical activity was changing the television channel. Millions of middle-class Americans started to tune in and get the message. Joggers filled the highways and byways. Nike no longer connoted a Greek god, but rather an expensive type of sneakers. Health clubs sprouted up and sprouts became the health food of choice. Americans stopped smoking and many more ate foods touted as 'natural', 'wholesome,' and 'healthy.'

When the Health Research Group (HRG) and other consumer activists began to spread the word about the Russian experiments and other disturbing findings on Red No. 2, the health reform movement had already plowed the ground for the seeds of doubt about the safety of food additives. Davis, Frederick, and others spoke not only to the committed, but to a larger audience of middle and upper-middle class Americans who had begun to have misgivings about the food supply and the FDA's ability to protect the public.

Adelle Davis, often called the 'high priestess of popular nutrition,' spread the word through frequent appearances on talk shows. Davis' lively style, coupled with a pontifical confidence in the correctness of her views, helped sell ten million copies of her books. To the legions of her devoted fans, Adelle Davis was at once "the immaculate scientist--she did indeed hold a master's degree in her field--and the feisty, but caring Earth Mother."³⁰

Davis charged that the modern American diet was the cause of most of the ill health in America and modern food production techniques were the root of the

³⁰Ronald M. Deutsch, Nuts Among the Berries, (Palo Alto, CA: Bull Publishing, 1977) 3.

problem. Americans had been lured into a craving for additive-loaded phony food by a powerful industry that controlled food advertising on television and in newspapers and magazines. The public had been brainwashed by hundreds of industry inspired feature articles designed only to increase sales. She denounced a powerful food industry that paid lobbyists millions of dollars to sway state and federal lawmakers to pass favorable legislation. Although she pinned the blame on legislators rather than the regulators, the message was clear--keep the pressure on the government to do right by the consumer and restrict the unnecessary, artificial additions in the food supply.³¹

As the ideas of the health reform and radical hygiene movements moved into the mainstream in the 1970s, the middle-class began to pay heed to their warnings and provide financial support for their work. The rounds of accusation and rebuttal found their way into the daily newspapers and evening news report, increasing public awareness of health issues, food and color additives, and the role of the FDA.

The growth of the magazine, Prevention, is instructive. Begun in 1950 by J.I. Rodale, as a vehicle for organic and health food theories, its circulation skyrocketed from several hundred thousand in 1966 to more than 2 million subscribers by the early 1970s. The restoration of a natural diet was Prevention's primary objective. Those who subscribed were acutely interested in the composition of the foods they ate, but were stymied by a government that required little or no labeling on most food products. Worse, they read in many of the magazine's articles that the FDA failed

³¹Adelle Davis, Let's Eat Right to Keep Fit, (New York: Harcourt Brace Jovanovich, 1970) quoted in Sheldon Zerden, The Best of Health: The 101 Best Books, (New York: Four Walls Eight Windows, 1989), 227.

to remove food additives that its own scientists indicated were potential carcinogens.³²

In the face of rising interest in food safety, and with consumer activists watching carefully, FDA had to produce some response to the Russian studies. On March 11, 1971, the FDA began the first of its own tests of the Russian findings. Dr. Jacqueline Verrett conducted the same type of experiments on chick embryos with Red No. 2 that she had done with cyclamates. Other agency scientists conducted teratology experiments to determine the effects of the dye on fetuses. Within six months, the agency had data indicating that pregnant rats ingesting various amounts of Red No. 2 had experienced a higher incidence of fetal deaths than the control group, although they found no birth defects.³³

Accordingly, on September 11, 1971, the FDA published a notice in the Federal Register announcing that it contemplated regulatory action. Citing its preliminary studies, the FDA warned that use of the dye might have to be restricted under its authority to "allocate the aggregate allowable safe tolerance of a color additive among users". Cosmetic and drug manufacturers were extremely concerned because under these rules they would have to compete for their share of Red No. 2 against the far larger use of the color by soda bottlers. FDA also proposed limitations

³²Levenstein, 162.

³³T.F.X. Collins and J. McLaughlin, "Teratology Studies on Food Colourings, Part I. Embryotoxicity of Amaranth (FD & C Red No. 2) in Rats," Food and Cosmetic Toxicology, 10, 619-624. The two scientists also did experiments on the metabolites of amaranth, which they also submitted. "Teratology Studies on Food Colourings, Part II. Embryotoxicity of R Salt and Metabolites of Amaranth (FD & C Red No. 2) in Rats," Food and Cosmetic Toxicology, 11, pp. 355-365.

of 30 parts per million in foods and drugs and 1,000 ppm in lipstick, thus reducing usage by 30%.³⁴

On November 12, 1971, FDA received a petition from Loren Anderson and Dr. Sidney Wolfe, a senior staff fellow at the National Institute of Health. Based on the Russian studies, the petition demanded termination of the provisional listing for the color additive, protesting that "the American people will not suffer from not having artificial red coloring." Wolfe would shortly leave NIH to take over Ralph Nader's Health Research Group, which had positioned itself as the FDA "watchdog."³⁵

The results of a November 18, 1971 meeting of FDA experts in toxicology, genetics, and reproductive physiology proved particularly interesting and useful to HRG. The experts met to evaluate the data from the Russian studies, the possible corroboration by the chick embryo study, and the incomplete data from FDA's own multi-generational reproductive study. The panelists indicated that it would be "prudent to limit drastically the uses of FD&C Red No. 2 only to indirect or incidental application involving food." That is, limit use of the color to such applications as food packaging where migration to food is minimal, color marking of animal feed additives, and internally only to the limited amounts in drugs and cosmetics. If the FDA later obtained more favorable data, the possibility remained for reconsideration of some other minor internal uses.

Based on their findings, the FDA Bureau of Foods scientists recommended a

³⁴36 Federal Register, September 11, 1971, p. 15044.

³⁵Letter from Loren Anderson and Dr. Sidney Wolfe to Dr. Virgil Wodicka, Bureau of Foods, 11/12/71. Docket No. 75N-0342, vol. 4. Food and Drug Administration.

maximum daily intake of no more than .075 mg/kg of body weight, which equaled 4.5 mg per day of the dye for a 132 pound person. But a single can of cherry soda, for example, contained as much as 62 mg of the Red No. 2. For all practical purposes, this meant banning the dye from food because the permissible intake was too low to permit effective coloring.³⁶

The FDA scientists' report presented a real problem for Edwards and FDA's senior management. They did not accept the scientist's conclusions, but could not ignore them entirely. Aware of the serious economic dislocation that a decision to ban would cause and concerned that the results of some of the experiments remained in dispute, Edwards did not want to act without additional scientific backing. The Commissioner enlisted the help of the Food Protection Committee of the National Academy of Sciences, which enabled him to put off the decision for a number of months as the NAS compiled its report. It also took the conflict out of the battlefield developing within his own agency. As an added benefit, by drawing on NAS expertise and prestige, he would gain added authority for whatever decision the FDA chose to make.

Edwards hoped the problems with color additives had been quietly buried at the National Academy of Science, at least for the time being, but HRG's Wolfe and his legal associate, Anita Johnson, did not intend to let the issue die. On February 10, 1972 they attempted to skirt the whole safety issue on a technicality. In a letter

³⁶"Red Food Coloring. How Safe Is It?" Consumer Reports (February, 1973): 130. The FDA scientists set 7.5 mg per kg. of body weight as the 'no-effect' level. Accepted scientific practice had set human tolerances at one-hundredth of this dose. Thus the scientists calculated .075 mg. per kg. of body weight as the maximum daily intake.

to the FDA they indicated that "the provisional listing of this dye, which has been repeatedly extended for nine years, expired on December 31, 1971; and thus, its continued use is in violation of the Color Additive Amendments of 1960. We hereby request that you act in accordance with the law and the findings of your own scientists and permanently ban the use of this hazardous chemical in all products."³⁷

Reviewing in detail the scientific reports that had been sent to NAS, the letter quoted from the conclusions of the November 18th memorandum of the FDA meeting recommending strict limitations. Using estimates from the FDA's own Office of Product Technology, HRG estimated that "the delay which has resulted from your failure to take action" resulting in the continued consumption of millions of dollars worth of this dangerous product in the form of "gelatin desserts, soft drinks, breakfast cereals, and dozens of other products containing this hazardous chemical."³⁸

The letter was written by a scientist with the technical proficiency to read and comment on scientific papers. Wolfe's objections could not be dismissed as the rantings of a "health nut." A response from FDA had to be couched in the language of science with counter arguments to his analysis of the data. Moreover, Wolfe knew how to pose the most unsettling questions.

Thus he closed the letter with questions about the safety of FD&C No. 40, a color that had been permanently listed in April 1971 and would probably be used by

³⁷Letter from Dr. Sidney Wolfe and Anita Johnson to FDA Commissioner Charles C. Edwards, February 10, 1972. Docket No. 75N-0342, Food and Drug Administration.

³⁸Ibid.

manufacturers if No. 2 were banned. This indicated that HRG had no intentions of letting up the pressure on FDA to demonstrate the safety of all color additives.

Consumer activists, who took the position that adding almost anything to the food supply was indefensible, could not stop until they had done what they could to removal all dangerous chemicals in the food supply.

The letter was released to the press by HRG on the same day as the National Academy of Sciences Ad Hoc Subcommittee on the Evaluation of Red No. 2 convened. The panel had been asked "to review and assess the available toxicological data provided by the FDA; to review toxicological judgments made by FDA with respect to the color; to provide general commentary on FDA's policy of restricting human exposure by allocating permitted usage patterns; and to recommend an Acceptable Daily Intake of the color to be used as a basis for recommending appropriate exposure levels."³⁹

FDA sent over its top official, Bureau of Foods Director Virgil Wodicka, along with ten other FDA officials to make its presentation before the Sub-committee headed by Dr. Julius Coon, chairman of the Pharmacology Department of Thomas Jefferson Medical College in Philadelphia. A three-man intra-industry task force, under the auspices of the Cosmetic, Toiletry & Fragrance Association also pressed its case. General Foods' John Kirschmann, Eli Lilly's Emmett Pierce, and Revlon's

³⁹National Academy of Sciences, National Research Council, Committee on Food Protection, Food and Nutrition Board, Ad Hoc Subcommittee on the Evaluation of Red No. 2, Report, June 1972, p. 1. [hereafter known as "NAS Report"] Docket No. 76C-0033, Exhibit No. 11. Food and Drug Administration.

Clyde Burnett represented the industry groups affected by the potential ban.⁴⁰

The Subcommittee heard testimony from Dr. Legator on his mutagenicity studies and from Dr. Verrett on the effect of Red No. 2 on chick embryos. In rebuttal, industry representatives presented preliminary results from experiments which showed no untoward effects from the dye. In its June 1972 report, the Ad Hoc Subcommittee pronounced itself "sympathetic with the policy of [FDA] to err on the side of safety" with its proposal to limit usage of the color. However, the committee expressed reservation with the research techniques of both Legator and Verrett, neither of which had been used on a large variety of substances. In Legator's case, results had not been correlated with other commonly used tests for mutagenicity. With Verrett's research, the Subcommittee noted that "the chick egg itself is a closed system and that nothing can be introduced into it which would improve the performance," whereas the injection of a wide variety of previously proven safe substances would damage the embryo. Despite this, the committee still had some concerns about reproductive effects caused by the dye.⁴¹

After analyzing all the available data, the Subcommittee concluded that none of the observations "is so conclusive or convincing that it can be extrapolated to health hazard in adults, pregnant women, or children." The Subcommittee considered that there was insufficient reason to reduce the extent of human exposure to Red No.

⁴⁰ NAS Report, 2. The inter-industry committee represented the following organizations: The Grocery Manufacturers Association, the Pharmaceutical Manufacturers Association, the Cosmetic, Toiletries and Fragrance Association, and the Certified Colors Industry Corporation (representing six suppliers of FD&C colors).

⁴¹NAS Report, 6.

2, a coloring agent "that has been in widespread use since the early years of this century without suggestion of harmful effects on human health." Further, in the view of the Subcommittee, the limitations on usage constituted "a premature and unnecessary measure at this time."⁴²

"The Subcommittee appreciates that some of the results reported on Red 2 may cause concern in certain quarters." Therefore, they suggested that a high priority be given to a more complete and definitive study of Red No. 2. F D A officials, who also believed that efforts to remove the dye had been premature and based on ambivalent experimental results used the NAS report to validate their position, to reject the advice of its lower-level scientists, and to sanction the continued use of Red No. 2, albeit at reduced overall levels. On July 4, 1972, FDA published a proposal in the Federal Register that the color be limited to 30 parts per million or roughly one ounce per ton of food. The same hypothetical 132 pound person could now ingest 90 mg/per day, which was 20 times the maximum level that had been proposed by FDA's own scientists. For lipstick, the maximum amount would be 1000 parts per million.⁴³

In the September, 1972 issue of Medical World News, Bureau of Foods Director, Virgil Wodicka, candidly admitted, "We're stuck with Red #2. If we went to the 0.5 milligram limit, we'd wipe out its use." In FDA's view it could not place such stringent limitations on this ubiquitous product without solid scientific evidence.⁴⁴

⁴²NAS Report, 8.

⁴³37 Federal Register, July 4, 1972, p. 13181.

⁴⁴Medical World News, (September, 1972) , p.

The FDA received responses to its proposals from both industry and consumer groups. FDA officials had previously asked the Distilled Spirits Institute to collect data from its members on their use of the color additive. Officials at the Institute replied that all companies agreed that Red No. 2 with its pure red color was indispensable. It pointed out that "an individual would have to drink four-fifths of a gallon of Sloe Gin per day for over two weeks in order to ingest the quantity of dye which might result in a harmful effect." The Institute found it hard to visualize such an abnormal drinking pattern and questioned "why the Food and Drug Administration would ignore advice solicited from such a prestigious organization as the National Academy of Science on the basis of limited and ambiguous data."⁴⁵

The FDA received communications from the National Bakery Suppliers Association, the Grocery Manufacturers of America, the Cosmetic, Toiletry, and Fragrance, Association, Pet Food Institute, and the National Confectioners Association (whose letter was written on stationery with the slogan, "EAT CANDY the ENERGY FOOD."), protesting the threatened ban.

Individual consumers wrote only about a dozen letters (only avid readers of the Federal Register and those directly involved would have known about the proposed change). Consumer groups provided the only counter-balance to the industry response. Writing on behalf of the Center for Science in the Public Interest, Michael F. Jacobson lambasted the Subcommittee's conclusions as "patently absurd

⁴⁵Letter to Hearing Clerk, Department of Health, Education, and Welfare in response to the Federal Register notice of July 4, 1972, from the Distilled Spirits Institute, August 23, 1972. Docket No. 75N-0342, vol. 1. Food and Drug Administration.

and irresponsible." To use the fact that it had been in use for 60 years without any obvious ill effects, Jacobson claimed, was irrelevant in teasing out such subtle, time-delayed effects as malformed babies, miscarriages, cancer, or mutations. Furthermore, Jacobson wanted to know how the FDA would control and limit ingestion of Red No. 2. For example, home food coloring kits contained four little bottles--red, blue, yellow and green--in concentrations of 3%.⁴⁶

The Health Research Group demanded a total ban. HRG questioned why the FDA had chosen to use 1/10 of the 'no observable effect level in animals' in determining the safe level for human consumption instead of the 1/100 level that NAS had recently recommended. It suggested that the only reason for FDA's tolerance of any use of Red #2 was its overly close relationship with industry. "Certainly a properly functioning FDA would not concern itself with maintaining the "market profile" of artificially red products, to be sure that no manufacturer suffers business losses when it switches to another dye or forswears use of artificial colors altogether." In re-analyzing the reports submitted to NAS, the Health Research Group found a number of incidents of fetotoxicity that it claimed had been overlooked or ignored by committee members.⁴⁷

In response to HRG's charges, NAS President Philip Handler wrote Edwards

⁴⁶Letter to Hearing Clerk, Department of Health, Education, and Welfare in response to the Federal Register notice of July 4, 1972, from Michael F. Jacobson, Co-Director of the Center for Science in the Public Interest, August 28, 1972. Docket No. 75N-0342, vol. 1. Food and Drug Administration.

⁴⁷Letter to Hearing Clerk, Department of Health, Education, and Welfare in response to the Federal Register notice of July 4, 1972 from Anita Johnson and Sidney Wolfe of the Health Research Group, September 5, 1972. Docket No. 75N-0342, vol. 1. Food and Drug Administration.

that he found the data a "legitimate source of concern" but he still supported the committee. He suggested to Edwards that research go forth vigorously "so as to reassure any who did not share their own belief that available evidence was quite unpersuasive."⁴⁸

FDA found itself trying to negotiate the outcome of Red No. 2 between increasingly polarized positions. At this point, its relationship with consumer activists was relatively new and untested. FDA had just begun to gauge the strength and the staying power of these groups. Its involvement with industry had been of long duration and had taken on a certain amount of predictability. But times had changed and to continue as it had in the past with industry gave the appearance of selling out and abdicating its responsibility to the American people, and probably opened the agency to at least one congressional hearings, where it would be raked over the coals.

On January 24, 1973 the Health Research Group again filed a formal petition "to prohibit continued certification of FD&C Red No. 2 because it lacks requisite legal status for certification and because there is substantial evidence that it is toxic." Despite the fact that its previous provisional listing had expired on December 31, 1971 and that the FDA had never promulgated safety tolerance levels as it had proposed in its July 4, 1972 Federal Register notice, the FDA had continued to certify over 270,000 pounds of the dye. The petitioners sought immediate repeal and the cessation of certification, citing past experiments and new Russian tests published

⁴⁸Letter from Dr. Philip Handler, National Academy of Sciences to FDA Commissioner Charles C. Edwards, December 6, 1972. Docket No. 75N-0342. Food and Drug Administration.

in 1972.⁴⁹

William F. Randolph, Acting Associate Commissioner for Compliance replied on behalf of FDA, "It is now general FDA policy that every citizen has a right to petition the Food and Drug Administration to take specified action, under the provisions of the Administrative Procedure Act and under general principles of law." The HRG petition would be filed with the Hearing Clerk. As the subject was currently under study, the FDA would publish its decision and respond to HRG's petition when it had resolved the issues.⁵⁰

Petitions to the FDA hardly qualify as the lead story on the evening news. Relatively few people were aware of what was transpiring at the FDA until the February 1973 edition of Consumer Reports magazine informed its several million subscribers that serious questions had been raised about Red No. 2. In an extremely detailed article, Consumers Union scientists evaluated the experimental evidence on which FDA had made its decisions, concluding that the "picture that emerges, unfortunately is far from reassuring." The Consumers Union medical consultants found the reports of early fetal deaths reported in Dr. Collins' FDA study and in the Russian study particularly disturbing. Industry scientists had protested that experiments, such as Dr. Collins, that depended on gavage feeding (in which the dye

⁴⁹Petition by Susan Massocchi and Health Research Group to Commissioner Charles C. Edwards, Food and Drug Administration. "Petition to prohibit continued certification of FD&C Red No. 2 because it lacks requisite legal status for certification and because there is substantial evidence that it is toxic." Filed on January 24, 1973 by Anita Johnson, attorney for petitioners.

⁵⁰Letter from Associate Acting Commissioner for Compliance, William F. Randolph to Anita Johnson, February 22, 1973. Docket No. 75N-0342, vol. 1. Food and Drug Administration.

is administered by a tube directly into the animal's stomach) resulted in much higher levels of fetal mortality. But Consumers Union considered the gavage method more akin to the way humans ingest the dye, since half of Red No. 2 intake came from colored beverages.⁵¹

Consumers Union (CU) strongly urged a ban on ingested Red No. 2 and told its readers that until this occurred "all women of childbearing age, especially those in the first three months of pregnancy, should consider avoiding artificially colored non-cola soft drinks--unless the label clearly indicates that the product contains no Red 2." If FDA did not ban the color, CU urged the agency to consider mandatory labeling: "The use of this product containing the coloring agent Red # 2 may be hazardous to your health and the health of your future offspring. It may affect your future reproductive ability and may result in future fetal deaths." The story with its strong warning was picked up by the New York Times, other newspapers, radio stations, and television.⁵²

Since the cyclamate fiasco, the public had witnessed a continual litany of scare stories about common foods and household products loaded with hidden dangers. During the 1970s, the media warned the public about mercury in tuna, hexachlorophene in soap, monosodium glutamate (MSG) in baby food, the hormone diethylstilbestrol (DES) in animal feed, and nitrites in fried bacon. Even the all-

⁵¹"Red Food Coloring, How Safe Is It?" Consumer Reports, (February, 1973): 131. Consumers Union had commented on the July 4, 1972 Federal Register notice, urging FDA to rescind entirely the Red 2 temporary tolerance which had been set at 1/10 the "no effect" level (1.5 mg).

⁵²"Red Food Coloring, How Safe Is It?", 133.

American backyard hamburger came under suspicion when scientists charged that meats cooked over charcoal flames caused cancer. The standard chemical danger story began with the orthodox disclaimer: most chemicals are beneficial, but.... There was always a 'but'--the latest exception to the rule. Although few substances were banned, at the time the drawn-out announcement process fostered a perception of technology out of control and led many to believe that 'nothing' was safe. To counter this impression, the government issued a popular pamphlet in 1979 entitled, "Everything Does Not Cause Cancer."⁵³

Even those foods that seemed the most natural, that came straight from the farm or the ranch and had always been touted as essential for good health were linked to declining health and a variety of illnesses. As a result, the consumption of whole milk dropped by over half and eggs and butter by one-third. Porterhouse steak and roast beef, those historic symbols of masculine success and contentment, now raised the specter of clogged heart arteries to the health-conscious middle class. In the 1970s beef consumption began a steady decline as consumers turned to poultry and fish in the belief that they were healthier.⁵⁴

By the beginning of the 1970s, attacking the food industries had become a mini-industry. The media eagerly read the reports and newsletters of consumer groups discussing the latest fears and dangers. These researchers could not be dismissed as quacks. "Chinese Restaurant Syndrome," the symptoms some people experienced after eating food made with MSG, had been first recognized by four

⁵³"Red Food Coloring, How Safe Is It?", 140.

⁵⁴Levenstein, 204.

scientists at New York's Albert Einstein College Hospital. Experiments by research scientists at Washington University in St. Louis experiments indicated that MSG might cause birth defects.⁵⁵

But the very nature of television, from which more and more people got their information, made it difficult to present a well-balanced and well-reasoned discussion of the risks involved in a particular product. The media had a difficult time explaining the subtle issues behind the often sensational headlines on the evening news. Widespread scientific illiteracy meant that any attempt to reach a broad audience required that health risk be explained from a fairly elementary perspective and in layman's language. The need to devote air time to defining fundamental concepts, left little time for explaining the assumptions on which risk assessments were based. Important qualifying material might be left out or presented in too condensed a fashion to be easily understood. Finally, TV fed on the sensational story, the crisis, so that small threats easily assumed gigantic proportions.⁵⁶

Numerous psychological studies have shown that the perception of risk is very much a function of how information is presented, for example whether the risk is voluntarily assumed or not. Based on the information they received from TV, newspapers, and magazine, people had the unsettling feeling that living had become far riskier than they had previously imagined and that they had little control over

⁵⁵Levenstein, 177.

⁵⁶Stephen Klaidman, "How Well the Media Report on Health Risk," Daedalus (1990): 123.

events.⁵⁷

In other times, the public had been content to delegate the assessment and response to risk to so-called 'disinterested' scientists. But Americans in an age of doubt and skepticism dismissed the very concept of objectivity embodied in the word 'disinterested.' It fell victim to a public that had become aware of the limitations of scientific wisdom and knowledge.

The basic questions came down to how safe is safe and who decides? For example, the Delaney Clause had been premised in part on the belief that only a few compounds caused cancer, that they would be quickly discovered, and that their removal would have little real effect on the American diet or lifestyle. Instead, explosive growth in the fields of toxicology, teratology (the effects of substances on the fetus), and mutagenicity combined with exquisitely sensitive new instrumentation meant that more and more compounds could be classified as unsafe.

Molecules of these products could now be routinely measured in parts per billion and in some cases, parts per trillion. In an April 30, 1973 editorial entitled, "Policy on Infinitesimals", the New York Times, commented on the findings of minute quantities of the hormone DES in beef products. "Such sensitivity in measuring infinitesimal quantities is a respectable scientific feat, but how meaningful is it as a

⁵⁷Peter M. Sandman in the November 1987 issue of the EPA Journal discussed "outrage" factors that influence the public perception of risk. They included: Voluntariness (coerced risks produce more concern); Control (when prevention is in the individual's hands, the risk though not the hazard seems lower than when they are in the hands of the government); Fairness; Process (does the agency come across as trustworthy, is the public part of the decision process); Familiarity (exotic, high tech risks provoke more outrage); memorability (Love Canal, Three Mile Island); Dread (some illnesses arouse more fear, even if the eventual end is the same, for instance, lung cancer and emphysema).

guide to the public?.... The Delaney amendment is an all or nothing affair, and presumably would have applied if the analytical equipment had found only one thousandth of a trillionth part of DES." To the editorial writers this sounded more like fanaticism than intelligent public policy. They advised Congress to give consideration to what meaning, if any, the law should give to infinitesimal quantities.⁵⁸

The increasingly strident level of discourse and the gulf developing between those who felt no risk should be taken in terms of safety and those willing to assume some level of risk in exchange for certain benefits led the National Academy of Sciences to sponsor a forum entitled, "How Safe is Safe? The Design of Policy on Drugs and Food Additives." Working from the assumption that "effective policy must recognize the interests and aspirations of all relevant constituencies," announcements had been sent to almost 1000 representatives of the legislative, executive, and judicial branches of government, the press, the legal profession, scientists, economists, consumer groups, and the general public. On May 15, 1973, 400 attendees were welcomed by the President of the National Academy of Sciences, Dr. Philip Handler, who told them, "All cost and risk-benefit analyses entail a greater or lesser degree of social, political, or ethical judgment. To the extent that they do, every layman is at least as well qualified as a scientist to participate in the decision making process."⁵⁹

Handler described a possible framework for establishing a safety policy.

⁵⁸New York Times, April 30, 1973, p. 28.

⁵⁹National Academy of Sciences, How Safe is Safe? The Design of Policy on Drugs and Food Additives (Washington, D.C.: National Academy of Sciences, 1974), 4.

Scientists can determine the discernable effects involved in a chemical's use. Deciding which effects constitute a risk and which a benefit is ultimately made by the public, acting either through its representatives or as individuals, but with a high degree of guidance from scientists, physicians, or other trained professionals. But deciding that the agreed upon benefit exceeds its agreed upon risks is a public, not a scientific, decision, which must be made in public forums.⁶⁰

Those appearing on forum panels raised many of the philosophical issues now facing the FDA as it translated the abstract principles of safety, health, or risk into actual policy. Dr. Jacqueline Verrett wondered, "When industry tosses around the term benefit-risk, what do they mean? Do they mean consumer health benefits weighed against consumer health risks? Or consumer economic benefit against consumer health risk? Or some kind of consumer social benefit, such as time saving, against consumer health risk? Or, on the other hand, do they mean industry economic benefit against consumer health risk?"

Sterling Drug's Dr. W. Clarke Wescoe explained the extreme difficulty of producing products in the risk-sensitive climate of the 1970s. "We live in a 'no-fault,' 'no-risk,' 'all-safe' society.... We strive in our preoccupation with those concepts for a circumstance that man has never enjoyed and for a utopian existence most probably beyond his reach." Although food risks had usually been expressed in terms of additives, he mentioned that foods in their natural state also contained harmful substances, such as aflatoxins in peanuts. Should society ban these, too?⁶¹

⁶⁰How Safe Is Safe? 14.

⁶¹How Safe Is Safe? 23.

Peter Hutt outlined the difficulties that FDA faced in safety decision-making. "Just one adverse finding, from whatever test method employed, seems sufficient today to call into public question the safety of virtually any ingredient used in food and drugs." Alluding to the growing sophistication of safety testing methodology, he felt that it was simply not feasible to retest all the components of foods and drugs on the market. Even with new products, it is doubtful that any substance has been, or can be, so thoroughly tested as to preclude further scientific questions. As had others, he mentioned the lack of a public or scientific consensus on the risk or uncertainty acceptable to justify marketing of any substance.⁶²

Hutt had referred to the use of non-voting consumer and industry members on its over-the-counter and biologicals technical advisory committees as an example of FDA's efforts to get a broader presentation of views. However, consumer advocate James S. Turner, questioned FDA's interest in representation from 'the entire public.' "It took us a very long time and a great deal of effort and push to get a consumer and an industry representative on those panels. I think that is an important step forward, and it is a model that I would use as an example." But consumers still had no voice on the prescription panels nor in discussions about food additives. Turner reminded the audience that like industry, the consumer groups had many points of convergence on issues, but it was not monolithic.⁶³

The forum proved a valuable means of exploring the parameters of a complex, multi-faceted problem. Commenting at the end of the session, President Handler

⁶²How Safe is Safe, 124-5.

⁶³How Safe Is Safe?, 45-6.

pondered the difference in thinking between the people he called 'scientists' and others in the audience. Although there was frequent mention of the risk-benefit equation, it was not used the same way by both groups. "The non-scientists who talked about safety seemed to mean absolute safety." They were not willing to balance this with any consideration of possible benefits, whereas the scientists who spoke about risks were quite willing to do so.⁶⁴

How did this philosophical debate relate to the real world problems of the FDA? FDA personnel for the most part were scientists. When it came to deciding the fate of a product such as Red No. 2, they did not accept the consumer view that any experimental data indicating safety problems became prima facie evidence for the immediate removal of the additive. Nor did they accept the view that aesthetic consideration had no place in a risk/benefit decision. FDA officials accepted industry arguments that the public had the right to buy aesthetically pleasing food and that pharmaceutical manufacturers needed color additives to identify drugs or make them more appealing to children. Following this logic, FDA officials had made it clear that they would not remove the color additive unless presented with incontrovertible scientific proof of its danger.

Consumer advocates had shown that they had the interest and the persistence to keep hammering at the FDA and they had increased the pressure by enlisting the aid of Senator Gaylord Nelson (D-Wisc). In January 1973, he introduced a bill to amend the Federal Food, Drug, and Cosmetic Act with the goal of "eliminating the use of unsafe, poorly tested, and unnecessary chemicals in the food supply."

⁶⁴"How Safe Is Safe?" p. 175-6

Senator Nelson testified that each year the FDA approved dozens of new food additives. He projected that "food additive sales will rise from the present \$500 million a year to \$756 million in 1980." Nelson knew that the bill had very little chance of passage or even getting out of committee. But he could schedule hearings on the bill, attract media attention to the problem of food safety, and give consumer advocates a forum to present their arguments against the further adulteration of the American food supply.⁶⁵

The FDA had already taken three years on the issue of Red No. 2 and it did not seem in a hurry to reach a decision. It now turned to a secondary issue. Reports of fetal damage from rats fed by the gavage method had recently surfaced. Had the procedure itself caused the untoward results, since this procedure is extremely stressful to the animals? The FDA placed a notice in the May 14, 1973 Federal Register announcing that it needed additional scientific judgment on Red No. 2 to determine the applicability to humans of results from studies conducted on rats fed FD&C Red No. 2 by gavage.⁶⁶

Although the notice indicated that interested individuals and organizations would have an opportunity to make presentations to an advisory committee, it limited these to "scientific experts competent in the fields relevant to this matter." The notice appeared on May 14th and the meeting was scheduled for May 16th. The F-D-C Reports, usually not overly critical of the FDA, printed this information under the title "Ironical Note," charging that the 'little bureaucrats' in FDA played the notice and its

⁶⁵Congressional Record, January 16, 1973, V. 119, No. 8.

⁶⁶38 Federal Register, May 14, 1973, p. 12642.

contents 'close to their vests' through the close of government business on Friday, May 11. "Either they didn't want the news out until it would be too late for people to appear on May 16, or they regard publication in the Federal Register as a charade or empty gesture."⁶⁷

Not surprisingly, the FDA consultants on the Advisory Committee concluded that the issue of gavage feeding required further study because all the experiments had not followed the same procedures or evaluated the results consistently. The FDA asked those who had performed the previous experiments, as well as scientists at the National Center for Toxicological Research, to conduct new experiments using the same protocol and dye from the same batch. The uniformity would facilitate comparisons of data. A decision on permanently certifying or banning Red No. 2 therefore was delayed for another thirteen months until at least June 6, 1974. Nothing could be decided until the experiments were ended and the scientists made their reports.⁶⁸

In the interim, the FDA turned its attention to the imminent departure of Commissioner Charles C. Edwards and the arrival of his successor, Dr. Alexander M. Schmidt from the University of Illinois, Abraham Lincoln School of Medicine in Chicago. Before moving to his new position as Assistant Secretary for Health at HEW, Edwards allowed himself a few moments reflection on his stewardship. In three and a half years FDA's budget had increased from \$88 million to almost \$180 million. The new commissioner would preside over a staff of almost 6,000. The

⁶⁷F-D-C Reports, May 16, 1973, p. T&G 3.

⁶⁸39 Federal Register, May 15, 1974, p. 17343.

FDA had undergone an almost total reorganization and had been given equal status with other agencies in HEW. "Three years ago our critics said we could never obtain the help of the nation's best scientists. However, today we have more than 300 of the nation's outstanding physicians and other scientists advising the Agency," Edwards related with evident pride. "And equally important, they are working with an Agency staff that is itself steadily improving in competence as well as numbers." Edwards took great pride in the fact that "we have reached a degree of stability after a long period of stress when the FDA was all but overwhelmed by its responsibilities and exhausted by the struggle just to keep up with each day's flood of problems."⁶⁹

Edwards had spent a significant part of his tenure beating back efforts to dismember FDA and subsume its parts into other agencies. In 1972, Senate critics had sponsored a bill to transfer its functions to a new and independent Consumer Safety Agency. Edwards and FDA met its critics head-on by acknowledging past mistakes, but it blamed them on inadequate manpower and resources. "The retail sales of products presently regulated by the FDA totaled \$240 billion in 1970.... Present FDA funding amounts to about four one-hundredths of one percent of this amount. This has to be the cheapest 'insurance policy' around--perhaps too cheap, because good science and good regulations don't always come at bargain prices."⁷⁰

In perhaps the most prescient of his final comments, Edwards reminded those who had a continuing interest in the FDA that "the era of insularity is over for the

⁶⁹Charles C. Edwards. "Meeting New Challenges" Food, Drug, Cosmetic Law Journal, 28 (1973): 4,6.

⁷⁰Edwards, "Meeting New Challenges," 6.

FDA. We are not and we should not be shielded from the scrutiny of the consuming public, the regulated industries, the scientific community , or any other interest that has a right to pass judgment on our performance." With that, he passed the reins to Schmidt.⁷¹

A cardiologist, who received his medical training in Utah, Schmidt had worked with Louis Goodman, co-author with Alfred Gilman, of the standard textbook on pharmacology. No newcomer to Washington, Schmidt has been selected to be a Fellow at the National Institutes of Health before moving on to University of Illinois, where he had honed his administrative skills. At a news conference shortly after his quiet swearing in on July 12, 1973, he indicated his satisfaction with the staff that Edwards had assembled. "Whether it is a conceit of mine, or just simply naivete, I believe that I will be able to influence the agency and have an impact--my own personal impact--even though there are people already on the job." He also acknowledged the value of having Edwards, who understood the pressures under which the FDA Commissioner operated, as his superior at the Department of Health, Education, and Welfare.⁷²

In Schmidt's opinion, Edwards had been brought in to bring the agency "up to speed" for the 1970s. He saw himself as providing continuity and stability to an organization that had recently undergone tremendous change and restructuring. "It was clear to me that my job, since I agreed with the directions that they were going

⁷¹Edwards, "Meeting New Challenges," 12.

⁷²Dr. Alexander M. Schmidt, FDA Commissioner, Interviewed by James Harvey Young and Robert G. Porter, August 9, 1985, transcript, p. 27, Oral History Program, Food and Drug Administration.

was to then take the FDA ship across the sea." Schmidt gave Edwards due credit for the advisory committee system and agreed with the policy of bringing the best scientific expertise to bear on problems facing the agency.⁷³

As Schmidt began to oversee the agency, Red No. 2 remained in another level of bureaucratic limbo as the scientists re-tested their rats and correlated their results in response to the questions about gavage feeding. Not only did the new experiments not provide the definitive data linking the dye to embryotoxicity, but the FDA was unable to reproduce the results of its original gavage experiment that had been most incriminating. At its June 6, 1974 meeting the Ad Hoc Advisory Committee presented its conclusion in one very long sentence, as if they wanted to blurt it out and get away before anyone could question them.

"Since FD&C Red No. 2 has no caloric value, but does provide cosmetic and aesthetic appeal which society may consider sufficient reason for its use, in spite of possible commercial overuse, the Advisory Group feels such use, if deemed appropriate by a significant portion of the exposed population, should be permitted as long as the color is safe in humans in usual doses employed, is shown not to produce deleterious affects in animals dosed comparable, and the metabolic fate is elucidated."⁷⁴

Based on the Committee report, the FDA felt that the issue of Red No. 2 permanent status had been sufficiently analyzed. From FDA's viewpoint, it had presented the available evidence to three outside scientific committees, none of which had found compelling reasons to recommend removal. Therefore, it had fulfilled its obligations to protect the public and could approve permanent listing for Red No. 2, which it had

⁷³Ibid. 24, 73.

⁷⁴Food and Drug Administration, Ad Hoc Advisory Group on FD&C Red No. 2, Report, June 6, 1974. Docket No. 76C--0033, exhibits P1-35, #15. Food and Drug Administration.

wanted to do all along.

But HRG had no intention of letting that happen. For four years, Wolfe and Johnson had never let up the pressure. They had attacked on all fronts using FDA's own administrative procedures and the federal courts. Their access to the media enabled them to keep the issue before the public and generate unfavorable publicity about FDA's handling of the issue, often citing the reports of FDA's own scientists.

Unable to effect a ban on Red No. 2 on the basis of its fetotoxicity, the Health Research Group switched gears and began to consider its cancer-causing potential. On October 31, 1974, HRG sent an eight-page letter to Associate Commissioner Lloyd Tepper documenting its allegations. Beginning with the FDA's own unpublished studies from the 1950s which showed an increase in tumors for mice and rats fed Red No. 2, HRG charged that the implications of these experiments had been ignored. "We now know, based on the above data, that the FDA has had in its possession for more than 15 years, the results of 3 studies in 2 species supporting the carcinogenicity of Red 2." According to HRG, this information combined with data from the Russian studies should have led to an immediate ban in 1970 on the grounds that it violated the Delaney Clause. "With strong fears of cancer, added to fetotoxicity, we believe that the risk of this chemical cannot be borne by the public for the sake of cosmeticizing synthetic foods, or for any reason." It is not clear from the letter how HRG obtained these unpublished FDA studies, but possibly they found them through an FOI request or from a source within the agency.⁷⁵

The ability of HRG to challenge FDA with its own data on strictly scientific grounds gave its accusations substantial clout. Associate Commissioner Dr. Lloyd Tepper sent the HRG letter to his Acting Director of the Bureau of Foods, Howard R. Roberts, who in turn asked the National Center for Toxicological Research (NCTR), which had an expertise in statistical analysis, to review the comments of Johnson and

⁷⁵Letter from Anita Johnson and Sidney Wolfe, Health Research Group, to FDA Associate Commissioner Lloyd Tepper, October 31, 1974. Docket No. 75N-0342, vol. 4. Food and Drug Administration.

Wolfe. While Dr. David W. Gaylor of NCTR found that two of the studies did not have statistically significant increases and questioned the results of the Russian studies, he concluded that "combining the results from these four studies presents very strong statistical evidence of the carcinogenicity of Red #2 in rodents.... Based on purely statistical calculations, there appears to be little doubt that Red #2 produces tumors in rodents."⁷⁶

This was a certainly a significant victory for Wolfe and Johnson in their four year battle to remove the color additive, but it was not the kind of victory that would make headlines on the news, outrage or frighten the public, and produce an avalanche of cards and letters that could be used as leverage to force FDA's hand. An allergist at the Kaiser-Permanente hospital in San Francisco, California became the unexpected source of invaluable publicity that re-energized the crusade to remove artificial colors from the American food supply.

⁷⁶Letter from Acting Director, Bureau of Foods, Dr. H.R. Roberts to Dr. Lloyd Tepper, Associate Commissioner of the FDA, November 7 1974. Docket No. 75N-0342, Vol. 4, #3. Food and Drug Administration.

CHAPTER 6

"DR. FEINGOLD'S DIET"

"People, natural foods, air, and water are made of chemicals.
All of these are safe.
Food additives are chemicals.
Therefore, food additives are safe."
Michael Jacobson's parody of the reductionist philosophy of food industry defenders.¹

"Erin Sharp is nine years old, pretty young to be reading food labels," announced CBS News Correspondence Sylvia Chase. "But Erin is not a junior health freak, she's hyperactive and she's on a diet that's supposed to keep her calmed down. That means any food that has artificial flavors or artificial colors has to go back on the shelf." Erin had taken part in a controversial experimental diet devised by Dr. Ben F. Feingold, Emeritus Chief of the Department of Allergy at the Kaiser-Permanente Medical Center in San Francisco, California. He claimed dramatic improvement in the behavior in hyperactive children without the use of powerful drugs that often caused dangerous and debilitating side effects.²

Appearing on national and local news shows around the country, Dr. Feingold brought videotapes of children fidgeting, unable to concentrate, bouncing off the walls. He then showed these same children a few weeks later quietly playing and

¹Michael Jacobson, Eater's Digest: The Consumer's Factbook of Food Additives, (New York: Doubleday, 1972), 15-16.

²Dr. Ben Feingold, Interview by Sylvia Chase, "Magazine," CBS Television Network News Show broadcast December 10, 1975. Although this show, for which a transcript is available, aired in late 1975, Feingold had appeared on numerous television shows and news of his diet had been reported in different media after he presented his finding to the American Medical Association meeting in June 1973. The publication of the hardcover version of the book in 1974 and the release of the paperback in 1975 added to his visibility.

reading after they had followed his restrictive diet. To drive his point home, Feingold then showed these same kids reverting back to their original behavior a few hours after being given an artificially flavored and colored soft drink. What parent would not begin to question his or her own child's eating habits after watching this demonstration?

Many of the claims that had been made against food additives had been based on the results of experiments with laboratory animals which had been given very high doses of the additives over their lifespan. Even those most intransigent in their opposition to color additives admitted that many of them were weak carcinogens, whose effects might not be discernable for years or even decades to a group of people whose number could only be statistically inferred.

A dramatic effect caused by food or color additives had been lacking until Dr. Feingold began to publicize his findings in the book, Why Your Child Is Hyperactive. He claimed that 50% of children diagnosed with Hyperkinesis-Learning Disability (H-LD) dramatically improved when put on a diet that eliminated all artificial flavors and colors. To a nation that had sat transfixed as the Watergate story unfolded, this was the "smoking gun" that proved that artificial ingredients added to the American food supply did indeed affect health. It gave credibility to the claims of food critics. Perhaps, those Hostess Twinkies and garish pink "Sno-ball" cakes were poisoning us, after all. Maybe danger did lurk in the multi-colored sea of soda Americans consumed.³ Hyperactive children, often diagnosed as dyslexic or with other

³Ben F. Feingold, M.D., Why Your Child Is Hyperactive (New York: Random House, 1974), 14.

mental or physical impairments, had sometimes been put on drugs, such as, amphetamines or Ritalin by desperate parents and teachers unable to find other ways to deal with their self-destructive behavior. Erin's parents' experiences reflected those of many parents whose children had been diagnosed as H-LD--complaints from teachers of inattention, disruptive behavior in class, visits to a psychiatrist, and powerful drugs like Ritalin that calmed her down for a few hours but made her anemic. Then they tried the Feingold diet with its dramatic improvement in Erin's behavior.

Feingold saw a close correlation between what he claimed to be a geometric increase in the prevalence of hyperkinesis and the use of food additives. "It is interesting to note that a graph projected for the estimated incidence of H-LD over the past 10 years parallels the S&P [Standard & Poor's] curves for the dollar value for soft drinks and synthetic flavors over the same period." Echoing the Health Research Group's message, Feingold charged that not a single food additives had ever been subjected to the careful pharmacological investigation required of other compounds.⁴

Parents, pouring over his book, worried whether they were doing their best to protect their children. But adhering to the Feingold diet required a radical change in the way Americans shopped, cooked, and ate. Red No. 2 was "everywhere--smeared

⁴Congress, Senate, Subcommittee on Health of the Committee on Labor and Public Welfare and the Subcommittee on Administrative Practices and Procedures of the Committee on the Judiciary, Examination of the Causes of Hyperactive Children and the Methods Used for Treating these Young Children: Joint Hearings before the Subcommittee on Health of the Committee on Labor and Public Welfare and the Subcommittee on Administrative Practices and Procedures of the Committee on the Judiciary, 94th Cong, 1st Sess., September 11, 1975, 6. [Hereafter cited as "Hearings. Hyperactive Children"]

on lips and floating in medicine," Feingold warned parents in his book. "It is in almost every corner of the supermart, down every aisle, from the 'deli' section to home remedies." Readers learned to their horror that even the vitamin drops they gave their new-born babies had artificial colors in them.⁵

Furthermore, inadequate or non-existent food labeling made it impossible to find out what foods contained artificial colors and flavors. Desperate parents pleaded for more complete and extensive labeling of prepared food. What was the use of knowing that your children could not tolerate certain additives, when you could not tell where they would be exposed to them? For years, nutritionists and public advocates had demanded that food labels list all ingredients, only to be outgunned and outmaneuvered by the Grocery Manufacturers of America, the American Dairy Association and other industry lobbying groups. In fact, some standardized foods, such as ice cream, butter, and mayonnaise did not have to list ingredients at all. Publicity generated by Feingold's book became part of the effort that resulted in the first meaningful, though minimal, ingredient listing on commercial food products.

Feingold, who presented his preliminary findings on dietary management at the American Medical Association's annual meeting in June 1973, received considerable national media coverage. Between 100 and 200 letters a week began arriving at his office at Kaiser-Permanente. A parent from Nokomis, Florida described her son who frequently "drew ghosts, dreamed about them and, in fact, at times ghosts would be uppermost in his whole realm for days at a time." After beginning the Feingold diet in February, 1974, and being ghost-free for two months, he was

⁵Feingold, 18.

accidently given Red Hawaiian Punch resulting in 2 1/2 days of ghost drawings and dreams. His next episode occurred after eating some candy. "God bless you in your great work--Please push on," she closed. "Please let us parents know somehow what has been learned."⁶

Feingold admitted that he could not identify the colors or flavors responsible for the children's hyperactivity. When CBS Correspondent Sylvia Chase asked about the mechanism of action that reduced the child's symptoms, Feingold responded, "We haven't the slightest notion." He happened on the diet when he treated a women for hives by eliminating some foods from her diet and noticed that it seemed to cure her anxiety as well. He said he did not wait for the scientific community to verify why or even if his theory is correct. "Instead, Dr. Feingold has gone out promoting his diet all over the country, straight to the grass roots," reported Chase. Ordinary people organized hundreds of local Feingold Associations.⁷

The Feingold hypothesis appeared so convincing because so little was definitely known about the causes of hyperkinesis. Authorities did not know if its causes were socially constructed, physiological, or biochemical; whether it was genetic or due to environmental factors or some combination of some or all of these factors. To further complicate the diagnosis, many factors affected behavior, from changes in barometric pressure to interactions within the family. Part of the diet's appeal was that it reinforced the public's intuitive feelings that Americans consumed

⁶Hearings. Hyperactive Children, 46.

⁷Dr. Ben Feingold. Interview by Sylvia Chase, "Magazine," CBS Television Network News Show broadcast, December 10, 1975

too much over-processed, unnatural foods, containing too many additives. The message of the natural food movement, Sidney Wolfe, and the hippies had finally hit home.

For balance, CBS News included Dr. Morris Lipton of the Nutrition Foundation, the research arm of the food industry, who charged that the diet was untested and that Feingold appealed to desperate parents willing to try anything. "He's very charismatic and very convinced of the effectiveness of his treatment. And I'm impressed by the fact that it isn't just the kid who goes on the diet; it's the whole family that goes on the diet."

After the commercial, Chase introduced FDA Commissioner Alexander Schmidt. "The FDA does not make scientific decisions casually," Schmidt told Chase. "I respect Dr. Feingold That is why we have said, 'Please submit a scientific protocol.'" The FDA had spent the better part of the last decade fighting against medical judgments based on anecdotal evidence. It had staked its claim on scientifically-based, adequately supervised, double-blind clinic trials to demonstrate efficacy. To accept Feingold's assertions based on letters from grateful parents, who fervently wanted to believe that their child had gotten better on an additive-free diet, undermined the foundation that FDA had so arduously constructed for its decisions beginning with the 1962 Kefauver-Harris Amendments.⁸

Feingold's promotion of his book and the proselytizing members of the Feingold Associations kept the issue of food additives before the public. The Health Research Group's October 1974 petition assured that the FDA had to respond to its

⁸Ibid.

questions about carcinogenicity before it could even consider permanent status for the Red No. 2, but the FDA still had hopes of finessing the situation.

Those were dashed as news of the December 19, 1974 New York Times front page story spread through FDA offices. The first paragraph of the story read, "The Food and Drug Administration plans to approve the permanent use of an artificial food coloring although some of the agency's own scientists say there are questions about whether it may cause cancer and fetal death." Sidney Wolfe could not have written a better lead paragraph with which to skewer the FDA. The article, which covered a full page inside the paper, left nothing out--the endless testing, the equivocal results placed before committee after committee, the intended restrictions never carried out--weaving together all the questions, suspicions, and adverse views on Red No. 2. The front page carried a picture of Dr. Jacqueline Verrett with a caption that read "She says evidence against Red No. 2 is strong."⁹

The article contained FDA assurances that it had evaluated new fetal toxicity tests and seen no harmful effects on reproductivity. As a result, Red No. 2 had been given a 'clean bill of health.' However, Dr. Thomas Collins, who had conducted the

⁹"FDA Approves a Challenged Food Dye," The New York Times, December 19, 1974, p. 1. The internal headline that ran across the full page read, "FDA Approves Use of a Food Dye Despite Questions About Link to Cancer." Other sub-stories within the text were titles, "U.S. Banned 11 Coal-Tar-Derivative Dyes Since 1919" and "Consumers Can't Tell Which Dyes Are Used." The coal tar story mentioned that Violet No. 1 had been banned in April 1973 after two Japanese studies showed that it caused cancer in female rats. (FDA had tested the dye but only in male rats.) Red No. 4 that had been demonstrated to be a weak carcinogen was limited to maraschino cherries and Citrus Red No. 2 could be used only to color oranges. Yellow No. 5, Tartrazine had been linked to allergic reactions in people sensitive to aspirin. The consumer story warned that manufacturers did not have to indicate which color was used in the product.

original FDA experiments in 1971 showing reproductive effects, and who had taken part in the new tests, indicated a certain amount of skepticism when interviewed. The new tests answered most of his questions about fetal toxicity, he said, but he still had some doubts. Although FDA had not authorized him to do so, he wanted to continue testing the dye to be "super-safe." And as if this were not bad enough, he added as an after thought, "Red No. 2 has not been proven safe in terms of carcinogenicity."

The reporter, Lucinda Franks, also interviewed Dr. David Gaylor, the chief statistician at the National Center for Toxicological Research, who had analyzed FDA's own experiments from the 1950s after the Health Research Group had made allegations that FDA knew years ago that Red No. 2 caused cancer in animals. Gaylor admitted that the tests raised doubts about the safety of the dye. "At the very least there should be new and immediate testing." Although he did not concur that the dye was a strong carcinogen, The Times story had him agreeing with the Nader group, that the test data had "cast the dye into suspicion."

Of course, the reporter talked to Dr. Jacqueline Verrett who maintained that there had been ample evidence to ban the dye. "But industry thinks a plate of food has to look like a Picasso painting--even if in the end what looks so colorful and good ends up killing you."

Consumer advocates charged that the food industry opposition kept the FDA from acting for the last three years. Dr. Virgil Wodicka, until recently head of the Bureau of Foods and now an industry consultant, did not quibble with the idea that the food industry strongly opposed the ban. Asked if the agency came under pressure, he answered, "Hell, yes. They [industry] were vocally unhappy about it."

But, of course, he then added that neither this nor his involvement with the issue influenced FDA's decisions. Wodicka argued that the agency "never felt Red No. 2 was that bad." In Wodicka's view industry toxicologists had raised some valid objections to the tests, they had been redone, and the new tests laid the controversy to rest. Wodicka's comments lent support to charges by Michael Jacobson and others of the overly cozy relationship between FDA and its regulated industry, as yet another high-ranking FDA official had used the revolving door--out of business, into the FDA, and out into the business world again. Wodicka's comments left the uncomfortable impression that the possibility of his eventual return to the business world influenced his decisions with regard to Red No. 2.

The article also included an interview with James Turner, long active in the consumer movement, who explained to the public how industry pressured FDA. An industry lobbyist calls up the FDA, sometimes daily, asking "What problems do you have? What can we do to assist? Do you know that this could destroy us economically? Would you like some eminent doctors to call you and testify that this dye is safe?"¹⁰

On the same day as the New York Times article, the National Foundation--March of Dimes Vice President for Medical Services, Dr. Arthur J. Salisbury issued a press release urging pregnant women not to eat or drink foods containing Red No. 2. But he lamented because of the inadequacy of current labeling, "until its use as a food coloring is banned, that is almost impossible." He demanded more research

¹⁰New York Times, December 19, 1974, p. 51.

into the safety of any compound added to food.¹¹

Other stories followed. Jean Carper, who had co-authored books with Jacqueline Verrett, wrote a story called the "Case Against the Red 2 Dye" in her syndicated newspaper column. She compared the FDA's indecision about the dye to the Perils of Pauline. "As we all lie bound to the tracks, captives of officialdom's dalliance with our safety, we can only wonder how and when the FDA plans to rescue us." She reported that Red No. 2 'by reliable tests,' caused birth defects, abortions, and possibly cancer in animals. The same results might occur in people. And why did we need this color? According to Carper, because replacement dyes, such as Red No. 40, do not combine well with other colors to produce a perfectly clear bottle of grape soda. Only a few special interests were keeping it on the market with the FDA's "lackadaisical concurrence."¹²

By the time the consultants who had given Red No. 2 qualified approval on the basis of fetotoxicity in June 1974 finally got around to submitting a written report, on December 20, 1974, the changed climate of opinion made it impossible for the FDA to slip a notice quietly into the Federal Register and give the color permanent status. The committee report has "opened it all up again and we'll have to take a fresh look," backpedaled Richard Ronk, head of the FDA's color additives department. He raised the possibility of limitations on use of the dye or even an outright ban. The news media, which got hold of this information at the beginning of

¹¹New York Times, December 20, 1974, p. 24.

¹²Jean Carper, "One Woman's Voice: Case Against the Red 2 Dye," newspaper column. Docket No. 75N-0342, vol. 3. Food and Drug Administration.

February, not only passed it on to the public but added its own fillip--that the committee had not been able to consider whether the dye was carcinogenic because the FDA had not asked it to evaluate this factor. However, Ronk did say that the possibility of cancer would be taken into consideration when determining the status of the color additive.

Ironically, industry, which consumer advocates and much of the public assumed had FDA's ear, had not benefitted from FDA flip-flopping on the status of the dye. General Foods had voluntarily banned it from its products in 1972, but had resumed using it in the fall of 1974. General Mills, which had also stopped using it in 1972, awaited a final resolution and Nabisco had decided to ban it permanently. Each change meant a costly reformulation of its products.¹³

The pressure continued to build. For two years Dr. Feingold had been writing to the FDA describing the effects of his diet and urging it to encourage the marketing of more foods free of artificial flavors and colors. He told Lucinda Franks in a February 9, 1975 New York Times story headlined, "F.D.A., in Shift, Tests Pediatrician's Diet for Hyperactive Children," that until recently FDA had been "like a brick wall, giving me no support, only discouragement, as though they were representatives of the food industry, rather than a government agency."

However, during the past year, the FDA began to shift its position, partly in response to a preliminary study by Dr. Keith Connors of Boston, funded by the National Institute of Education. The study showed dramatic changes in 8 of 10 children placed on the diet. FDA quietly persuaded the Food Research Institute of

¹³New York Times, February 2, 1975, p. 39.

the University of Wisconsin, a recipient of both government and food industry funding, to set up a one-year highly controlled study to scientifically test Feingold's theories. If the results confirmed his assertions, then more testing would be necessary to determine if only certain colors and flavors caused hyperactivity. Publicly, the FDA refused to warn parents of any possible link between artificial dyes and hyperkinesis without the statistical evidence to support this conclusion.¹⁴

Every news story about Feingold reinforced the idea of hidden dangers in the American diet and gave another tiny stab of recognition that "if we are what we eat," we were indeed in trouble. In the 1970s, many researchers and epidemiologists had begun to conclude that the vast majority of cancers were caused by diet or environmental factors. But the FDA, the public's protector, not only would not ban color additives, but would not require complete labeling so that those who wanted to take matters into their own hands could avoid harmful substances. Ruth Oliver's letter was fairly typical of the hundreds received by the FDA. Hand-written on note paper, she repeated facts from Jean Carper's article and ended, "This is one more step for us its citizens losing faith and confidence in the integrity of our government." She received the standard reply letter to the effect that the FDA would not allow anything in the food supply that was dangerous and that they continued to study the color additives. It is doubtful that she found this reassuring.¹⁵

Congress also started to hear from a worried public. In April, 1975,

¹⁴New York Times, February 9, 1975, p. 41.

¹⁵Letter from Ruth Oliver to Sherwin Gardner, December 30, 1974. Docket No. 75N-0342, vol. 3. Food and Drug Administration.

Representative Pat Schroeder of Colorado received a letter from Josh Been, which she forwarded to the FDA. Mr. Been wrote that his wife was pregnant and he was worried about "this poison" that the FDA allowed in foods. He hoped that Representative Schroeder would investigate because "The FDA needs to be straightened out and re-educated so that they can do the proper job our tax money pays them to do"¹⁶

Schroeder received a four page reply in which FDA presented its case based on the scientific evidence then available. The FDA thought the carcinogenicity question had been satisfactorily resolved, "however, we recognize that there are members of the scientific community who question the results of these same studies." Therefore, FDA had decided to submit the data to its newly established Toxicology Advisory committee for further evaluation.

FDA's handling of Red No. 2 was certainly a far cry from the manner in which it dealt with cyclamates. In 1969, it made its decision using its own in-house scientists and selected consultants and faced little or no opposition from the public or industry. With Red No. 2, however, the FDA had spent the last three years reacting to charges from the consumer community, defending its data, and re-testing its hypotheses and actual experiments on Red No. 2. Although opponents had not forced the dye off the market, they had certainly kept it from being permanently listed. This in itself constituted a significant victory, because once it received its permanent

¹⁶Letter from Josh Been to Representative Patricia Schroeder, March 24, 1975. Letter from Representative Patricia Schroeder to Acting Commissioner Sherwin Gardner, April 8, 1975. Docket No. 75N-0342, vol. 3. Food and Drug Administration.

status, the legal barriers to removal were considerable and success far less likely.¹⁷

Congress did not have to depend solely on the Food and Drug Administration or its disgruntled employees for information about the agency. It could investigate issues involving the executive branch through the General Accounting Office (GAO). In a letter dated January 30, 1975, Senator Gaylord Nelson requested that the GAO review the Food and Drug Administration's methods for determining the safety of three additives--Red No. 2, saccharin, and aspartame. The GAO asked FDA for all the data that it had on the dye, including the reports of all completed, as well as ongoing, experiments. In the course of gathering pertinent data, its investigators questioned agency personnel about an FDA two-year chronic feeding study.¹⁸

Observant readers may have taken note of a passing reference to problems with this experiment in the December 19, 1974 New York Times story. Scientists, requesting anonymity, alleged that the experiment, which had been designed to be the definitive cancer study on the dye, was "in a mess." Not only had the study been left virtually unmonitored by scientists for a year, but they contended some of the lab animals appear to have been placed in the wrong cages, many animals died without being examined, and that only 50 out of the original 500 rats survived until the completion of the test. These factors made the experiment results highly

¹⁷Letter from Robert C. Wetherell, Jr. Director, Office of Legislative Services to Representative Patricia Schroeder, April 23, 1975. Docket No. 75N-0342, vol. 3. Food and Drug Administration.

¹⁸Report of the Comptroller General of the United States to the Honorable Gaylord Nelson, United States Senate, Need to Establish the Safety of Color Additive FD&C Red. No. 2, October 20, 1974, 1.

questionable.¹⁹ An information memorandum from FDA Acting Director for the Bureau of Foods Howard Roberts to the Associate Commissioners for Compliance and Science conceded that the experiment had been flawed to the point that it "place[d] severe limitations on the usefulness of the data derived from this study." FDA's effort to maintain Red No. 2 seemed more and more doomed.²⁰

The cooler weather and golden reddish leaves signaled the return of fall and the Senators and Representatives, who had escaped the capital's heat and humidity during the summer recess, to Washington. Re-energized, they prepared to do battle with the federal government bureaucracy. Commissioner Schmidt and his predecessors had spent enough time under the klieg lights in Congressional committee rooms to know that in any controversy involving the FDA, at least one representative or senator would be persuaded, sooner or later, that important facts had not been adequately considered, or appropriate weight had not give been given to a particular viewpoint.

Senator J. Glenn Beall, Jr. of Maryland, a member of the Senate Health Subcommittee, decided to champion the cause of Dr. Feingold and question why the FDA had not acted on his recommendations. Dr. Feingold had previously written to him about a bill Beall sponsored to improve the teaching of reading. Feingold pointed out that a child's reading problem might be related to hyperactivity. Beall became a convert, writing to the FDA, the National Institute of Mental Health, and the

¹⁹New York Times, 12/19/74, p. 1

²⁰Memorandum from Howard R. Roberts, Acting Director, Bureau of Foods to Associate Commissioners for Compliance and Sciences, July 14, 1974. Docket No. 75N-0342, vol. 3. Food and Drug Administration.

Washington Post and urging Chairman Kennedy to hold hearings to examine the continued use of artificial food additives.²¹

With the zeal of a convert, Beall saw danger in all additives. Personally, he was prepared to banish them all, but if they had "a true function in the distribution of our food supply, preserving shelf life and all," he might relent. But, he concluded, colors and flavors had no nutritive value and therefore on a risk versus benefit basis they should be removed.²²

Senator Edward M. Kennedy scheduled hearings for the beginning of September. During his testimony, Commissioner Schmidt took pains to apologize to Senator Beall for leaving the impression that he and the FDA had been disinterested in the subject. He told Beall that FDA had a great interest in Dr. Connors' study of the Feingold diet, agreeing that it needed to be followed by larger studies. Executive branch officials testifying on the Hill engaged in a carefully choreographed dance with legislators. Since they were dependent on Congress for their budgets, they had to maintain a certain level of deference, at the same time protecting their independence. FDA would not be pressured into approving Feingold's theories, but would cooperate.²³

In order to get more definitive answers on the effectiveness of the Feingold diet, the FDA had joined with other government agencies to form an inter-agency

²¹Letter from Senator J. Glenn Beall, Jr. to Senator Edward M. Kennedy, October 30, 1973. Hearings. *Hyperactive Children*, 58, 59. The article by Senator J. Glenn Beall, Jr. appeared in the Daily Record, November 7, 1973.

²²Hearings. *Hyperactive Children*, 51.

²³Hearings. *Hyperactive Children*, 75.

committee to develop a scientific protocol to answer the questions posed by the Connors study. Schmidt portrayed the interagency group as a mechanism by which all the resources of the government could be brought to bear on the problem. Kennedy and Feingold saw the interagency group as another layer of bureaucracy, committee meetings, and delay.

Feingold supporters hoped that further experiments would not only vindicate their faith in the diet, but would force the FDA to acknowledge the detrimental effect of color additives and thus remove them from the market. Acknowledging consumer concerns about food additives, Schmidt informed the Committee that the FDA had reversed itself and might now consider the possibility of approving a label-symbol to advise consumers that products carrying the logo contained no artificial flavors or colors, as long as the company did not claim any health benefits based on this fact.

The hearings ended in relative victory for Dr. Feingold--he had the promise of a large scale government-sponsored study of his theories, FDA gave consideration to product labeling, and he had had a congressional forum in which to espouse his ideas. But Feingold and the opponents of Red No. 2 could expect little more from Congress at this point. While they awaited confirmation of Dr. Connors' study, attention turned to the FDA.

Bad news comes in threes. The first of these ill winds blew in October 15th. "The news tonight is that the United States is number one in cancer," began Dan Rather introducing CBS Reports' TV special, 'The American Way of Cancer.' Rather informed his audience that the Food and Drug Administration enforced a Federal law, the Delaney Clause, which prohibited the addition of any known cancer-causing

substance to food. But, he intoned ominously, there are loopholes in the enforcement of the law that allowed cancer causing chemicals to slip through. In the course of the hour, Rather investigated the link between pesticide residue, diethylstilbestrol (DES), sodium nitrite, Red No. 2, and cancer.

The segment on Red No. 2 began with an interview with the ever present Dr. Jacqueline Verrett. To his rehearsed surprise, she informed him that red dye is used not only in foods that looked red, but in chocolate cake. The labeling requirements do not force the manufacturer to reveal a specific dye, she informed the audience. She discussed the 1950 FDA tests and the Russian experiments. When Rather asked her why the United States had not banned the dye, she answered "I think the answer is probably more economics and politics than science." And to confirm in the public's mind not only the FDA's disregard for the public's health and consumer issues, but also its ineptness, she mentioned the botched FDA experiments.²⁴

The second inauspicious sign appeared on October 24, 1975 with the release of the GAO report on Red No. 2 requested by Senator Nelson. The Report blamed the FDA for permitting the continued use of Red No. 2 in food, drugs, and cosmetics for 15 years without making a final determination of its safety. FDA's action, the report asserted, unnecessarily put the public health at risk.

The GAO questioned the interpretation by FDA's Ad Hoc Advisory Group of the study to evaluate the gavage procedures and their effect on embryotoxicity. Thus challenged, the FDA Bureau of Food scientists backtracked and agreed to re-evaluate

²⁴"The American Way of Cancer," CBS Reports with Dan Rather, October 15, 1975, CBS Television Network files.

these studies, eventually agreeing with GAO contentions that the Advisory Group's conclusions were insupportable. The question would now have to be referred to the Toxicology Advisory Committee before any other action could be taken. In unequivocal terms, the GAO told the FDA to minimize any further risks to the public by acting "promptly to establish the safety of Red No. 2 or take appropriate regulatory action."²⁵

The report became available to the press late Friday, October 24th, and was widely covered on national TV news and in the Saturday newspapers. The press coverage had a decidedly anti-Red No. 2 slant. FDA top brass conceded privately that the report made the agency vulnerable, although publicly they took the position that the color additive had not been proven unsafe or harmful. "The General Accounting Office's report on Red No. 2 probably has a stronger base in political science than in biological science," the F-D-C Reports editorialized, but it had no doubt that it would increase consumer and congressional pressure on FDA to ban the color.²⁶

The Cosmetic, Toiletry, and Fragrance Association quickly issued a press release denouncing the GAO report for its serious deficiencies. "It is apparent that the investigators did not have the assistance of biologically trained scientists in preparing this report." Unfortunately for both sides, and especially for the public, proof never came in black or white, but in as many shades of gray. It often came down to a matter of interpretation. But in the game of test results, positive results

²⁵GAO Report, p. 25.

²⁶F-D-C Reports, October 27, 1975, p. 20.

generally beat negative or ambiguous results.²⁷

The third strike came from FDA's newly created Toxicology Advisory Committee convening for the latest round of evaluations on November 20-21, 1975. In an interesting development, FDA Associate Science Commissioner Dr. Lloyd Tepper, announced that the entire meeting would be open to the public and that the closed executive session had been canceled. FDA believed that under the Freedom of Information Act it could close executive sessions for deliberations, but feared that it would be sued if it did so. Dr. Sidney Wolfe had won a legal challenge to closed executive sessions, although the order had been stayed. FDA did not wish to risk a disruption of this important meeting by a legal challenge from Wolfe, although Tepper made it clear that this did not set precedent. In line with the Federal Advisory Committee Act and its policy of openness, FDA made a tape recording of the proceedings, minutes were obtainable from the executive secretary, and copies of the minutes were on display in the Hearing Clerk's office.²⁸

In the morning session, FDA officials went over the numerous experiments that had been done on Red No. 2, tried to explain the mix-ups in its two-year feeding study, and answered questions from a group of 'outside' experts. In the afternoon session, which included public comments, Dr. Burdick from the Inter-Industry Color Committee, and Dr. Wolfe and Ms. Johnson of the Health Research Group made

²⁷Cosmetic, Toiletry and Fragrance Association, Inc., News release, "Industry Comments on GAO's FD&C Red No. 2 Report," November 3, 1975. Docket No. 75N-0342, vol. 3. Food and Drug Administration.

²⁸Minutes of the Toxicology Advisory Committee, FDA, November 20-21, 1975, pp. 1-2. Docket No. 75C-0033, vol. 2, Tab 6. Food and Drug Administration.

presentations. Committee members asked Dr. Wolfe which of the cited studies supported the carcinogenicity charge. He replied that confirmation came not from any single study, but from the cumulative weight of the evidence. Johnson reviewed the Color Additives amendment concluding "If there are safety questions--and we believe there are--those questions should be resolved. The provisional listing should be terminated and the questions resolved while the dye is off the market." She then addressed the legal issue of burden of proof, which rested with industry to prove the safety of its additives.

This discussion went to the heart of the "how safe is safe" problem. For HRG, the preponderance of even equivocal evidence was reason enough to ban the dye. To HRG and other consumer organizations, modern commercial food production was itself suspect: by its very nature it damaged the product, not for the purpose of increasing the food supply or improving its nutrition, but simply to maximize profits. "I have concluded that the biggest problem with additives is not their inherent toxicity but rather the kinds of food that they make possible--foods that are low in nutritional value, high in fat," said Dr. Michael Jacobson in an interview given to the FDA Consumer. "It's the artificial coloring, flavoring, preservatives, thickening agents, flavor enhancers, and emulsifiers that make highly processed junk foods possible and encourage their use."²⁹

After an arcane scientific discussion that questioned the quality of the experiments, the strain of rat used, and whether the dye, its metabolites, or impurities

²⁹"Food Regulation: A Consumer Advocate's View," FDA Consumer, (May 1977): 6.

had been responsible for the effects seen, the members of the committee finally concluded that they did not find strong evidence to indict the dye either for fetotoxicity or carcinogenicity. Dr. Edward A. Smuckler summed up the problem facing them and any group that had to certify that a substance had no potential to harm. He had a problem with the quality of some of the data, but he basically felt that Red No. 2 was innocuous. "On the other hand, in a day and age when all our moves are scrutinized by people who may not understand some of the gut reactions that go on with science, I think we are obliged to err on the side of conservatism and say we cannot give a definitive recommendation on the long term safety of this material."

Despite Dr. Tepper's prodding the committee refused to even indicate what stance Commissioner Schmidt should take on the issue. Could the committee, at least, give him some idea of the degree of urgency, Tepper asked? Dr. Thomas Tephly felt he could go as far as to say that "while the suspicion that Red 2 may be a weak carcinogen has not been dispelled neither has there been any strength to the evidence that it is carcinogenic." The Committee quibbled over whether Schmidt should say no 'strong' evidence or no 'compelling' evidence, settling for no 'convincing' evidence, but the bottom line was that the committee could not bring itself to say unequivocally that Red No. 2 was safe. Even the illiterate could read the writing on the wall.³⁰

The committee's need to re-evaluate statistical evidence, view pathology slides, and receive additional information meant that it could not reach a decision until

³⁰Minutes of the Toxicology Advisory Committee, FDA, November 21, 1975, Friday afternoon session, p. 5. Docket No. 75C-0033, vol. 2, Tab 6. Food and Drug Administration.

early 1976, but events had begun to overtake the Advisory Committee's deliberations, whatever the eventual outcome. On December 28th, Commissioner Schmidt appeared on the CBS Sunday morning political interview show, "Face The Nation." Lesley Stahl, Lee Thornton, and Washington Post columnist Morton Mintz peppered the Commissioner with questions about the FDA's handling of a number of contentious issues. Thornton began her questioning by saying, "The FDA seems to be bogged down on the red dye No. 2 issue." Schmidt protested this characterization and began to talk about the evaluation process. "Red number two is probably the most studied chemical in the food supply, certainly the most studied color. We know the most about it. And there are no studies that prove that Red No. 2 causes cancer." They then sparred over whether it caused birth defects, Thornton citing the Russian studies.

Lesley Stahl then asked, "Why if there have been unresolved questions about whether it can cause cancer, why haven't you taken it off the market while you resolve these questions.?" Schmidt stumbled around the answer coming back to the fact that it's an unresolved question. Stahl shot back, "Well, why don't you approve it then?" Schmidt said that if it were an imminent hazard, then the FDA could move quickly and remove it from the market, but if it is not, "then we have to go the legal route. And we are a country of laws and we cannot be arbitrary and we cannot take something off the market and then contest the issue. The way the law is, we contest the issue...." Before he could finish, Stahl said what had surely crossed the minds of many viewers. "While we're still eating these foods, you contest the issue." In light of the pervasive fear of cancer and doubts about the ability and willingness of

the government to protect the health and safety of its citizens, the interchange was hardly reassuring.³¹

The Washington Post in a January 2, 1976 editorial, citing a pattern of confusion and delay, complained "that the agency decided to take action only after outside pressure gave it little choice. Whether this pressure came from congressional hearings, litigation from public interest groups, research from outside the agency or newspaper stories, the FDA was put in the position of following rather than leading." Conceding the complexity of the issues with which the FDA dealt and its need to operate within the legal parameters that Congress set, the editorial asked "Must it take years and years to protect citizens from threats to their health? Is the agency incapable of taking an initiative?"³²

Consumer activists opposed to additives certainly seemed to have the FDA on the run. However, like the distant hum of the approaching vanguard of another crusade, the public began to hear other voices who challenged the 'fear mentality' fostered by consumer advocates. "How extraordinary!" Adam Wildavsky marveled. "The richest, longest-lived, best protected, most resourceful civilization, with the highest degree of insight into its own technology, is on its way to becoming the most frightened. Has there ever been, one wonders, a society that produced more

³¹"Face The Nation," CBS News. Interview with Alexander M. Schmidt, December 28, 1975. Face The Nation-1975: The Collected Transcripts from the CBS Radio and Television Broadcasts, v. 18. Metuchen, NJ: Scarecrow Press, 1976

³²"A Lack of Initiative At the FDA," Washington Post, January 2, 1976, p. 23.

uncertainty about everyday life?"³³

Wildavsky and other conservative commentators, pushing an anti-regulatory agenda, saw a direct link between the growing number of media stories about defective products, polluted air, and dangerous additives and a growing government apparatus that took it upon itself to define risks, devise solutions, and force society to abide by the resulting constraints. They viewed consumer advocates and their friends in the media as part of a sectarian culture in America that was hostile to industry, especially large corporations. In language reminiscent of anti-czarist conspirators, they described a network of activist organizations that protested against environmental hazards in order to undermine the political and economic power of industry. The leadership of these organizations, convinced of the moral purity of their cause, sounded the call: the world as we know it will end unless the risk is eliminated. The public, lemming-like, absorbed their message and hysterically pressured their political representatives to do something, anything, to eliminate the danger.³⁴

One might have expected the food industry to be in the thick of the fray denouncing the motives, tactics, and facts of the consumer advocates. It chose not to counter-attack directly, assuming any response on its part would be discounted as self-serving. Instead it drew on its supporters--often those in the academic community, who benefitted from industry-funded grants or institutes--to defend its good name. "Food additives keep our food supply plentiful, attractive, inexpensive,

³³Aaron Wildavsky, "No Risk Is the Highest Risk of All," American Scientist, 67 (January/February 1979): 32.

³⁴Mary Douglas and Aaron Wildavsky, Risk and Culture. (Berkeley: University of California Press, 1982).

nutritious and pleasing to the palate," Elizabeth M. Whelan wrote in an Op-Ed page piece for the New York Times in the midst of the hue and cry over Red No 2. She argued that preservatives significantly reduce food spoilage, and that chemical fortification had all but eliminated scurvy, rickets, and goiter. Whelan, who with Dr. Frederick Stare, Chair of the Harvard Department of Nutrition, had written Panic in the Pantry: Food Facts, Fads, and Fallacies, argued that everything, including additives and pesticides, was natural and that modern technology was superior to nature. These arguments would not be decisive in terms of Red No. 2, but as the 1970s progressed, they would continue to garner support.³⁵

As the revelers rang in 1976, consumer activists had every reason to believe that victory was at hand, while those at FDA headquarters had little reason to rejoice. An embattled agency, whose future appeared uncertain, the FDA saw itself as besieged on all sides by a host of attackers--Senator Kennedy and a half dozen other congressional investigating chairmen, the Health Research Group and other consumer and health organizations, crusading press and TV journalists--each with their own motives and agenda--pressing toward the destruction of the agency under the banner of providing better protection for the public.

Less than two weeks after having reassured the public on "Face of the Nation" of the safety of Red No. 2, Commissioner Schmidt had to announce that new evidence refuted that statement. Three days after Schmidt's appearance on Face the Nation, Dr. David Gaylor of the National Center for Toxicological Research submitted

³⁵Frederick Stare and Elizabeth M. Whelan, Panic in the Pantry. New York; Atheneum, 1975. New York Times, July 23, 1975, p. 35.

his report to the Toxicology Advisory Committee, which had asked him to evaluate FDA's long-term feeding study. Although it had significant flaws because of the animal mix up, it still remained possible to compare the group receiving the highest dose of Red No. 2 to the control group. "Based upon the pathological findings of the recent FDA study," Dr. Gaylor concluded, "it appears that feeding FD&C Red No. 2 at a high dose results in a statistically significant increase in a variety of malignant neoplasms among aged Osborne-Mendel female rats." The FDA study appeared to corroborate the findings in the 1970 [Andrianova] Russian study.³⁶

On January 8, 1976, Schmidt released the full text of Dr. Gaylor's December 31st memorandum to Dr. Lloyd Tepper, accompanied by the statement: "In light of continuing public concern and the serious new questions about carcinogenesis raised by Dr. Gaylor's analysis, the Commissioner concludes that a study adequate to dispel all such questions must be performed before the color additive can be demonstrated to be safe as required by the act...." The press release explicitly mentioned that the memorandum was an internal FDA document and ordinarily not releasable, but that it was being distributed because of widespread interest in the safety of FD&C Red No. 2. Given the suspicion and mistrust that had accompanied FDA's handling of the situation, to maintain even a semblance of integrity, the FDA needed to keep

³⁶Memorandum from Dr. David W. Gaylor, National Center for Toxicological Research, to Dr. Lloyd Tepper, Chairman, FDA Toxicological Advisory Committee. "Statistical Analysis of Malignant Tumors Observed in the FDA Study Rats Fed FD&C Red No. 2," December 31, 1975. Docket No. 76C-0033, P-142. Food and Drug Administration.

everything as open and above board as possible.³⁷

F-D-C Reports headlined the story, "Kiss Red No. 2 Goodby!" From an industry standpoint, the story had developed so quickly that no one at FDA's operating levels ventured an opinion on how regulatory details might be handled or what would happen to existing inventories. If the provisional listing were to be withdrawn from food, drugs, and ingested cosmetics, a company could petition for its use in externally applied drugs and cosmetics, the paper noted. However, it speculated that no firm would seek that kind of publicity, especially now that the FDA had new regulations requiring the listing of color additives on the labels of cosmetics.³⁸

Eight days later a group of scientists from FDA, the Toxicology Advisory Committee, and the National Cancer Institute presented their findings to Commissioner Schmidt. The minutes of the meeting indicate the difficulties facing the scientists. Under normal circumstances, this was not the experiment the scientists would have used to decide the fate of a controversial product. The FDA experiment had unexplained mix-ups in the animals, most of the animals had died and started to decompose before samples could be taken for pathological examination, and many of the tumors were those common to aged rats. Therefore, members of the committee had little confidence in any conclusions that could be drawn under these circumstances.

³⁷FDA Commissioner Alexander M. Schmidt, Press release, January 8, 1976. Food and Drug Administration.

³⁸F-D-C Reports January 12, 1976, p. 19.

But these were not normal circumstances. Red No. 2 had stayed under its provisional status for too long, HRG charges that had been ignored for too long, and the public had been hearing stories about everyday products that turned out to be dangerous for too long. The scientists could not stand on principle and refuse to make a decision. In the end the group concluded that whatever else the study did or did not prove, it could not be used to demonstrate the safety of Red No. 2.³⁹

Therefore, FDA Commissioner Schmidt had no choice but to announce, "Red No. 2 has been allowed for use on a provisional basis while the Food and Drug Administration conducted animal studies on its safety. We have just learned that our latest study cannot establish the safety of Red No. 2. Indeed, the study raises again certain safety questions. Therefore, I am now revoking FDA's provisional approval for all uses of this color additive in foods, drugs, and cosmetics." Schmidt sought to reassure the public that it had no reason for alarm as the FDA had no evidence of any public health hazard from foods or other products containing Red No. 2.⁴⁰

The notice of the termination of the provisional listing and certification of FD&C

³⁹Working Group on FD&C Red No. 2, Minutes, National Institutes of Health Campus, January 14, 1976. Docket No. 76C-0033, vol. 2, tab 9. Food and Drug Administration. The group had four reasons to suspect that Red No. 2 did not cause cancer: There were no statistically significant increase in malignant tumors among male rats; there were no unusual or unique tumors observed; there were no increase in tumors in specific organs among high-dose animals; and if the malignant and benign tumors were combine, there were no statistical significant difference in number of tumors between the high-dose and low-dose. Information Memorandum from John Jennings, Associate Commissioner for Medical Affairs to Commissioner Alexander M. Schmidt, January 16, 1976. Docket No. 76C-0033, vol. 2, tab 10. Food and Drug Administration.

⁴⁰FDA Commissioner Alexander M. Schmidt, Press release, January 19, 1976, Food and Drug Administration.

Red No. 2 appeared in the February 10, 1976 issue of the Federal Register. After describing its testing history and the questions that had arisen about it (but not mentioning the persistence of the Health Research Group), the FDA gave its rationale for action. "Because of the widespread use of FD&C Red No. 2 and the persistent questions about its safety, at least in the public's mind [emphasis added], FDA decided to refer this study and all of the other studies that have been presented ... to the agency's newly established Toxicology Advisory Committee." As far as the FDA was concerned, the danger and concern existed in the public's mind, not theirs. The next statement specifically mentioned the fact that certain members of the committee "expressed the opinion that there appeared to be no immediate cause for concern and that the continued use of FD&C Red No. 2 did not pose a hazard to public health." To underline the fact that the FDA did not see this as an imminent danger and also to minimize the cost to manufacturers of this action, the FDA did not require the recall of products already containing the dye or those in the process of being made.⁴¹

At the end of February, Commissioner Schmidt gave an interview to U.S. News and World Report, which the magazine titled "Dangerous Food and Drugs: Behind the Furor." The editors asked if the world had become more dangerous or was more being learned about the hazards in food and drugs? Schmidt thought that conditions actually were getting better. Risks from food additives were small compared to the risks from dirt, microbiological contamination, or lead that were in foods years ago and had now been reduced to practically zero. But, he added "we

⁴¹41 Federal Register, February 10, 1976, p. 5823-4.

are getting more and more demands to remove something because of just a suspicion that it might be harmful." He reminded readers that for the FDA to remove a product immediately, the law required proof of imminent hazard.⁴²

After four years of petitioning, testifying, and protesting, the Health Research Group and other consumer activists had succeeded in removing Red No. 2 from the American market. But Canadian health officials did not follow suit. On February 2, 1976 the National Health and Welfare Minister Marc Lalonde announced that after careful evaluation of all available evidence, and consultation with health experts in other countries, the Health Protection Branch (HPB) concluded that insufficient data existed to remove the color from foods sold in Canada. The Canadian scientists had deep reservations about the usefulness of the FDA study, especially the fact that the tumors were not organ specific and the fact that the male control rats had more tumors than male rats fed the highest amount of the dye.⁴³

The HPB was particularly concerned about Dr. Verrett's experiments for mutagenicity, although they admitted that the FDA had not based its determination on this data. Instead the HPB took out its ire on the Canadian Broadcasting Corporation for including her on its January 25 program, Market Place. "The chick embryo technique was replaced in 1966 at HPB by more reliable techniques that employ mammalian species. HPB deplores the fact that CBC's Market Place did not

⁴²"Dangerous Foods and Drugs: Behind the Furor," U.S. News and World Report, 80 (February 23, 1976): 52.

⁴³"Canadian Position on the Food Colour Amaranth," News Release, Health Protection Branch, February 2, 1976. Docket No. 76C-0033, exhibit 18. Food and Drug Administration.

check on the reliability of the chick embryo test." The news release ended by mentioning that FD&C Red No. 40 was not available in Canada because two years before HPB had concluded that evidence submitted by the manufacturer with respect to safety was inadequate. Ironically, in the United States many manufacturers had already switched to Red No. 40, which had been permanently listed, although few found the color as satisfactory.⁴⁴ The manufacturers of Red No. 2, who had sold almost a million pounds of the dye in recent years, refused to accept FDA's decision and took their case to court. The United States Court of Appeals for the District of Columbia rejected the challenge to Commissioner's decision to terminate the provisional listing of FD&C Red No. 2.⁴⁵

The FDA issued a Denial of Petition for Permanent Listing of FD&C No. 2 on April 9, 1976. The Commissioner concluded that the adverse implications of the FDA study could not be ignored. New studies to dispel all such questions "must be performed before the color additive can be found safe." The FDA's unstated position was that no forthcoming studies were ever going to be able to prove beyond a shadow of doubt that Red No. 2 was unequivocally safe. Only this type of proof would be able to pass the political firestorm that would ensue if FDA tried to permanently list the dye.⁴⁶

The FDA had been faced with just such a situation with cyclamates. After the

⁴⁴Ibid.

⁴⁵Certified Color Manufacturers Association v. Mathews, Civil Action 76-0153 (D.C. Cir, July 6, 1976)

⁴⁶41 Federal Register, April 9, 1976, p. 15053.

removal of the sweetener, its manufacturer, Abbott Labs, had petitioned the FDA in 1973 to have it re-approved, submitting sixteen volumes containing 440 scientific papers in defense of its position. In contrast to FDA's original procedures and because of the continuing interest in non-nutritive sweeteners, Commissioner Schmidt announced that the FDA intended to allow the maximum public and scientific participation throughout the decision-making process.

The hearings occurred in the midst of the controversy over Red No. 2. The FDA demanded additional scientific data--lifetime rat-feeding study, additional data on reproductive organs and the cardiovascular system from Abbott Labs. While the additional data "may seem formidable... FDA is of the opinion that it is well worth the scientific effort to decide in a very definitive way whether cyclamate can be safely used as an artificial sweetener." But in the end, despite compelling data to buttress its case, Abbott could not produce the incontrovertible evidence and thus convince the FDA to reverse its original position. On September 16, 1980, FDA formally denied Abbott Labs 1973 petition for reapproval of cyclamate.⁴⁷

Both cyclamate and Red No. 2 had become public issues that transcended their basic scientific questions to become the focus of larger public concerns about the safety of the food supply and its relationship to illness, especially cancer. Both products became the catalysts for a re-examination of a larger class of products of which they were a part. As a result of the cyclamate situation and the recognition

⁴⁷William R. Havender, "The Science and Politics of Cyclamates," The Public Interest, 71 (Spring 1983): 18. See also Wayne L. Pines, "The Cyclamate Story," FDA Consumer, (December 1974-January 1975): 19-27. Linda C. Cummings, "The Political Reality of Artificial Sweeteners," in Harvey M. Sapolsky, Consuming Fears, (New York: Basic Books, 1986).

that few food additives had ever been tested for safety, President Richard Nixon ordered a complete review of products given GRAS (Generally Recognized As Safe) status.

Prompted by the Red No. 2 controversy, FDA announced that it had completed a review of the 84 colors still remaining on the provisional list and had considered giving permanent status to 20, terminating 12, and specifying tests needed for approval of the remainder. FDA extended its decision date on chronic toxicity feeding studies for 32 provisional colors for four years until January 31, 1981. HRG filed suit, calling the four year extension for colors which had remained on the market without proof of safety for more than 14 years "arbitrary and capricious."⁴⁸

Although the FDA won the case on appeal, HRG won a more important prize. It forced the FDA to open its decision process on the remaining color additives to public scrutiny. If it were going to allow industry to drag out the color approval process for years, FDA would now have to do so in public. Industry semi-annual progress reports and requests for postponement would be on display in the Hearing Clerk's office; requests for postponements that had been granted would be published in the Federal Register. Continual pressure by HRG had forced a remarkable degree of public accountability on the part of the FDA.⁴⁹

Advocates on both sides of the issue have continued to debate whether the public had been saved from a dangerous product or had been stampeded into a panic based on a dubious set of facts. Science could not provide the definitive answers to

⁴⁸F-D-C Reports, February 28, 1977, T&G 2.

⁴⁹F-D-C Reports, January 2, 1978, T&G 4.

policy questions on safety. Attempts to eliminate Red No. 2 outraged companies dependent on it, especially because of the equivocal experiments on which they believed the decision had been based. In the old days, economic impact and regulatory procedure would have been the only considerations, but now skilled consumer activists knew how to obtain critical information, get access to the media, and make a case before the public for the dangers inherent in allowing the product in question to remain on the market for even one more day. To consumer advocates safety had to be the main consideration. They had seen direct evidence in some cases, and had strong suspicions in others, that corporations put profits before the public's health and safety. In the end, perhaps, it is not so important which side was right but that an outside organization forced the FDA to make this a matter of public policy. This is the scenario that most often comes to mind when the the question of public pressure on the FDA is discussed. FDA and industry on one side and the public or its representatives on the other side in an unequal battle where a small group of doughty consumer defenders armed only with persistence, determination, and access to the media tries to compete against FDA's bureaucratic power and industry's money. But public pressure is a complex, unpredictable, and even at times irrational process. Little more than a year later, the public again found that a commonly used substance caused tumors in laboratory rats, but this time the outcome was remarkably different.

CHAPTER 7

"SACCHARIN, FDA'S BITTER PILL"

Prefiguring an industry that would boom in the 1980s, Dr. Sidney Wolfe commented, "It is unfortunate that it is not commercially feasible to market in soft drink machines cans of cold water, which would quench the thirst of people...."¹

Cartoonists had a field day drawing burping rats and people surrounded by cases of diet soda. It was hard to take the proposed ban on saccharin seriously when the FDA itself said that the average person would have to drink 800 12-ounce diet sodas a day for life to equal the saccharin given the rats in the Canadian study on which the ban was based. Late night comics made jokes about people drowning from all that liquid before they died of anything else. Representative Andrew Jacobs, Jr. (D-Ind) proposed that saccharin containers be labeled, "Warning: The Canadians have determined that saccharin is dangerous to your rat's health." But an American public wedded to its diet soda soon stopped laughing and started protesting when it realized that the FDA was serious about the ban. Because the FDA had removed the only other approved artificial sweetener, cyclamate, in 1969, the future appeared none too sweet.²

The FDA had no intention of becoming the source of material for comedy routines when Dr. Sherwin Gardner, Acting Commissioner of the FDA, announced on March 9, 1977 that the FDA proposed to ban saccharin. The decision, made after

¹The Saccharin Ban: Risks vs. Benefits, John Charles Daly, moderator, A Roundtable held on April 21, 1977, sponsored by The Center for Health Policy Research of the American Enterprise Institute, Washington, DC, 10.

²The Saccharin Ban: Risks vs. Benefits, Roundtable, 2.

Careful consultation with the Health Protection Branch of the Canadian government, rested on two factors: 1) a Canadian government study showing that saccharin, when fed in high doses to rats, caused malignant bladder tumors; and 2) the Delaney clause of the Federal Food, Drug, and Cosmetic Act which prohibited the use in food of any ingredient shown to cause cancer in animals or man. FDA had obtained preliminary results of the study at a March 7th meeting in Ottawa with Canadian scientists. Previous animal tests had not demonstrated with any degree of certainty that saccharin caused cancer, but these new Canadian tests presented unequivocal evidence that the substance produced malignant tumors in rats. Simultaneously with the FDA announcement, the Canadian government's Health Protection Branch (HPB) issued its own press release indicating its intention to ban saccharin from the food supply.³

The Canadian HPB had initiated a study in February 1974 to evaluate the toxicity and carcinogenicity of pure saccharin and orthotoluenesulfonamide (OTS), a contaminant which resulted from the manufacture of saccharin. Scientists fed 50 male and 50 female rats a diet containing 5% saccharin. In addition, 50 female and 50 male offspring of these rats received the same regimen beginning in utero and continuing throughout their life span. Another 100 rats were fed diets containing various amounts of OTS and the experiment included a control group of 50 male and 50 female rats.

³Food and Drug Administration, Press release, Intent to ban saccharin use in food, No. P77-12 (March 9, 1977). Canada, Ottawa, National Health and Welfare Ministry, Health Protection Branch, Canadian Position on Saccharin, News release 1970-44, (March 9, 1977).

Pathologists from the United States, Great Britain, Europe, and Canada evaluated the results of the completed study in early 1977. The scientists found 7 male and no female rats in the first generation had bladder tumors. Twelve males and 2 females in the next generation developed cancer. "In sharp contrast, in 100 control animals--those not fed saccharin or OTS-- only 1 developed a tumor." Moreover, the low incidence of tumors in the animals fed OTS clearly resolved the earlier speculations that OTS and not saccharin may have been responsible for the cancers in the test animals.⁴

For those familiar with toxicology studies, feeding test animals extraordinarily large doses of a chemical to test for carcinogens was considered standard procedure. But information about toxicological testing was not included in the FDA press release. Without this clarification, it became easy for those opposed to the ban to ridicule both the enormous amounts of saccharin fed to the rats and the FDA, which based its decision on this experiment. The same testing methods had been used in testing for FD&C Red No. 2 and cyclamate, but in those two cases those who questioned the use of these large doses did not get the media's, and therefore the public's, attention.

With or without a knowledge of toxicology, the fact that FDA had said it considered banning saccharin suggested to most consumers a serious situation and a clear reason to refrain from using the product. However, the FDA muted the effect of its statement by stressing that "saccharin has been in use for more than 80 years and has never been known to harm people...." Critics of FDA's handling of the situation charged that this was technically true, but inaccurate. Significant doubts

⁴42 Federal Register, April 15, 1977, p. 20000.

about the sweetener's safety had been part of its history almost from the beginning. Saccharin had a formidable opponent in Harvey W. Wiley, Chief Chemist of the Department of Agriculture and father of the Pure Food and Drug Act. Although he hated all adulterants, he appeared to have a special dislike for saccharin, which was one of the first two substances proposed for a ban under the provisions of the 1906 Pure Food and Drug Act.

In 1908, a delegation representing the saccharin interests visited President Roosevelt to protest. The manufacturer of canned corn told the President that he had saved \$4000 the previous year by using saccharin instead of sugar. "Mr. President, and everybody who ate that corn thought that they were eating sugar," Wiley interrupted, "whereas they were eating a substance that was highly injurious to health." The President, according to Wiley, "turned upon me, purple with rage, and with clenched teeth, said, "Why, Doctor Rixey gives it to me every day. Anybody who says saccharin is injurious to health is an idiot."⁵

Despite Wiley's efforts to ban saccharin, it remained on the market, although classified as a "food for special dietary use," primarily for diabetics. The development in the 1950's of a variety of dietetic foods containing a mixture of cyclamate and saccharin stimulated the growth of the non-nutritive sweetener industry. Questions again arose about the safety of saccharin in the 1960s and early 1970s, but experiments did not produce definitive results that would remove the only non-

⁵Carol Levine, "The First Ban: How Teddy Roosevelt Saved Saccharin," Hastings Center Report, (December, 1977): 6-7.

nutritive sweetener left on the market after 1969.⁶

Those critical of FDA's management of the problem charged that nowhere in its announcement or press release did FDA state saccharin presented a health hazard to humans. To the contrary, the news stories based on FDA sources claimed that the agency had "no evidence that saccharin has ever caused cancer in human beings [emphasis added]." This was another instance in which the FDA released a technically true statement that was not an accurate reflection of the case. In fact, it contravened the longstanding FDA position that data demonstrating animal carcinogenicity was strong evidence that the same substance caused cancer in humans.⁷

To further confound the consumer, at the same time that FDA indicated that it intended to completely end the use of saccharin, it also stated that it saw no need to initiate a product recall. "Since the Canadian data do not indicate an immediate hazard to the public health, we do not consider the recall of existing products to be necessary." The Delaney clause prohibition was absolute--if it caused cancer in animals at any dose, it had to be banned-- but it did not indicate any time frame for removal. In sum, the picture painted by the release, and carried by the press, was: saccharin was essentially harmless, but the FDA was forced to ban it because of an

⁶Linda C. Cummings, "The Political Reality of Artificial Sweeteners," in Harvey M. Sapolsky, ed., Consuming Fears (New York: Basic Books, 1986), 130.

⁷Walter B. Schultz, "Bitter Aftertaste of Saccharin," Food, Drug, Cosmetic Law Journal 40 (1985): 72.

inflexible law.⁸

Ironically, Canada faced none of the furor that the United States did in banning saccharin because it still had a non-nutritive sweetener on the market--cyclamate. The Canadian government had not been convinced by the data presented in 1969 that cyclamate presented a threat to the public health.⁹

Thus began what Consumers Report called "The Great Saccharin Snafu." During the ensuing months, a confused public found itself bombarded by diametrically opposed views from its scientists, politicians, and news analysts. The FDA frantically tried to explain its position in response to an unprecedented outpouring of public anxiety, consternation, and outrage. How had an agency now experienced in handling controversial decisions, that had been operating under a magnifying glass for almost a decade, gotten itself into this predicament?¹⁰

Many of the public relations problems that confronted the FDA in the subsequent months, arose from the fact that news of the study had already begun to leak out, necessitating a hastily called press conference late on the afternoon of March 9th. According to Richard M. Cooper, former FDA Chief Counsel, worries about the possibility of just such a leak had caused the agency to delay drafting its

⁸Congress, House of Representatives, Interstate and Foreign Commerce Committee, Saccharin Study and Labeling Act, H.R. 8518. Report 95-658, 95th Cong., 1st Sess., (October 3, 1977), 17.

⁹Cummings, 117. Cummings contends that with cyclamate banned, it became impossible to act against saccharin. "Thus, the consequence of the FDA's action against cyclamate is the continued marketing of substitutes, which are not necessarily less dangerous."

¹⁰"The Great Saccharin Snafu," Consumers Report, (July 1977): 410.

press release until the last minute. The unfortunate reference to the 800 cans of soda might have been deleted had the statement undergone a more rigorous review. To make matters worse, "the agency failed to advise relevant congressional committees in advance of this major announcement and consequently in the crucial initial reports in the press it received no help from those in Congress who usually supported strong public health regulation."¹¹

"Everybody knew saccharin was going to be the biggest thing we'd ever handled," remembered Wayne L. Pines, FDA's Public Information Officer. A major announcement by the Food and Drug Administration usually had up to 50 reporters and 7 television crews covering it. Reporters were given a press release following an extensive question and answer period in which the agency officials explained the rationale for its decision and provided other facts and background material.¹²

However, on March 9th, a dozen members of the Hanafi Muslim sect had seized 3 buildings in Washington and had taken more than 130 persons hostage, commanding the attention of the nation and its news services. Many reporters who would normally have been at FDA headquarters were covering the other story or tied up in the monumental traffic jams resulting from this crisis. Therefore, they based their stories on what could be gleaned from the short press announcement, thus leaving the public with an incomplete understanding of why the FDA would take the only approved artificial sweetener off the market.

¹¹Richard M. Cooper, "Saccharin--Of Risk and Democracy," Food Drug Cosmetic Law Journal, 40 (1985): 45-6, footnote 40.

¹²Wayne L. Pines and Nancy Glick, "The Saccharin Ban," FDA Consumer, (May 1977): 10-13.

In trying to understand the agency's mis-assessment of the public mood, one official reflected on its experiences involving other allegedly cancer-causing agents, such as chloroform or Red No. 2. Public interest groups had campaigned relentlessly to remove these food additives and colors from the food supply, especially after scientists had begun to construct a causal link between contaminants in the food supply and pollutants in the environment and the increased incidence of cancer. In these situations, when the FDA did not move immediately to remove these products, the public reaction was "By God, the FDA is trying to kill us by allowing Red Dye #2 to remain in our food supply." The negative response to its action on saccharin caught FDA officials off guard. Fears about cancer had become so strong and pervasive by the 1970s that banning a suspected carcinogen had consistently found support in Congress and the public. The saccharin ban was not expected to be popular, but "it was assumed that the public's fear of cancer would be the overriding concern."¹³

However, in terms of saccharin, another equal and opposite force worked against its removal. While Americans had taken much greater interest in their health, they also placed great store in the way they looked. Thinness, which had become an obsession with many Americans, overrode other health considerations--'Better dead, than overfed!' In many people's minds, an artificial sweetener had become essential for losing weight or maintaining that loss while satisfying their sweet tooth. And now the FDA wanted to remove it.

United States and Canadian officials had anticipated panic, not outrage, from

¹³Scott Lucas, The FDA, (Millbrae, CA: Celestial Arts, 1978), 146.

a public that had just found out it had been ingesting a proven carcinogen. Officials themselves knew such widespread anxiety was uncalled for. The normal risk of bladder cancer in the absence of saccharin is 1.50% over a lifetime--that is 150 cases for every 10,000 people. The Canadian results, translated into these terms, would mean an increase in risk to 1.54% for those who drank one can of diet soda a day. Dr. Alexander M. Morrison, head of Canada's Health Protection Branch, said he had wanted to dramatize for the public that saccharin "wasn't of cyanide potency." It was calculations by his staff that resulted in the mythic 800 cans per day.¹⁴

In retrospect, FDA officials conceded, "We did make perhaps too strong a statement denying any cause for widespread public alarm because of the effects seen in rats. If replicated in human beings over a long period of time the results were predictable, but for a period of three or four months of additional consumption by people there would probably not be much incremental risk. But we should have said that nonetheless those rodent tests are reliable indicators of human hazard...."¹⁵

As Wayne Pines later wrote, saccharin "touched off a public reaction seldom experienced even for an agency used to being in the midst of controversy." The scope of the 40,000 letters that FDA received within a month of its March 9th announcement (which eventually reached 150,000 pieces of mail) ranged from diabetics and weight watchers fearful that they had lost the last approved artificial sweetener, to those questioning the reliability of the scientific evidence. Some correspondents raised the banner of "freedom of choice"--the right to choose which

¹⁴Consumer Reports, "The Great Saccharin Snafu," 411.

¹⁵Lucas, 146.

risks to assume--and protested the increasing government involvement in their personal lives. Others raised questions about the troubling inconsistencies in the government regulation of product risk. How could the government remove saccharin, which it admitted acted as a weak carcinogen, but leave tobacco, an acknowledged highly potent cause of cancer and heart disease, on the market?¹⁶

The saccharin situation demonstrated only too clearly the difficulty of determining what the "public" wanted, even for an agency that had made prodigious efforts to make itself accessible to the public and had ample experience with the diversity and unpredictability of public involvement. After all, barely a year before, the FDA had bowed to the wishes of consumer activists and removed FD&C Red No. 2. In that situation the results had been equivocal, merely linking Red No. 2 to cancer in rats by statistical analysis. With saccharin, the linkage was much stronger, but the public refused to accept FDA's decision.

In many people's minds, the situation transcended the actual facts regarding saccharin and focused on the larger public policy issues surrounding the Federal Food, Drug, and Cosmetic Act, and especially the amendment to it called the Delaney Clause. Many letter writers, as well as scientists and columnists in newspapers, in magazine, and on television focused on the absolutist nature of the Clause, which precluded the FDA from considering any benefits provided by the food additive in its

¹⁶FDA Consumer, May 1977, p. 10. Cigarettes do not come under the provisions of FD&C Act. Congress had determined by law that cigarettes are not to be regulated from a health standpoint except for a warning label. In 1995 FDA Commissioner David Kessler proposed regulating cigarettes as drug delivery system and limiting their distribution to children and adolescents. FDA has been inundated in an avalanche of mail in response to that proposal.

decision.

The law was straightforward, mandatory, and clear. The officials who regulated food and drugs had taken oaths to uphold it. It required that saccharin be banned, wrote Richard M. Cooper, then Chief Counsel of FDA in an article aptly called, "Saccharin--Of Risk and Democracy." Although the law left some discretion for the review of scientific judgments before initiating regulatory action, the time had come for action, not more review.¹⁷

Despite the limited coverage of the press conference and the lack of background information, the saccharin story made both the front page and the editorial page of The New York Times. The editorial writers castigated the Delaney clause for forcing the FDA's hand. "The unqualified nature of the Delaney clause prohibits rational decision-making," the editors wrote, "There is no room for weighing the benefits of saccharin or whatever other substance is involved against its costs. Yet such cost-benefit analysis is basic to any sensible judgments." The editorial staff repeated the 800 bottle number, FDA's statement that in 80 years there had been no evidence that saccharin had ever "produced a single cancer in a single human being," and extended its sympathies to "the unfortunate rats who had to endure this experiment."¹⁸

Television morning news programs gave the story full coverage, focusing on both the amount of saccharin given the rats and the Delaney Clause. The comments of Jules Bergman, science editor on "Good Morning America" reflected a growing

¹⁷Cooper, 34.

¹⁸New York Times, March 11, 1977, pp. 1, 26.

anti-regulatory mood of the nation by the late 1970s. He stated unequivocally, "This is a classic case of regulation out of control. The Delaney Amendment to the Food and Drug Act compels the FDA to ban any substance causing cancer in animals or man, as proven in appropriate tests [but] those tests are never defined." He ended with a reference to the 800 cans of diet soda.¹⁹

The Washington Post may have been one of the lone voices praising the FDA's decision. Its editorial writers gave their support to the uncompromising language of the law because of the difficulties in defining acceptable risks to public health even with all evidence at hand. The Post came down on the "better safe than sorry" side of the equation, concluding "there is, after all, another substitute for sugar. It is called self-discipline, and it is generally considered very safe." Consumer activists who had previously been able to command center stage on health and safety issues found themselves shunted to the wings by outraged consumers and an effective soda industry public relations campaign.²⁰

As soon as the news got out, the FDA found itself under attack. "All day long we've been taking calls from people, some of them in tears, demanding that we leave saccharin alone," said one FDA officials. "One diabetic called from Jacksonville, Florida, and said he was a personal friend of Jimmy Carter's," said Wayne Pines. "I sent him a copy of the law that was the basis for this action. Congress passed the law, we didn't."²¹

¹⁹Cooper, 46.

²⁰"Saccharin: A Bitter Pill," Washington Post, March 14, 1977, p. 22.

²¹Washington Post, March 15, 1977, Sec. B, p. 1.

To trace the economic impact of the FDA's position, reporters descended on the Sherwin-Williams Company, the sole producer of saccharin in the United States, with sales of about \$10 million a year. "We're sort of keeping our heads down for a while to see what actions are being taken," said William P. Inman, vice-president of the company. The New York Times gave the story a local slant as the Cumberland Packing Company, makers of the Sweet 'n Low brand of saccharin had its manufacturing plant in Brooklyn. The 500 jobs the company provided to an economically depressed section of New York City would be eliminated if the FDA finalized the proposed ban.

"These are good people--hardworking, reliable, the mainstays of their families and this whole neighborhood," Marvin Eisenstadt, executive vice president of the company, told reporters. "They find it hard to understand, and so do I, how a product that has been in use for 80 years without problems or harm to anybody can suddenly be banned on the basis of such a silly experiment."²²

Mr. Eisenstadt's initial fears for his company appeared unfounded. The proposed ban would not go into effect until mid-July and by March 21st, Newsweek magazine reported that Cumberland was doing a record business supplying the needs of hoarding customers. "In New York, one mother-and-daughter team purchased 21,000 saccharin tablets and scooped up \$20 worth of sugarless gum."²³ Reports of supermarket running out of diet soda and other diet foods due to hoarding began to appear. Business Week's March 28th story included a quotation from a soft

²²New York Times, March 11, 1977, p. 28.

²³Newsweek, 89 (March 21, 1977): 65.

drink maker that "our switchboards have been going like crazy. We're having a hard time keeping our product in stock." Not only did the company not expect to cut back on production, but it might have to increase production if demand continued as it had in the last few weeks.²⁴

Three weeks later, the situation had gotten even better for Cumberland. The factory more than doubled its normal production to meet the demand. People have sent in "\$300 and \$400 checks," Eisenstadt commented. "It's the people crying out that they want these products, and if the Government will stop production in one fell swoop, they'll buy a lifetime supply."²⁵

In one of the many failures of communication between the FDA and the public, neither the agency nor the news services made it clear to the public that the FDA had not made any decision yet on saccharin. It merely proposed to ban the chemical. Before this became a finalized regulation, FDA's own procedures required public hearings and opportunities for public comment. The ban could not have gone into effect before July at the earliest and there always existed the possibility of protracted legal fights by the manufacturers of the bulk chemical and diet food and drink companies. But of course, the absolutist language of the Delaney Amendment also meant that FDA had almost no options on the issue--unless Congress chose to change or modify the law.

The public's disregard for the evidence presented by the FDA of saccharin's danger resulted in part from the masterful job the Calorie Control Council, the diet

²⁴"Saccharin's Sour Future," Business Week, (March 28, 1977): 95.

²⁵New York Times, March 29, 1977, p. 22.

soda trade group, did in presenting its side of the story. The Council had kept itself apprised of the situation concerning the saccharin experiments. Moreover, the industry had decided that if the experiments turned out to be positive there would not be a reprise of the cyclamate fiasco when they had capitulated before evaluating the situation.²⁶ Within days the Council had placed the following full page advertisement in the nation's newspapers.

²⁶Consumers Report, "The Great Saccharin Snafu," p. 413. Interestingly, before embarking on the saccharin experiment, the Canadians sent the council and other interested parties a copy of the study protocol, which the Calorie Control Council returned with no adverse comments. Further, in October 1976, the Council held its annual meeting in Ottawa, Canada and had Dr. Harold C. Grice of the Health Protection Branch as one of its principle speakers. At this point, Dr. Grice was able to conclude that OTS was not carcinogenic, which pleased the group. Only later when the same experiments revealed that carcinogenicity of saccharin itself did the Council decide that the study wasn't "so great after all."

Government Of The People, By The People, and For The People (except in the case of Saccharin)

The majority of American people disapprove of the proposed ban on saccharin. A recent Louis Harris survey confirms it.

However, the U.S. Government's Food and Drug Administration intends to ban saccharin in foods, beverages, and all other products. To soften the blow and quiet the voice of protest, the FDA announced it would consider allowing saccharin to be sold over the counter as a drug. But...

IT IS NOT CERTAIN YOU WILL BE ABLE TO BUY SACCCHARIN OVER THE COUNTER

Frankly, the FDA action is confusing and there is a catch. Weigh carefully the statement by Donald Kennedy, Commissioner of the Food and Drug Administration: "I want to make it clear that permanent approval of saccharin for drug use is not automatic."

To run the drug tests the FDA would require "5 years at a minimum" states Dr. Leonard Haimes, President of the American Society of Bariatric Physicians.

The fact is, saccharin is not a typical drug since its sole function is to provide sweetness without calories. Thus, saccharin may not be as easy to buy as you've been led to believe.

SACCCHARIN IS BEING BANNED ON INSUFFICIENT EVIDENCE.

The FDA is basing its proposed ban chiefly on the results of a single unfinished Canadian test of 200 rats that were fed the human equivalent of over 1,250 twelve ounce beverages a day over a lifetime. Quite frankly, there is considerable scientific disagreement over this test's validity due to the "mega-doses" of saccharin fed to these rats.

On the other hand, and what you may not know, the large body of existing research does not indicate that saccharin causes cancer in animals or humans. There have been at least a dozen experiments on animals conducted over the last decade, which the National Academy of Sciences reviewed, and they concluded

that no regulatory action against saccharin was indicated.

More importantly, there have been at least six studies involving a large number of humans (more than 60,000) with no evidence that heavy saccharin ingestion results in an increase in bladder cancer.

Of course, the most rigorous "test" could well be the fact that saccharin has been in use for over 80 years without a single case of cancer attributed to it.

If any cancer danger is demonstrated from diet foods and beverages containing saccharin, everyone agrees that they should be taken off the shelves. But, at this point, there appears to be a lot of confusion, controversy and insufficient evidence to ban saccharin. And more time to sort it all out seems justified.

THERE IS NO SUBSTITUTE FOR SACCCHARIN AVAILABLE

Many people are under the mistaken impression that American industry has a substitute waiting in the wings, ready to go as soon as the saccharin ban goes into effect. This is totally untrue.

"No other alternate sweetener is far enough along ... there is nothing around the corner next year to look forward to," according to FDA Deputy Commissioner Sherwin Cardner. This means that if saccharin is banned, millions of diabetics may not experience the taste of sweetness for a long time, perhaps ever, in their diet foods and soft drinks. And millions of weight-conscious Americans will have to forego the benefits of low calorie sweetened soft drinks, candy, gum, and desserts.

WHAT CONGRESS DOES WILL DEPEND ON YOU

Both Senator Edward Kennedy and Representative Paul Rogers have suggested that a thorough scientific review should take place. Independent scientists should judge the data on saccharin and especially the validity of the Canadian experiment as it relates to humans.

We think this is a sensible and essential suggestion and we urge you to urge Congress to support that proposal and provide the time necessary to judge all the data.

Without your support, the ban on saccharin will become a reality we'll all have to live with.

THE CALORIE CONTROL COUNCIL

P.O. Box 2040
Washington, D.C. 20013

The Calorie Control Council is an international association of manufacturers and suppliers of dietary food and beverages.

YOU'VE GOT TWO WEEKS TO BE HEARD!

Below you'll find a list of government leaders who have a special interest in the proposed ban on saccharin. Phone them! Write them, and do it before May 18. That's the date the FDA puts saccharin on trial in a public hearing. Let them know you support postponement of a ban so an independent and thorough scientific review can be made to evaluate the total evidence on saccharin.

Paul G. Rogers
Congressman, Chairman,
Sub-Committee on Health and Environment
2415 Rayburn
House Office Building
Washington, D.C. 20515
(202) 224-3121

Edward Kennedy
Senator, Chairman,
Sub-Committee on Health and Scientific Research
310 Senate Courts Building
Washington, D.C. 20510
(202) 224-3121

Donald Kennedy
FDA Commissioner
5600 Fishers Lane
Rockville, Maryland 20852
(301) 443-3380

OR WRITE YOUR REPRESENTATIVE

Address:
House Office Building
Washington, D.C. 20515
(202) 224-3121

The Calorie Control Council took the lead for the industry, the soft drink firms preferring to remain off stage in order to protect their marketing image as purveyors of wholesome goods. The advertisements had three objectives: to convince the drinking public that saccharin was, and had always been safe, that it was needed by a large portion of the public, and that the FDA's decision had been the arbitrary action of a regulatory agency far removed from the control of the public. In addition, the advertising planted doubts about the validity of the scientific studies by ridiculing the amounts of saccharin consumed by the rats. The highly successful ads generated thousands of pieces of mail to both the FDA and Congress. Stories in other newspapers and weekly news magazines incorporated its "facts" and viewpoints. The U.S. News & World Report story, "Fight Starts to Beat the Ban on Saccharin," incorporated the Council figures of 1250 twelve-ounce cans or 4000 packets of saccharin a day to equal the amount of saccharin consumed by the rats.²⁷

In another story the next week, the magazine highlighted the Orwellian idea of an intrusive, controlling government, asking editorially, "How capricious does our Government intend to be--and how far can it be allowed to go--in limiting freedom of choice by individual citizens?" Americans should be made aware of the arguments for and against the use of saccharin and then left alone to make a free choice, much as they did with tobacco, or driving on highways that claim 45,000 lives a year." The editorial writers compared the ban on saccharin to the failed prohibition against whiskey. As had other newspapers and magazines, the editorial writers concluded

²⁷US News and World Report, 82 (March 28, 1977): 49.

that the Delaney clause stood between Americans and their right to voluntary decision-making.²⁸

The New York Times, in an editorial entitled, "Nobody Loves the F.D.A." summarized the 'no-win' situation confronting the agency. Caught in the cross-fire between nervous consumers and powerful industries, alternately charged with admitting harmful additives into the food supply or colossal overregulation, it had been charged with finding some sensible path. The editorial doubted that many Americans would want to return to the pre-thalidomide days, but "lines must be drawn. When does a substance become harmful? What is acceptable risk? In any area embracing both law and science, the calculus must be a delicate one. Congress must re-evaluate both the FDA and what we expect of it and redesign the agency for the task."²⁹

The F-D-C Reports, evinced no such sympathy for FDA's plight. Instead it rebuked the FDA for the cavalier manner in which it announced its decision. Why, it asked, had there been no discussion of the Delaney Clause, its intent and whether it might require revision. The article concluded the Delaney Clause had to be evaluated in a public process with the country as a whole, its scientists, public officials, and private citizens involved in the discourse.³⁰

The proposed saccharin ban had again generated extensive coverage and publicity for the Food and Drug Administration. In a Gallup poll taken between March

²⁸US News & World Report, 82 (April 4, 1977): 84.

²⁹New York Times, March 16, 1977, Sec. A, p. 22.

³⁰F-D-C Reports, April 4, 1977, pp. 13-14.

18 and 21, 1977, adult respondents were asked if they had heard about the FDA's banning of saccharin. An astonishing 93% responded yes. Unfortunately for the FDA, this recognition did not mean approval of the actions that placed it in the spotlight. In response to a Harris survey question, "Do you support the ban on saccharin, or do you think people ought to have the right to buy products with saccharin if they still want to?" 76% of the adults answering a poll taken between March 26 and April 2, 1977 said "let the people buy it."³¹

Heeding the full-page ads in their morning papers that "YOU'VE GOT TWO WEEKS TO BE HEARD!," the public eagerly made its opinion known to the FDA and to its congressional representatives. Recounted California Senator S.I. Hayakawa, "Letters, telegrams, and phone call are coming into my office.... and I am sure the offices of my colleagues as well at an astounding rate." One constituent wrote, "With the help of many products containing saccharin, I have lost 64 pounds; I still have to lose 100 more pounds or I will surely die." In another letter, John Sewing, explained how saccharin affected his family. "We have 2 diabetic boys [who] have few luxuries with regard to the food they eat.... So when we top a meal off with a sugar-free drink, it is a real treat for them. They feel just like those of us who are not diabetic, and they forget for a minute they have a disease for which there is no cure."³²

³¹Institute for Survey Research, Temple University. March 17-21, 1977. National Science Foundation sponsor. Louis Harris Associates, March 26 and April 2, 1977. The Roper Center for Public Opinion Research, University of Connecticut, Storrs, Connecticut.

³²Congress, Senate, Subcommittee on Health and Scientific Research of the Committee on Human Resources. Examination of the Risks Included in the Use of Saccharin and the Decision by the Food and Drug Administration to Ban the Substance From the Market: Hearings before the Subcommittee on Health and

The decision to withdraw saccharin elicited more protests to Congress than any issue since President Nixon's "Saturday Night Massacre," in which he fired Special Prosecutor Archibald Cox during the Watergate crisis. Approximately one-quarter of the United States population, an estimated 50-70 million people, used products containing non-nutritive sweeteners. These included 80% of the 10 million diabetics and one-third of all children under ten. Thousands of people wrote to their representatives demanding a moratorium on the ban and an independent and thorough scientific review.³³

Both Senate Edward M. Kennedy of Massachusetts and Representative Paul G. Rogers, whose subcommittees had held numerous hearings on the FDA, announced investigative hearings. Congress had stepped in to prevent Food and Drug Administration actions before, for example in 1976 when FDA attempted to regulate vitamins. The saccharin situation was more complicated because of the Delaney Clause and Congress would have to consider not only what to do about saccharin but whether to change the underlying food and drug laws.³⁴

As opposed to the red dye issue, saccharin did not present a neat dichotomy of consumer advocates demanding the removal of a dangerous substance on one

Scientific Research of the Committee on Human Resources, 95th Cong., 1st sess., June 7, 1977, 5,6. [Cited hereafter as *Hearings, Saccharin Ban*]

³³Committee on Saccharin and Food Safety Policy, Institute of Medicine/Assembly of Life Sciences, Saccharin: Technical Assessment of Risks and Benefits, Part I, November 6, 1978, E-1. Contract 223-78-2145. [Cited hereafter as *Saccharin: Technical Assessment*]

³⁴Almost twenty years later, the FDA would again attempt to place limitations on the sale of vitamins. Again an outcry from the public and the health food industry would cause Congress to thwart FDA action.

side and industry on the other. The American Diabetes Association, which organized its local affiliates into letter-writing campaigns, argued that since obesity was often associated with the adult-onset diabetes, the risk of cancer from saccharin consumption is far less serious than the risks associated with other health hazards that would arise if saccharin were banned. The Juvenile Diabetes Foundation's letters had a particularly poignant message. "Without easy access to saccharin-sweetened soft drinks and foods, the nation's 300,000 children afflicted with diabetes would be further denied a normal childhood." The American Cancer Society's Frank J. Rauscher, explained its position: "our concern is that obesity is a disease of major consequences," and may itself predispose individuals to various forms of cancer.³⁵

For the general public saccharin based products, especially soda, had become linked to efforts to reduce weight. The FDA was attempting to remove a product whose use from 1961 to 1977 had increased at the rate of nearly 25 percent per year, largely because of the growth of the diet soft drink industry, which accounted for 74% of total production. Although the public was not aware of it, saccharin was also used in many prescription and over-the-counter drugs (especially those intended for pediatric use and for use by diabetics), and in lipsticks, mouthwashes, and toothpastes. As had been the case with Red No. 2, consumers were surprised to find that they had been consuming an additive without their knowledge.³⁶

Saccharin had been approved for use under the 1958 Food Additives Amendment to the Federal Food, Drug, & Cosmetic Act and given Generally

³⁵The Saccharin Ban: Risks vs. Benefits, Roundtable, 5.

³⁶42 Federal Register April 15, 1977, p. 19996.

Recognized As Safe (GRAS) status. When concern about saccharin's safety arose in the late 1960s, the FDA asked the National Academy of Science's Committee on Food Protection to form an Ad Hoc Committee to re-evaluate the safety of non-nutritive sweeteners. The Committee concluded that an intake of 1 gram or less of saccharin per day by an adult presented no hazard. However, the committee recognized that by the standards of the day the carcinogenicity studies on saccharin were inadequate. In the time honored manner of government inquiries, it recommended further studies, which were completed in 1970 with inconclusive results.³⁷ The Wisconsin Alumni Research Foundation (funded in part by the Sugar Association) undertook a two-year feeding study, which indicated an increased incidence of bladder tumors in male rats, especially those in the second generation. These results prompted the FDA in 1972 to remove saccharin from its GRAS list.³⁸

The following year an FDA-sponsored set of experiments produced similar findings. Fed on doses as high as 5% and 7.5% of total diet, rats developed tumors. A NAS evaluation in 1974 could again reach no definite conclusion, but raised other questions. Perhaps the carcinogen was not saccharin but an impurity produced during the manufacturing process, orthotoluenesulfonamide (OTS).³⁹

Because this could not be determined based on previous experiments, the FDA declined to remove saccharin from the food supply, preferring to issue an Interim Food Additive Regulation to permit continued limited use of saccharin pending

³⁷Saccharin: Technical Assessment, 1-3.

³⁸37 Federal Register February 1, 1972, p. 25705.

³⁹42 Federal Register, April 15, 1977, 19999.

completion of more studies to resolve these questions. While there remained some dispute among scientists, most could not say with certainty that saccharin was safe.⁴⁰

As with Red No. 2, the FDA managed to postpone the day of reckoning on saccharin for a number of years but the Canadian studies provided the FDA with irrefutable evidence. Now it had no choice but to remove saccharin from interim approval status and therefore prohibit its use in foods and drugs, unless it could find some way to circumvent the Delaney Clause.

The Food and Drug Administration's decision to leave saccharin on the market while it continued testing again pointed to a fundamental question of regulatory philosophy that had arisen over Red No. 2 and other products alleged to cause cancer or other health problems: When a question of carcinogenicity was raised by reliable researchers, should FDA allow continued use of the product or should FDA seek its immediate removal from the market? FDA could not ordinarily require the temporary removal of an ingredient, forcing re-formulation and relabeling of other products, and then rescind the ban if further testing proved negative. In this particular case, removing the last non-nutritive sweetener would expose the

⁴⁰Richard M. Cooper in his article, "Saccharin--Of Risk and Democracy, wrote "The sudden demise of cyclamates during 1969-1970 reinforced FDA's belief that some status intermediate between GRAS and disapproval was needed." FDA proposed to establish a regulation authorizing interim food additive approvals. 36 Federal Register, December 8, 1970, p. 18,623. Such an approval would be available after a responsible and substantial question of safety has been raised regarding a substance previously listed as GRAS and the main weight of the scientific evidence still indicated safety (at least within certain limits). This proposed regulation was made final on June 18, 1971. 36 Federal Register, June 25, 1971, p. 12,109. "On that very day, FDA also proposed to remove saccharin from the GRAS list and to give it interim food additive approval."

bureaucratic to a storm of criticism. In an increasingly anti-regulatory environment, the decision would be held up as a glaring example of bureaucratic arrogance and over-reaching. Congressional efforts to limit FDA had already begun. Recently Representative Symms of Idaho had introduced a bill with over 100 co-sponsors to repeal the efficacy standards of the Kefauver-Harris Amendments in a effort to curb FDA's regulatory powers. Although it never got out of committee, it indicated the sentiments of a significant number of representatives.⁴¹

Amid the sound and fury over saccharin, the Food and Drug Administration had another leadership change, the third Commissioner since 1970. Commissioner Alexander Schmidt had decided to return to the University of Illinois' Abraham Lincoln Medical Center as its Vice-Chancellor effective December 1, 1976. Schmidt had made it clear to all concerned when he accepted appointment as FDA Commissioner that he intended to remain for only three years. After all the controversy under his watch, Schmidt received praise perhaps unexpected quarters. Senator Edward M. Kennedy in his opening statement at a hearing convened to discuss the allegations of dissident FDA employees and critics of the agency commented, "I do not question, and have never questioned, the integrity, honesty, and decency of Dr. Alexander M. Schmidt." Kennedy mentioned his efforts to correct problems within the agency in an open way without attempts to hide or cover up embarrassing matters. "I believe that the FDA is better now than when he first arrived." Considerable praise from a senator who had done his best to keep the FDA and Schmidt on the hot seat for most of his tenure.

⁴¹F-D-C Reports, April 28, 1977, p. 24.

Now that Schmidt was returning to the University Of Illinois and praise from the Pharmaceutical Manufacturers Association would not provide ammunition to his enemies, President C. Joseph Stetler commented, "No Commissioner had ever served in a more difficult period. The demands made upon him by Congress and others, in and out of government, have at times approached the impossible. Through it all, he had maintained a sense of balance and his sense of humor."⁴²

As they searched for a new Commissioner, Deputy Commissioner Sherwin Gardner temporarily assumed direction of the agency. No one expected the search would be easy. Finding a candidate with impeccable scientific credentials, an ability to operate in the Machiavellian politics of Washington, good media skills, and the desire to take one of the most difficult and thankless jobs in Washington, posed almost insurmountable difficulties. Those inside and outside the FDA wondered about the long term questions facing the agency: Would Schmidt's efforts to establish a scientific process and approach to FDA decision-making continue? Would his successor take a safe, more non-confrontational course in order to silence Congressional investigating committees, vocal consumerists, and the press?

At the beginning of 1977, President Jimmy Carter announced that Dr. Donald Kennedy had accepted appointment as Commissioner of the Food and Drug Administration. As the avalanche of protest over saccharin continued in Washington, Dr. Kennedy left the quiet of Stanford University for the maelstrom of Washington.

⁴²Congress, Senate, Subcommittee on Health and Scientific Research of the Committee on Human Resources. 1976 Drug Reform Act: Hearings before the Subcommittee on Health and Scientific Research of the Committee on Human Resources. 94th Cong., 2nd Sess., June 29, 1976, 2, 63.

A neurophysiologist and Dean of the University, Kennedy was well-known for his calm manner and ability to work with diverse groups, traits that would stand him in good stead in the coming months. It seemed doubtful, however, that even a person of Kennedy's stature could bring sane and reasoned discourse to this emotion-laden issue.

Commissioner Kennedy's inaugural press conference came on April 14, 1977, the day before the FDA publish its proposals for saccharin in the Federal Register. The FDA announced that it intended to revoke saccharin's interim food additive regulation under which it was permitted to be used in prepackaged foods, such as soda, and as a tabletop non-nutritive sweetener. Unwilling to ignore the needs of diabetics and the obese, the FDA asked for comments on a proposal to review new drug applications for marketing saccharin as a single-ingredient drug, available in tablet, powder, or liquid form without a doctor's prescription. Since drugs did not come under the strictures of the Delaney Clause, the FDA could take into consideration its medical benefits for these groups.⁴³

At the press conference a reporter asked what role the public outcry and political pressure had on the proposed rule making. "I think the decision to proceed in this direction has been a decision entirely on its merits as nearly as I can examine my conscience," Kennedy replied with a straight face. There is nothing 'improper' in listening to the public, he added. "In fact a 60-day comment period that is required following a notice of proposed rulemaking is designed to give the Agency the views

⁴³42 Federal Register, April 15, 1977, p. 19996.

of the public. We'd be foolish if we didn't listen to them."⁴⁴

Asked about the inherent danger of saccharin, Kennedy, new to the job of Commission but no Washington novice, sidestepped the question. Calling it a weak carcinogen, he added, "It is strong enough to be concerned about, but compared to other carcinogens that are present as unavoidable contaminants in foods and environmental chemicals, it tests out as substantially weak."⁴⁵

The Federal Register proposal fulfilled FDA's March 9th commitment to address the issue promptly. Its action seemed like a reasonable compromise. Companies submitting New Drug Applications (NDA) for saccharin would have to present sufficient evidence of its effectiveness in controlling obesity or maintaining diabetics on their sugar-free regimens. Richard Merrill, FDA's General Counsel, had conceded at the press conference that manufacturers might not be able to prove claims of effectiveness and in that case it would not be made available.⁴⁶

In explaining FDA's proposal to consider saccharin as an over-the-counter drug, Commissioner Kennedy recognized the novelty of this approach. "I know of no other drug whose only purpose is to change the taste of food," he said. "I know of no other drug which is to be taken not for what it can accomplish in itself, but because the only alternative--in this case sugar--must be avoided. But for those individuals

⁴⁴F-D-C Reports, April 18, 1977, p. T&G 1.

⁴⁵F-D-C Reports, April 18, 1977, p. B-4.

⁴⁶42 Federal Register, April 15, 1977, p. 19996. Other sections of the proposed rule indicated that the agency would not put insurmountable roadblocks in the way of manufacturers trying to get approval for saccharin as drug. US News and World Report 82 (June 25, 1977): 82.

who must limit their sugar intake the benefits of saccharin may well outweigh any potential risks that we can now project."⁴⁷ Since the FDA could not control over-the-counter use, all products would have the following warnings: "For use as a non-caloric sweetener when sugar-restricted diets are medically indicated, as in patients with diabetes," as well as "Warning: Saccharin causes bladder cancer in animals. Use of saccharin may increase your risk of cancer."⁴⁸

Pharmaceutical manufacturers complained bitterly over the proposed removal of saccharin as an inert ingredient in an estimated 600 drug products and over-the-counter medications. The Pharmaceutical Manufacturers Association excoriated the FDA for requiring companies to reformulate their products "in order to lend respectability to a political answer to a hypothetical medical problem." PMA President C. Joseph Stetler termed the proposed regulation "illogical since an individual could consumer as much saccharin as he desires in pill or powder form, but the same individual, when taking a prescription drug, under a physicians's supervision, for a limited time, would be forced to ingest a product not sweetened with saccharin." He observed that many medicine would be so bitter without it that oral ingestion would be difficult if not impossible. Not only was sugar not sweet enough in the amounts used in drugs, but it presented insurmountable problems in terms of stability and compatibility.⁴⁹

The informal hearings held on May 18th and 19th, did not produce the public

⁴⁷FDA Consumer (May 1977): 11.

⁴⁸42 Federal Register, April 15, 1977, p. 20004.

⁴⁹F-D-C Reports, May 23, 1977, pp. 15-16.

demonstration, complete with placard waving protestors, that might have been expected from an issue that had caused an avalanche of protest mail to descend on Washington. Nevertheless, more than one hundred people filled the hearing rooms at FDA headquarters and 22 made presentations. Dr. Leonard Halmes, President of the American Society of Bariatric Physicians, obesity specialists, said "The American public is addicted to sweet taste; it can't go cold turkey." In addition to Dr. Halmes, eight witnesses representing diabetes organizations, and Rep. James G. Martin, who had sponsored legislation to prevent the FDA from banning saccharin, were among those who spoke. Consumer activist James S. Turner and HRG's Dr. Sidney Wolfe supported the FDA's position. Dr. Wolfe charged that the Calorie Control Council "appears to be developing a specialty in curing cancer by public relations, for they have orchestrated today's appearance of opposition to the FDA saccharin ban."⁵⁰

The FDA would continue to consider making saccharin a drug. But if it could not be a food additive, it could not be used in diet soda and that was what the public really wanted. From this point on, control of the saccharin issue began to slip from FDA's hand to those in Congress only too eager to please their constituents on an issue that did not require any federal expenditures and dovetailed nicely with a growing anti-government mood.

Members of the legislative branch threw themselves into the fray from the very beginning. Congressman James G. Martin, (R-North Carolina) attacked from two directions. He announced plans to introduce legislation to keep the agency from imposing a ban on saccharin until the subject could be fully debated in Congressional

⁵⁰New York Times, 5/19/77, p. 8.

hearings. More significantly for the overall regulation of foods, Martin drew up legislation to "modernize" the Delaney Clause in light of technological advances in analytical chemistry and toxicology. A former chemistry professor at Davidson College, Representative Martin called the FDA's action on saccharin "a foolish overreaction and irrational interpretation of the Federal law."

More than 200 Members of the House--close to a majority-- co-sponsored a bill, HR 8518, that would add an element of flexibility to the Delaney clause by giving the Secretary of Health, Education, and Welfare authority to assess the risks and benefits of food additives before imposing a ban. Martin was careful to explain that in his bill the Secretary could only consider a 'public benefit,' not private economic benefits or other interests in his decision. "Somebody has to show that a substantial benefit is being banned along with the substance."⁵¹

Before Commissioner Kennedy arrived in Washington, Representative Paul G. Rogers (D-FL) Chairman of the Subcommittee on Health and the Environment had held hearings on saccharin. The Committee heard testimony on March 21st and 22nd from Acting FDA Director Gardner, HRG's Dr. Sidney Wolfe, scientists, and representatives of the American Heart Association, the two Diabetes associations, and other health organizations. Their statements indicated to the committee that valid differences of opinion existed among eminent scientists and epidemiologists and "thus, there appeared to be a need to resolve the differences of opinion, to allow time for further investigations into the carcinogenic potential of saccharin, and to prevent

⁵¹"Saccharin's Dead, Dieters Are Blue, What's Congress Going to Do?" National Journal 9 (June 4, 1977): 256.

any precipitous action by Congress to modify the Delaney clause."⁵²

To accomplish this, Rogers introduced the Saccharin Ban Moratorium bill, HR 8518, on June 13th. The bill would prohibit the HEW Secretary from taking any action to prohibit or restrict the sale of saccharin for eighteen months pending the outcome of further studies. Rogers' proposal mandated a one-year Institute of Medicine/National Academy of Science study of the validity of animal testing in predicting human cancer, health benefits of food additives, and the place of risk/benefit issues in banning a food additive.⁵³

Hearings on a companion bill, S. 1750, began on June 7, 1977 before the Senate Subcommittee on Health and Scientific Research. In his opening remarks Sen. Kennedy, Chairman of the Subcommittee, reflected on the cavalier manner in which the FDA made its initial public announcement. "No regulatory action in recent memory has so angered the American people." FDA's mishandling of the situation had the potential "to completely dismantle a protective barrier--the Delaney amendment--without having a better replacement, or any replacement at all."

However, Senator Kennedy praised the new FDA Commissioner for trying to lay the facts before the American public. Unfortunately, by the time Commissioner Kennedy took office, the soda industry's 'media blitz' had done its damage. Senator Kennedy worried that "a regulatory process that flies in the face of overwhelming

⁵²Congress, House, Interstate and Foreign Commerce Committee, Saccharin Study and Labeling Act: Hearings Before the Interstate and Foreign Commerce Committee, 95th Cong., 1st Sess., 1977, H.R. 8518. [Hereafter cited as Hearings, Saccharin Ban.]

⁵³Congress, House of Representatives, Committee on Interstate and Foreign Commerce, Report No. 95-658, Saccharin Study and Labeling Act, H.R. 8518, 95th Cong., 1st Sess., (October 3, 1977), 8.

public opposition can undermine the credibility of all public regulatory efforts." He knew that regulatory efforts faced an increasingly hostile environment in the late 1970s. Business executives and their supporters blamed government regulation for a range of ills from increasing the consumer prices to reducing the incentive for innovation to impairing productivity.⁵⁴

Public ambivalence about FDA's decision arose as much from the lack of unanimity among experts over the significance and meaning of the scientific evidence, as from the desire for diet soda. While the FDA and the Canadian Health Protection Branch staunchly stood by the scientific validity of the experiment's methodology and results, from the beginning some scientists had publicly questioned the scientific basis on which the decision had been made.

Dr. Marvin A. Schneiderman, of the National Cancer Institute, had defended using rats for toxicological testing because they could be mass produced to genetically consistent specifications, including their known background rates of cancer. Thus, the use of one strain of rats in an experiment serves to minimize some of the natural variations in cancer response rates in a diverse population.⁵⁵ At the same time, University of Nebraska scientist, Dr. Philippe Shubik, observed that they have limitations as research subjects because "rats of all groups tend to have bladder problems other than cancer, raising questions about the vulnerability of their urinary tracts."⁵⁶

⁵⁴Hearings, Saccharin Ban, 1.

⁵⁵New York Times Magazine, May 15, 1977, p. 90.

⁵⁶"The Saccharin Ban," Newsweek (March 21, 1977): 67.

If saccharin caused bladder cancer in rats, then epidemiological studies should have shown a similar rise in human bladder cancers. Newsweek magazine summarized arguments made by Dr. Kurt Isselbacher and Dr. Philip Cole in the New England Journal of Medicine. They contended that "at least 7 pertinent epidemiological studies show that bladder-cancer mortality patterns in England and Wales [whose populations consumed large quantities of saccharin during sugar shortages in World Wars I and II] are not correlated with saccharin consumption." Nor did diabetic patients have an excess mortality from bladder cancer, despite their relatively high consumption of saccharin."⁵⁷ But Richard D. Lyons, writing in The New York Times, explained the biochemical similarity between rats and humans and that nearly every chemical known to cause cancer in humans caused cancer in rodents.⁵⁸

These disagreements among scientists and statisticians left the public baffled, added to its anxiety, and fed its growing disillusionment with science as the answer to the problems facing American society, in general, and this subject in particular. Under the circumstances, many Americans without the scientific background to decipher the competing arguments, chose to ignore the scientific evidence and discount the danger.

In the arcane world of science, legislators were in the same perplexing position as the public. They lacked the expertise to interpret the scientific data at the core of

⁵⁷"Saccharin--the Bitter Sweet," New England Journal of Medicine, 296 (June 9, 1977): 1349-50. Newsweek, (March 21, 1977): 67.

⁵⁸New York Times, April 3, 1977, Sec. IV, p. 9.

important public policy issues. The Senate Subcommittee tried to obtain independent technical information on the risks associated with saccharin by requesting a report from the congressional Office of Technological Assessment on March 24, 1977. The OTA could only affirm that "saccharin is a carcinogen in animals," but could not extrapolate its findings to risks for humans.⁵⁹

Nor could it provide scientific guidance to the Committee on legislative alternatives. OTA panelist, Dr. Frederick C. Robbins, feared that if banning saccharin were to lead to an increase in obesity, the resulting increase in hypertension, diabetes, and coronary disease would conceivably do more harm than even the most pessimistic estimates of the harm that could come from bladder cancer. But fellow panelist Dr. Joyce McCann countered, "although this might be a relatively small risk, we have a body burden of carcinogens, and we need to be very careful about adding to the burden."⁶⁰

Having come no closer than the public in finding a definitive scientific answer, Senator Kennedy commented that the hearings went beyond the immediate question of the scientific validity of the tests. As were so many decisions that the FDA now had to make, the issue came down to a philosophical evaluation of risk. "If there is an unknown risk which one can choose or choose not to be exposed to, should the Government allow us to make that choice ourselves, or should it make it for us? Should we be allowed to choose on behalf of our children? When is a federal

⁵⁹Congress, Office of Technology Assessment, Cancer Testing Technology and Saccharin, (October, 1977), 4,5.

⁶⁰Hearings, Saccharin Ban, 93, 27, 19.

decision necessary in order to protect the public health and safety, and when is it an inappropriate infringement on personal liberty?"⁶¹

Commissioner Kennedy, appearing before the Committee, expressed his concerns about legislative infringement on FDA's functioning. He stood by the scientific evidence on which FDA had based its decision and wondered aloud whether Congress intended to institute a "compound-by-compound" regulatory action of its own. He noted that even without the Delaney Clause, "the general provisions of our food safety laws would have occasioned the withdrawal of saccharin on the same evidence." If Congress considered intervening in the saccharin situation, he concluded, then the resulting bill must contain "guarantees to consumers that not only with respect to individual labels, but with respect to all advertising, and all possible routes of information, that consumers have adequate information to make what is a truly free choice."⁶²

Senator Kennedy announced his support on June 10, 1977, for Representative Rogers bill providing for an eighteen-month "breather" period for saccharin. "I believe that, because of divisions in the scientific community, because of the divisions in the OTA panel, because of the genuine uncertainty on each side of the risk/benefit equation, the individual ought to be fully informed and then allowed to make a personal decision." He cautioned that the saccharin situation should not be seen as a precedent, nor did it indicate his support for getting rid of the Delaney Clause. "The current dilemma is a rare example of a good and necessary law, drafted years ago,

⁶¹Hearings, Saccharin Ban, 1-2.

⁶²Hearings, Saccharin Ban, 9, 102.

that is now unable to accommodate itself to a situation that could not have been anticipated."⁶³

Anita Johnson, of the Health Research Group, called Kennedy's action "shocking," questioning "how the prime author of the war on cancer can support [a move] directing FDA to leave a known carcinogen in the food supply." Her only solace came from the fact that Congress viewed saccharin as a unique situation and did not see it as a precedent for undermining the food laws.⁶⁴ But HRG did not have the backing of the public on the issue. A letter to the New York Times captured the mood of the country. The author blamed the saccharin ban on the American public's "chemophobia" which he attributed to the "[Ralph] Nader-[Barry] Commoner-[Jacqueline] Verrett brand of posturing on manmade food additives, coloring preservatives and pesticides."⁶⁵

As the Congress considered saccharin moratorium bills in both the Senate and the House, a Canada study sponsored by the National Cancer Institute of Canada and three Canadian universities found epidemiological evidence linking saccharin to bladder cancer in humans. The researchers concluded that using saccharin increased the risk of bladder cancer by 60% with the fraction of bladder cancer cases attributable to saccharin amounted to about 7%, a figure consistent with animal

⁶³F-D-C Reports, June 13, 1977, pp. 4, 5.

⁶⁴"Saccharin ban reversal gains more support," Chemical and Engineering News (June 20, 1977): 19.

⁶⁵New York Times, March 28, 1977, p. 28.

studies.⁶⁶

The new Canadian study showed caused the FDA to rethink its position. "If, in fact, the risk to humans does turn out to be as serious as the Canadian study suggests, it would cast some questions on the wisdom of our original proposal even to make it available as an over-the-counter single ingredient drug." Commissioner Kennedy, however, assured Congress that saccharin would remain on the market until at least October.⁶⁷

Like much science, the Canadian epidemiological study was not above dispute. The September 7, 1977 issue of the prestigious British medical journal Lancet called its conclusions into question and its case against saccharin "unimpressive." Lobbyists for the Calorie Control Council quickly distributed copies of the report to the media and congressional members with a two-fold intent--to convince the public that the scientific results could not be trusted and to bolster support for the upcoming bills. Unlike the cyclamate situation, the diet beverage industry did not intend to fold its tents and go home.⁶⁸

"Breather" bills were approved by the House Health Subcommittee on July 11th and the Senate Human Resources Committee on July 13th. The extent of advertising during the 18-month moratorium remained the only controversial element. In an attempt to salvage some of his health crusading image, Senator Edward M. Kennedy demanded full warnings on packages, in stores, and on advertising for the

⁶⁶H.R. Report, 95-658, p.9.

⁶⁷F-D-C Reports, June 20, 1977, p. T&G 13.

⁶⁸New York Times, October 5, 1977, p. 18.

product in exchange for his support of the moratorium bill. But despite a joint statement by FDA Commissioner Donald Kennedy, Federal Trade Commission Chairman Michael Pertschuk, and National Institute of Health Director Donald L. Frederickson urging Congress to mandate saccharin warnings on both electronic and print advertising for "all products containing saccharin," the Senate committee voted no, requiring printed warnings only on food products.⁶⁹

On September 15th, by an overwhelming majority of 87 to 7, the Senate led by Senator S.I. Hayakawa (D-Calif), indicated that they had gotten the message from their constituents and passed the Saccharin Study and Labeling Act. The bill instituted an 18-month moratorium on FDA action against saccharin. Despite the considerable influence of Senator Kennedy, pressure from media interests produced a bill that required no warnings on radio, newspaper and magazine advertisements. Senator Gaylord Nelson thundered that the bill was an assault on the Delaney Clause "and the mandate in that law is to protect the safety of the food chain. Should we continue to corrupt the food chain of this country with a proven carcinogenic agent in order to sell soda pop? That's what its all about--soda pop."⁷⁰

On October 17, 1977, the House voted 375 to 23 to impose an 18-month moratorium after 40 minutes of debate. The House legislation left the labeling requirements for saccharin within the purview of the FDA. Representative Andrew Maguire (D-NJ), a consistent opponent of the moratorium and efforts to water down

⁶⁹F-D-C Reports, September 19, 1977, p. 9.

⁷⁰House Conference Report No. 95-810, November 3, 1977. In conference, the House managers accepted the Senate bill, S. 1750, Saccharin Study and Labeling Act, with modifications. New York Times, September 16, 1977, p. 14.

the Delaney Clause, objected to the failure of the House to include a labeling provision. He suggested facetiously that, instead of a warning label, the manufacturer provide an "assurance" label reading, "Assurance: Saccharin does not cause cancer, in the opinion of your Congressman, despite all scientific evidence to the contrary."⁷¹

In a last ditch effort "to let people make a choice when adequately informed," FDA Commissioner Kennedy appeared as "surprise witness" in search of mandatory labeling for all products at the Senate/House conference committee on the bill. The resulting legislation authorized FDA labeling authority to continue after the 18 month moratorium expired--with the HEW Secretary authorized to 'revise or remove' labeling if necessary to "reflect the current state of knowledge concerning saccharin." With this completed, the Congress enacted the Saccharin Study and Labeling Act on November 3, 1977, which President Carter signed twenty days later.⁷²

The most significant portion of the moratorium bill, from the perspective of public policy, instructed the Secretary of Health, Education, and Welfare to contract with the National Academy of Sciences' Institute of Medicine to conduct a two part study. Within one year, the Institute would report to the Secretary on the chemical identity of any impurities contained in saccharin, the toxicity and carcinogenicity of such impurities, and the health benefits, if any, to humans resulting from the use of non-nutritive sweeteners in general, and saccharin in particular. A second broader report due in 18 months would consider public policy for food additives, especially

⁷¹House, Moratorium on Saccharin Ban, 95th Cong., 1st Sess., 1977, H.R. 8012. New York Times, October 18, 1977, p. 1.

⁷²Saccharin Study and Labeling Act, P.L. No. 95-203, 91 Stat. 1451 (1977). F-D-C Reports, November 7, 1977, T&G 10.

whether there should be a weighing of risks and benefits in making regulatory decisions respecting such additives.⁷³

The NAS/IOM's first report, Saccharin: Technical Assessment of Risks and Benefits, issued in November 1978, had been eagerly awaited as the final word on saccharin. Its panel of thirty-seven scientists, clinicians, lawyers, economists, political scientists, and public advocates had been carefully selected to cover as many specialties and viewpoints as possible to forestall claims of bias. Predictably, the report satisfied neither side. The committee accepted the validity of the animal tests on saccharin. But on its effect on humans, the most important point of the study, the panelists concluded that the epidemiological studies did not provide clear evidence to support or refute an association between past saccharin use and bladder cancer in males.⁷⁴

The panel could not determine if there were benefits from using saccharin because of the sparse and often inadequate data available. In response to the arguments put forth by diabetics and the obese, the committee recognized "a perceived need or psychological reliance on non-nutritive sweeteners by certain segments of the population," but refused to draw conclusions about the implication of this. Initially, the panel intended to state bluntly that no benefits existed, but "members said that as the report proceeded through drafts the conclusions were

⁷³Saccharin Study and Labeling Act, P.L. No. 95-203, 91 Stat. 1451 (1977).

⁷⁴National Academy of Medicine, Institute of Medicine, Committee for a Study of Saccharin and Food Safety Policy, Saccharin: Technical Assessment of Risks and Benefits. Report of Panel I, November 1978, p. xi, 3. Food Safety Policy: Scientific and Societal Considerations. Report of Panel II, March 1979.

toned down to read 'there are no studies that permit an objective assessment of asserted health benefits.'⁷⁵

"The NAS has not given us one whit of additional help on the policy problems," a staff member on the Senate Subcommittee on Health and Scientific Research fumed. The FDA took what comfort it could from the report, calling it objective and comprehensive, pulling from it those parts that supported its position. The American Diabetes Association also held to its original position, reiterating "we plan no change in our advice on the use of saccharin by diabetic persons.... When compared to the risks from cigarettes, coffee drinking, and other common habits, the risk from saccharin is small." Ronald Kalkoff, an endocrinologist who chaired the ADA panel on saccharin and sat on the NAS panel, continued, "It does affect the quality of life for diabetics, particularly teenagers who get peer pressure to consume common foods."⁷⁶

In a letter to HEW Secretary Joseph A. Califano, Jr., NAS President, Dr. Philip Handler, summed up the basic indecision of the panel: They had concluded that 'there is a risk of a risk.'"[emphasis added]⁷⁷ Hardly the answer that FDA wanted. The differences among the participants resulted from seriously differing value systems. Those who saw the issues of food safety as numerous and complicated found it unreasonable to expect the average consumer to be able to make informed

⁷⁵Saccharin: Technical Assessment, ES-7.

⁷⁶"NAS Saccharin Report," Science, 852-3.

⁷⁷Letter from National Academy of Sciences President Philip Handler to Secretary of Health, Education, and Welfare, Joseph A. Califano, Jr., February 28, 1979, p. 1.

choices, even with labeling and logos. In their view, government had to insure maximum safety--an approach exemplified by the Delaney clause. Other panelists took the opposite approach--that consumers should be given clear warnings and then allowed a free choice when the danger did not prove excessive.

Some panelists would give agencies little discretion over additives. Other participants, emphasizing the intricate nature of the problem and the rapid changes occurring in science, favored allowing agencies to operate in the broad context of well-defined principles, while assuring greater participation of the public in agency deliberations.⁷⁸

The second part of the report, appearing on March 1, 1979, recommended that FDA institute "a single policy applicable to all foodstuffs, food additives, and food contaminants and that the public official responsible for implementation of that policy be given sufficient flexibility to factor risks, benefits, and other considerations into account when making a decision."⁷⁹

The apparent unanimity in deriving the general principles on which the Food and Drug Administration should regulate the food supply evaporated on the specifics of saccharin. The panel enumerated FDA's options from total ban to total availability, neither of which they thought advisable. "All committee members believe it desirable for the FDA to take steps to educate users as to saccharin's risks and to encourage the search for alternative non-nutritive sweeteners." The committee did not see

⁷⁸National Academy of Sciences/Institute Of Medicine, Food Safety Policy: Scientific and Societal Consideration, Part II, March 1, 1979, 9-3 to 9-6. Cited hereafter as NAS/IOM, Food Safety Policy.

⁷⁹Letter from Handler to Califano, p. 2.

consideration of saccharin as an individual item by Congress as either efficient or likely to contribute to sound regulatory policy.⁸⁰

In the conclusion of his letter to HEW Secretary Califano, Dr. Handler returned to the idea that risk is intrinsically a political decision, based on scientific facts. "I am pleased that this report makes evident that the three dozen individuals who served on the overall committee and its two principle panels were a microcosm of the American public. The issues stand revealed; decision can be made only by the political process." As the panel's recommendations demonstrated, even a political forum can not always derive the solution to a question of risk.⁸¹

FDA Commissioner Kennedy expressed a natural reluctance to 'play God' in regulating the nation's food supply, observing that "historically, the FDA has functioned primarily as a cop. If it finds that chemicals in food--additives, contaminants or natural ingredients--are a hazard to health, it restricts or bans them no matter what their benefits. That's quite different from acting like a judge, weighing the degree of danger and balancing it against benefits." Agency officials would have liked authority to weigh the health benefits of a substance, but shied away from the policy implications of taking into account costs or public preferences. Those questions involved political choices for Congress to decide.⁸²

The public had looked to Congress, which in turn had looked to science.

⁸⁰NAS/IOM, Food Safety Policy, 10-6.

⁸¹Letter from National Academy of Sciences President Philip Handler to Secretary of Health, Education, and Welfare, Joseph A. Califano, Jr., February 28, 1979, p. 3.

⁸²New York Times, March 11, 1979, IV, 20.

When science did not provide a clear answer, Congress listened to its constituents, as it had done before with vitamins, and acted in accordance with what it discerned to be the majority sentiment. The Saccharin Study and Labeling Act expired on May 23, 1979. Congress extended the moratorium for two years and has continued to do so ever since. The initial rationale for the moratorium was to permit an independent scientific panel to review the safety and benefits of saccharin. The extension of the moratorium reflected both public demand for saccharin and congressional unwillingness to go on record as favoring a permanent exemption from the general food safety law for this confirmed animal carcinogen.⁸³

Congress chose to make saccharin a specific and limited exception. Both Senator Kennedy and Representative Henry Waxman (D-Calif), who had replaced Representative Rogers on the House Committee on Interstate and Foreign Commerce, indicated that they would make only minor changes to the food laws and would not tamper with the Delaney Clause. It is doubtful if Waxman could have accomplished this in the House, even had he chosen to do so. Any changes in the Clause would have to get past the Chairman of the powerful House Rules Committee,

⁸³Cooper, "Of Saccharin and Democracy, p. 49 footnote 52. The original moratorium expired May 23, 1979. Because Congress had not enacted an extension, FDA was free to resume proceedings to ban saccharin, but waited for a congressional decision before doing so even though this was technically a violation of the Delaney Clause. Congress passed P.L. 96-273, which permitted the use of saccharin in soft drink and diet food for two years. P.L. 97-42 extended the moratorium for through 1983, P.L.98-22 until 1985, P.L. 99-36 through May 1, 1987. The Congress then added five years to the ban by enacting P.L. 100-71. Extensions were passed either by voice vote or by overwhelming majorities on all occasions. The extensions do not entirely prevent FDA from taking action against saccharin but only bar the agency from taking actions based on research findings from before 1978. If new evidence of health risks are discovered, FDA has authority to ban the use of the sweetener.

James J. Delaney. And to those with the temerity to tamper with his law, Delaney provided the perfect rejoinder: 'Are you for a little bit of cancer?'"⁸⁴

Former FDA General Counsel Richard Cooper reflecting on the saccharin controversy concluded that the outcome probably would not have been different even if FDA had explained its reasons for removing saccharin more clearly. "A political system as sensitive to popular wishes as ours could not function as effectively as ours does if on issues where public opinion is as clearcut as it was on saccharin that opinion is disregarded as having been created somehow illegitimately." Congress was performing its appropriate political role. For Cooper, the saccharin case taught that public opinion "sets limits to how far zealous protection of the public health can, or should, go."⁸⁵

The FDA had been willing to concede these limits for a product that presented an inconclusive public health threat, such as saccharin or vitamins, but not in situations involving significant public health threats or where its regulatory powers to protect the public would be compromised. In the midst of the storm over saccharin, the FDA faced a challenge on laetrile, the alleged cancer cure, that produced an emotional response equal to, if not surpassing, that of the sweetener. In the case of saccharin, FDA made its case to the public and Congress and then capitulated gracefully, salvaging what it could when the tide of public opinion ran against it. However, FDA refused to surrender on laetrile. It could not allow the use of laetrile without undermining its regulatory existence and the hard fought efficacy

⁸⁴US News & World Report, 82 (March 21, 1977): 49.

⁸⁵Cooper, 62.

requirements of the Kefauver-Harris Amendments.

The FDA had declared the sale of laetrile, a compound derived from apricot pits, to be in direct violation of FDA law pertaining to the status of new drugs, thus prohibiting its shipment in interstate commerce. Saccharin supporters and laetrile proponents had both been outraged by the Food and Drug Administration's actions in their respective cases and resorted to freedom of choice arguments. However, most saccharin users saw FDA's decision as merely arbitrary and unnecessary while laetrile's supporters saw the action as part of a larger, orchestrated effort by the government to destroy American liberty.

Conservative political critics joined with health advocates and laetrile spokespersons in declaring that patients had the right to choose their own form of cancer therapy without interference from the medical community or the government. The drug became a cause celebre for politically conservative groups, such as the John Birch Society, which bankrolled the Committee for Freedom of Choice in Cancer Therapy, the leading advocacy organization. Many of laetrile's most active lobbyists were part of a broader right-wing reaction against the liberal, regulatory "excesses" of the 1960s. They opposed all types of governmental interference in the actions of individuals, including seat belts and fluoridated water.

Laetrile proponents generally adhered to a naturopathic philosophy of health. In this view, disease affects the whole organism and has its origins in a perturbation of natural harmony. Emphasizing the responsibility of the patient for his or her own health, adherents prescribed a healthful lifestyle, with an emphasis on nutrition and personal health practices. Modern medicine and the importance of the physician

were downplayed. The charges of the cancer medical establishment, the pharmaceutical industry, and the FDA that laetrile was a 'hoax' or fraud would have little influence on those who accepted this view of health and medicine.⁸⁶

Laetrile attracted mainstream news coverage when popular actor Steve McQueen developed cancer, wanted to use laetrile, and was forced to go to Mexico to receive treatments. Newsweek made it the cover story of its June 27, 1977 issue and conservative syndicated columnist, James J. Kilpatrick, extolled the virtues of laetrile in his column on seven separate occasions.⁸⁷ The 'freedom of choice' issue became the single most effective argument that laetrile proponents used in pressing their case in the courts, the state legislatures, and the media. But proponents also benefitted from the disillusionment with medical, scientific, and governmental authority in the 1970s. A behavioral survey sponsored by the FDA and other federal agencies revealed that 42% of American adults would not be persuaded by almost unanimous expert opinion that an unorthodox "cancer cure" held out false hope.⁸⁸

Public pressure caused both houses of Congress to hold hearings on the matter. At Senator Edward M. Kennedy's July 12, 1977 hearings, laetrile supporter

⁸⁶Gerald E. Markle and James C. Petersen, "Social Context of the Laetrile Phenomenon," in Gerald E. Markle and James C. Petersen, eds., Politics, Science, and Cancer: The Laetrile Phenomenon, (American Association for the Advancement of Science, AAAS Symposia Series, 1980), p. 154.

⁸⁷Newsweek, (June 27, 1977): 48-56. James J. Kilpatrick's columns appeared on August 21, 1975; February 10, 1976; April 1, 1976; May 13, 1976; April 19, 1977; December 8, 1976; February 9, 1978.

⁸⁸James Harvey Young, "Laetrile in Historical Perspective," in Gerald E. Markle and James C. Petersen, eds., Politics, Science, and Cancer: The Laetrile Phenomenon, (American Association for the Advancement of Science, AAAS Symposia Series, 1980), 39.

Robert Bradford said, "The FDA MUST get off the backs of physicians, cancer patients, and ourselves. What, in the name of humanity, is this agency doing? Whom does it represent? Surely, not the people.... How is it possible that at a time when our nation is flooded with heroin, cocaine, uppers and downers, and is literally awash in marijuana, the federal government sees fit to expend millions and millions of dollars of taxpayer funds to suppress the extract of apricot kernels? Where is the logic? Where is the morality?" Although Congress held hearings, it chose not to intervene as it had done with saccharin or vitamins. Allowing the use of a substance that had shown no scientific evidence of efficacy to treat a possibly fatal disease like cancer had the potential for undoing all regulatory requirements for drugs. The Congress was not prepared to take that step.⁸⁹

Commissioner Donald Kennedy met the 'freedom of choice' argument head on, contending that it was a slogan used to promote "a cynical and cruel hoax." Congress had decided by enacting the food and drug laws "that the absolute freedom to choose an ineffective drug was properly surrendered in exchange for the freedom from the danger to each person's health and well-being from the sale and use of worthless drugs."⁹⁰

The FDA refused to acknowledge any anecdotal evidence of laetrile's value. To legalize laetrile with no objective evidence of its usefulness in curing cancer would

⁸⁹Congress, Senate, Subcommittee on Health and Scientific Research of the Committee on Human Resources, Banning of the Drug Laetrile from Interstate Commerce by the FDA: Hearings Before the Subcommittee on Health and Scientific Research of the Committee on Human Resources, 95th Cong., 1st sess., July 12, 1977, 272-274.

⁹⁰James Harvey Young, 32.

initiate "a remission of standards that take us back to the 'snake oil' days." Later, as evidence of laetrile toxicity began to appear, FDA used this information to counter-balance pro-laetrile arguments. As FDA's Dr. Robert Temple noted, "for the public the lack of effectiveness simply fails to generate an emotional response equal to the fear of cancer....Surprisingly, the small but growing body of evidence that laetrile is harmful is proving as powerful a public argument as that it is useless."⁹¹

Proponents of laetrile used every avenue open to them to get around the FDA prohibition against interstate shipment of the drug. Proponents pressured state legislatures to approve the use of laetrile within their states and by the summer of 1979, 21 states had enacted such legislation. (Many of the legislators hoped that they could please their constituents by passing the law, and then have their state Health Department rule against its use).⁹²

In each state a similar scenario ensued. A cooperative assemblyman introduced the bill. Hearings followed, replete with the anguished drama of those facing a dread disease. TV cameras recorded the events, which were also widely reported in the press. "In news coverage, unorthodoxy--the underdog, the challenger, received the greater play."⁹³ The FDA was specifically prohibited by law against lobbying on state legislative actions, but FDA officials could testify at legislative hearings. Moreover, on an informal level, the FDA encouraged its supporters to take

⁹¹F-D-C Reports, December 19, 1977, p. T&G 10.

⁹²Department of Health, Education, and Welfare. *Final Report of the Review Panel on New Drug Regulation* (Dorsen Report). May 1977, 61.

⁹³ James Harvey Young, 28.

the more general political implications of this issue seriously and act accordingly.⁹⁴

Well-funded pro-laetrile organizations made use of the courts, both in claiming that laetrile was not a 'new drug' within the meaning of the FD&C Act and by initiating a class action suit on behalf of cancer victims and their spouses.⁹⁵ In *Rutherford v. United States*, District Court Judge Luther Bohanon decreed that the federal government was immediately to cease interfering with the use or transportation of laetrile. "By denying the right to use a non-toxic substance in connection with one's own personal health care, FDA has offended the constitutional right of privacy." The U.S. Court of Appeals for the Tenth Circuit recognized FDA's broad discretion to determine a drug's status, but ruled that it must present substantial evidence to classify it as a new drug. It required FDA to compile an administrative record to determine if it was a "new drug" as defined by law and whether it had been exempted from pre-marketing approval by reason of being "grandfathered."⁹⁶ To meet the requirements of the court, the FDA invited written comments and held a public hearing on May 2-3, 1977 at Kansas City. Based on the information received, FDA published a Commissioner's decision on laetrile ruling that distribution of laetrile in

⁹⁴Robert F. Rich, "The Political Implications of Laetrile: Who Gets What, When and How" in Gerald E. Markle and James C. Petersen, eds., Politics, Science, and Cancer: The Laetrile Phenomenon, (American Association for the Advancement of Science, AAAS Symposia Series, 1980), 77.

⁹⁵*Rutherford v. United States*, 424 F. Supp. 105 (W.D. Okla. 1977). *Gadler v. United States*, 425 F. Supp. 244, 246 (D. Minn. 1977).

⁹⁶*Rutherford v. United States*, 452 F.2d 1137 (10th Cir. 1976) and the order of the District Court in *Rutherford v. United States*, 424 F. Supp. 105 (W.D. Okla. 1977). Patients that had affidavits from their physicians that they were terminally ill may obtain laetrile through importation or interstate transportation.

published a Commissioner's decision on laetrile ruling that distribution of laetrile in interstate commerce is in violation of the Federal Food, Drug, and Cosmetic Act and subject to regulatory action.⁹⁷

But the matter did not end there. The FDA appealed the case to the United States Supreme Court on a petition for a writ of certiorari. On June 18, 1979, a unanimous Supreme Court reversed the 10th District, holding that the safety and effectiveness standards in the FD&C Act do apply in this case. The court reasoned that even terminally ill patients have an interest in drugs that are safe and effective.⁹⁸

Greater openness, public participation, public pressure, congressional involvement--all now accepted practices at the FDA--went just so far. When it came to the principles on which the FDA had been established and the foundations of laws on which it had built its regulations and rulings, some challenges were not negotiable. Even Congress had seemed to agree with this. If the evidence of immediate danger to users of saccharin had been available, there would have been no question of its removal--no matter what the outcry from suffering diabetics or dieters who would now be dependent on will power. But in intervening on saccharin, Congress had not questioned the FDA's basic authority to regulate drugs.

The laetrile problem was different. If Congress or the FDA allowed the use of an unproven drug with no efficacy data as a sympathetic gesture to desperately-ill

⁹⁷FDA Administrative Record, Laetrile, Docket No. 77N-0048. Food and Drug Administration. "Laetrile: Commissioner's Decision," 42 Federal Register, August 5, 1977, pp. 39768-39806.

⁹⁸United States v. Rutherford, No. 78-605. 442 U.S. at 555-57.

cancer patients, what would stop any other group of suffering patients from demanding to use an untested product. Once the battlements of FDA law had been breached, the entire edifice would eventually crash down. Neither the FDA, nor the Congress, nor the majority of Americans wanted to see this happen.

As can be seen from both saccharin and laetrile, the neat dichotomy of consumers on one side and FDA/industry on the other does not do justice to the complexity of public involvement in FDA decision-making. The more complex the issue, the more likely it was to emphasize internal divisions behind the solid facade of 'the industry position' or to demonstrate that medical and industry objectives did not necessarily correspond, or highlight the volatility of public opinion. A seemingly simple idea--providing information to patients about the drugs they consumed--provides a casebook study of the difficulties of meshing the demands, the philosophical positions, and the needs of consumers, physicians, pharmaceutical manufacturers, wholesalers, pharmacists, and hospitals.

CHAPTER 8

"THE MYSTERIOUS PILL BOTTLES IN THE MEDICINE CABINET"

By changing only a few words in the ancient ethical statutes of the Royal College of Physicians, it would now read: "physicians should tell patients about the medicines which are prescribed them, particularly the potent ones, lest, by not knowing, the patients harm themselves."¹

Countless patients have handed a prescription to their neighborhood pharmacist incredulously inquiring, "How do you read that scrawl?" Even if they had been able to decipher the physician's illegible handwriting, they would still be faced with the effects of an old medieval maxim that dictated "in the presence of the patient, Latin is the language." For centuries the ethics of the medical profession discouraged the disclosure of drug information to patients. The 1647 version of the Code of Ethics of Royal College of Physicians warned "let no physician teach the people about medicines, or even tell them the names of the medicines, particularly the more potent ones, such as purgatives, opiates, narcotics, abortifacients, emetics or any other which are particularly dangerous, for the people may be harmed by their improper use. This under penalty of forty shillings." The arcane and mysterious world of the alchemist, the chemist, and the pharmacist remained closed to the layperson.²

More than three hundred years later, the situation remained essentially as it

¹Albert Jonsen, "Medical Ethicist Perspective," in "Patient Package Inserts: Content and Format," Proceedings of the Conference Sponsored by the Food and Drug Administration, Washington, D.C., December 11-12, 1978. Docket No. 79N-0186, vol. 2, Food and Drug Administration.

²Statuta Collegii Medicorum Londonii Caput 22 de conversatione morali in C. Clark, The History of the Royal College of Physicians (Oxford, England: The Clarendon Press, 1964).

had been in the seventeenth century. The doctor told the patient only the information he deemed necessary, usually something on the order of "take two of these and call me in the morning." The pharmacist both by custom and law was forbidden to dispense medical information and thus could only refer the patient back to the doctor. Few medical sources existed for the general public and few availed themselves of those which were available. In the more trusting atmosphere before the 1960s, most people put their faith in their doctors and asked few questions.

The proposal to provide patient package inserts, written information given directly to the consumer by the manufacturer, grew out of the same set of forces that repeatedly confronted the FDA in the 1970s. Reassured by changes in the medical establishment that they had a "right to know" about their illness and a voice in its treatment, worried about the state of its health, and educated by the consumer movement to demand a responsive government, the public that had demanded food labeling laws and truth in advertising wanted more information about those little pill bottles that filled the bathroom medicine cabinet.

Paradoxically, products as potentially hazardous as prescription medications were often dispensed with little more than a "use as directed" label, whereas over-the-counter medications such as aspirins or antihistamines contained extensive usage labeling. Even simple surgical procedures, often posing less serious risks to the patient, routinely required explanatory patient consent forms. But the patient receiving a prescription for a drug that could produce severe adverse reactions and whose usage might entail complex risk/benefit considerations often received little or no information on which to make this decision either from the doctor or the

manufacturer.

Before 1906, the absence of regulations requiring manufacturers to disclose the contents of their medicines effectively kept the public in the dark about nostrums with enticing names, like Hedakecure or Sooth the Baby. Muckraker Samuel Hopkins Adams' Collier's magazine articles on the patent medicine industry, 'The Great American Fraud,' attempted to enlighten the public. The stories exemplified the progressive era belief in expose and education as a precursor to reform. "Gullible Americans will spend this year some seventy-five millions of dollars on the purchase of patent medicines. In consideration of this sum it will swallow huge quantities of alcohol, an appalling amount of opiates and narcotics, a wide assortment of varied drugs.... and far in excess of all other ingredients, undiluted fraud." Ignorance was not bliss. Many a woman became an opiate addict after complaining about real physical problems to a doctor, who taking her complaints for nervousness or hysterics, gave her a prescription for laudanum, a form of opium, to calm her.³

The passage of the 1906 Pure Food and Drug Act, banning misbranded and adulterated food and drugs from interstate commerce, seemed a step forward. However, in *United States v. Johnson*, the Supreme Court ruled that the 1906 law did not prohibit false therapeutic claims but only false and misleading statements about the ingredients or identity of a drug. Congress enacted the Sherley Amendment in response to the Court ruling. But it undermined the Amendment's effectiveness by requiring the prosecution to prove that the promoter of a worthless drug had

³James Harvey Young, Pure Food: Securing the Federal Food and Drugs Act of 1906 (New Jersey: Princeton University Press, 1989), 201.

deliberately lied in order to defraud the public, a fact almost impossible to establish in most cases.⁴

The 1938 Federal Food, Drug, and Cosmetic Act substantially expanded the federal labeling requirements for drugs to include directions for use, indications, and contraindications. The law exempted two groups of drugs from labeling with 'adequate directions': 1) those whose common uses were known to the ordinary individual, such as aspirin, and 2) those drugs and devices identified with what came to be called the Rx Legend, "Caution: to be used only by or on the prescription of a (physician, dentist, or veterinarian.)" Significantly, any information with respect to the uses of Rx Legend drugs were required to appear "only in such medical terms as are not likely to be understood by the ordinary individual."⁵

Thus the FDA attempted, for the first time, to restrict to professional channels certain medical products deemed to be unsafe for lay use. In its 1939 annual report, FDA indicated its policy: "Many drugs of great value to the physician are dangerous in the hands of those unskilled in the uses of drugs." The FDA warned that drugs of this sort must be marked conspicuously so that they would not end up in over-the-counter sales. Pharmacists became legally liable for selling a 'legend' drug without a bona fide prescription.⁶

The thousands of new drug products developed by the pharmaceutical industry

⁴Wallace Janssen, "Outline of the History of U.S. Drug Regulation and Labeling," Food, Drug, Cosmetic Law Journal 36 (1981): 428.

⁵Ibid., 431.

⁶Food and Drug Administration, Annual Report, 1939, (Washington, DC: GPO, 1940).

after World War II presented problems for pharmacists, who found it difficult to distinguish between legend and over-the-counter drugs. They appealed to Senator Hubert H. Humphrey of Minnesota, a former pharmacist, to sponsor clarifying legislation. The Durham-Humphrey Amendment of 1951 supplied the long-needed statutory distinctions between prescription drugs and over-the-counter (OTC) products. To protect the consumer, labeling for OTC products had to include the name of the product, net contents, and active ingredients. It also had to specify adequate directions for use, identify any habit-forming ingredients, and have simple cautionary warnings: 'Do not drive or operate machinery when taking this drug,' or 'If pain persists for more than 10 days consult a physician.'

However, if the drug was too dangerous for self-use, or required extraordinary means for administration, such as a parenteral injection, or was used for a disease that the patient could not be expected to treat himself, then the law restricted dispensing to prescription use only and relieved the manufacturer of providing patient labeling. Instead, for these prescription drugs, the manufacturer had only to make information available to the prescriber. The physician or dentist in turn used his discretion in deciding what information, if any, he conveyed to the patient.⁷

The label on the bottle of pills or tube of ointment that the pharmacist handed to the patient contained only the dispenser's name and address, the name of the prescriber, and the number and date of the prescription. Since the pill bottle did not even include the name of the drug, millions of American medicine cabinets were

⁷Durham-Humphrey Amendments, P.L. No. 82-215, 65 Stat. 648 (1951).

crammed with mysterious bottles and tubes of medicine from long forgotten illnesses.⁸

The Durham-Humphrey law codified into federal law the medical professional's right to prescribe drugs and the pharmaceutical professional's responsibility as the licensed custodians of drugs for the community. In the days before an army of involved consumer activists, this law, which affected every person in the United States who needed a prescription, passed with little public notice and virtually no press coverage.

Under provisions of the new drug labeling law, the FDA now had the legal authority to require that each prescription drug package include professional information. But the FDA medical staff expressed reluctance to initiate this practice "fearing that physician information in the package could end up in the hands of the lay public and encourage dangerous self-treatment." (Although it was unlikely, either the doctor or the pharmacist might give the package insert to the patient.) They also argued that package labeling could not provide complete information or be kept up-to-date. Instead, the FDA chose to assume that practitioners would keep themselves apprised of drug developments through their professional journals and medical texts, therefore making the insert unnecessary.⁹

The situation remained unchanged until passage of the 1962 Kefauver-Harris

⁸William M. Heller of the U.S. Pharmacopeial Convention in J. Alexander Murray, Pharmaceuticals in North America: The Public Interest. Institute for Canadian-American Studies, 22 (1980): 82. Changes in the law in the 1980s gave pharmacists greater latitude in discussing their medications with patients.

⁹Janssen, 430, 435.

Amendments. The new law transferred jurisdiction over medical advertising of prescription products from the Federal Trade Commission to the FDA. It required that advertising copy and all sales literature include full information on adverse effects and contraindications to provide a balanced picture. The new law required that the most vital, up-to-date information about a prescription drug appear in its labeling, which included a package insert.¹⁰

The new law reflected the pre-eminent place of pharmaceuticals in the treatment of an extraordinarily broad range of diseases in the postwar years. The 1940s and 1950s witnessed the beginning of a revolution in pharmaceutical science that produced many of the so-called 'wonder' drugs. The drugs discovered since 1938--antibiotics, tranquilizers, vaccines, hormonal drugs, cortico-steroids, birth control pills, diuretics--represent some of the most important achievements in modern medicine.

Pharmacy shelves were crammed with thousands of these new drug products. While some of them deserved the approbation 'wonder drug,' others were merely slight chemical variations of existing pharmaceuticals, "me-too" drugs. The constant introduction of new products or new combinations of existing products changed the field of medicine so rapidly that textbooks and journals scarcely kept pace. Physicians became dependent for drug information on manufacturers' representative, usually called detail men, who passed out free samples, promotions, and glossy sales brochures that touted the benefits of their new products but minimized their hazards. Of course, full information could be obtained on request, but busy doctors often did

¹⁰Kefauver-Harris Amendments--PL 87-781 76 Stat. 780 (1962).

not ask and the companies did not offer. FDA feared that "the drug manufacturers were replacing the medical schools as the principal source of information for physicians in their use of new drugs"¹¹

The new FDA regulations provided the physician with a more objective evaluation of the drugs he prescribed--if he had the time or inclination to read the detailed package insert--but his patient was no closer to receiving information. The FDA still acceded to the medical profession's belief that access to this material would confuse and frighten the patient. Until the late 1960s, "both doctor and patient accepted the authoritarian curative role of the physician as the appropriate avenue of health."¹²

As the only emissaries from the distant world of science that most people ordinarily encountered, doctors held a singular place in the popular imagination. In nation-wide opinion polls conducted in 1947 and 1963, physician ranked as the second most desired job, next to Justice of the United States Supreme Court. But change was on the way. The first group to challenge the authority of doctors and the pharmaceutical industry was one of the prime beneficiaries of the pharmaceutical revolution.¹³

¹¹Janssen, 435.

¹²Preventive Medicine USA: Health Promotion and Consumer Health Education, A Task Force Report sponsored by The John E. Fogarty International Center for Advanced Study in the Health Sciences, National Institutes of Health and the American College of Preventive Medicine, (New York: Prodist, 1976), 7.

¹³Renee C. Fox, "Medicalization and Demedicalization," in Doing Better and Feeling Worse: Health in the United States, ed. John H. Knowles, M.D., (New York: W.W. Norton, 1977), 20.

Oral contraceptives, introduced in 1962 and commonly referred to as "the Pill" by the news media, seemed to be the answer to the need for a safe and effective means of birth control. Hailed as another example of the American pharmaceutical industry's prowess, the Pill promised to give women greater control over their reproductive lives. Soon, however, both physicians and women's groups began to hear anecdotal evidence about major complications associated with its use. To test the effectiveness of oral contraceptives in preventing pregnancy, oral contraceptive manufacturers had conducted clinical trials in Puerto Rico and Haiti in the 1950s on a relatively small number of women. Although researchers quickly documented what they termed "mild side effects"--nausea, headache, dizziness, weight gain--more than five years passed before reports of serious complications began to appear.

Several English reports of pulmonary embolisms (blood clots) and cerebral thrombosis (strokes), rare disorders in healthy young women, proved sufficiently alarming to cause the FDA to appoint a committee to study the problem. Although this committee and another two years later concluded the incidence of blood clots in pill users did not exceed that of non-users, reports continued to surface and to worry doctors and women's health groups.¹⁴

Concerned that neither the FDA, the manufacturers, nor most physicians gave adequate credence to the reported side effects of these powerful hormonal medications, women's health groups began to investigate the safety of oral contraceptives. Barbara Seaman opened Pandora's box when she published The

¹⁴Alfred Goodman Gilman, Goodman and Gilman's The Pharmacological Basis of Therapeutics, (NY: Macmillan, 1985), 1434.

Doctor's Case Against the Pill in 1969. Combining a review of the research literature with dramatic clinical narratives, Seaman presented evidence that linked the pill to a long list of diseases and medical conditions. She charged that physicians did not consider their patient's family medical histories before prescribing oral contraceptives nor did they informing them of the risks involved. FDA approval was no guaranty of safety or efficacy. "Oral contraceptive have passed through the FDA without being subjected to recognized standards of scientific experimentation for safety."¹⁵

For many women in the 1960s, especially feminists, the pedestal on which society had placed doctors had begun to crumble. They rebelled against the paternalistic attitude many doctors adopted towards their female patients. They argued that male-dominated medicine was sexist in its diagnosis, its treatment, and its very conception of female pathology.

Feminists protested against a medical profession that still subscribed to Victorian beliefs of female physical inferiority and Freudian views of female neuroses based on psychological taboos associated with reproduction and sexuality. The medical profession willingly accepted undocumented beliefs that dysmenorrhea, nausea in pregnancy, the pain of labor were all psychogenic disorders, caused or aggravated by women's 'temperament'. As a consequence, doctors routinely dismissed women's complaints and concerns as emotional with no 'real' physical

¹⁵Barbara Seamen, The Doctor's Case Against the Pill, (New York: Hunter House, 1969).

basis.¹⁶

Convinced that doctors purposely kept women ignorant about the workings of their body, especially its reproductive functions, feminists worked assiduously in the 1960s to remove the shroud of mystery reminiscent of a medieval guild from the practice of medicine. Feminist groups published books, such as the classic Our Bodies, Ourselves, organized self-help groups, and disseminated tracts on self-examination. Feminists took the position that the patient had a right to full disclosure of all pertinent facts about her health and treatment.¹⁷

Pressured by women's groups, Senator Gaylord Nelson began congressional hearings in March 1970 to investigate claims that women had not received information on which to make decisions about oral contraceptives. Because they would be taken by healthy young women for an indeterminately long period of time, the oral contraceptives presented special problems in terms of risk/benefit decision-making. Interrupting the hearings from the audience, Alice Wolfson, a civil rights

¹⁶Robert Crawford, "Individual Responsibility and Health Politics in the 1970s," in Health Care in America: Essays in Social History, ed. Susan Reverby and David Rosner, (Philadelphia: Temple University Press, 1979), 248. 25 years later, almost half of all medical students are female, universities have programs in women's health, and governments have offices of women's health. In 1994 and 1995 alone, women's health issues have been a focus of the International Year of the Family; the Cairo International Conference on Population and Development; the Copenhagen World Summit on Social Development; and the United Nations Fourth World Conference on Women in Beijing, China.

¹⁷The Boston Women's Health Book Collective, Our Bodies, Ourselves: A Book By and For Women, (New York: Simon and Schuster, 1971). Flora Davis. Moving the Mountain: The Women's Health Movement in America since 1960. New York: Simon and Schuster, 1991, p. 228-9. In one of the more memorable phrases of this period, Robin Morgan, advocating self-examination as a political act, intoned, "The speculum may well be mightier than the sword."

activist and member of the first 'women's group' in New York City, demanded to know why no women--even Seamen--were allowed to testify. TV cameras recorded the disruption as Seamen and other women joined the protest.¹⁸

At the time of the 1970 Senate Pill hearings, the FDA had no organized system for consumer input, and women's health activists knew of no direct way to affect the agency's decision-making process. Contacts with consumer-minded Congressional members provided some political access "if only [for] those women within the emerging movement who felt entitled to ask the government to address their needs (most often middle-class white women with political connections.)" Women's health advocates quickly learned that direct action and media involvement were means of capturing the public's attention.¹⁹

Midway through the Senate hearings, Newsweek published the results of a Gallup poll revealing that two-thirds of women taking the pill had never been warned by their doctors of any hazards. In response to this startling revelation, the Nelson hearings, and women activists like Barbara Seamen, the FDA announced plans for a warning to be attached to each package of oral contraceptives.²⁰

Commissioner Edwards, appearing before Senator Nelson's Committee, endorsed the use of patient package inserts (PPIs) for oral contraceptives, basing his

¹⁸Personal communication with Barbara Seamen.

¹⁹Cynthia Pearson, "National Women's Health Network, Women's Health Issues, and the Food and Drug Administration: Two Decades of Activism," Essay from National Women's Health Network, p. 2.

²⁰Silverman, Milton and Philip R. Lee, Pill, Profits, and Politics, (Berkeley, CA: University of California Press, 1974), 102.

arguments on the concept of 'patient consent.' As definite risks had already been associated with birth control pills, and alternative means of birth control existed, "patient preference rather than pure scientific and medical judgment may be the primary determinant. PPIs are a means to insure that women who desire to use this method are adequately informed."²¹

Senator Nelson called Edwards' announcement a "tremendously significant step" and said he was "courageous" for bucking "medical politics." This was not entirely accurate. Recognizing the unique properties of the birth control pills, Edwards pointed out that the FDA had no intention of extending the policy to other drugs, (though this did not preclude FDA from doing so in the future.)²²

The FDA may have been traversing new ground, but it did so gingerly, mindful of the minefield it had entered. It remained highly deferential to the needs of both the pharmaceutical industry and the medical community. While publicly stating that it "expected complete cooperation from manufacturers in the current atmosphere of public concern over the safety of OCs", the FDA allowed drug companies wide

²¹The first product to require patient inserts were isoproterenol inhalators used in the treatment of asthma. These inhalators intended to increase air passage flow paradoxically could produce the opposite effect (bronchoconstriction) if used improperly. In 1968, the FDA required manufacturers to include a brief two sentence warning informing patients not to exceed the prescribed dose. 33 Federal Register 8812 (1968). Because there was nothing controversial in either the warning or the usage, it received no publicity. The FDA also produced PPIs for insulin, which is self-administered. To use the medication properly and avoid reactions from either over or under-dosing, patients must be made aware of and understand a significant amount of information.

²²Congress, Senate, Select Committee on Small Business, Subcommittee on Monopoly, Competitive Problems in the Drug Industry, Pt. 15: Hearings before the Select Committee on Small Business, Subcommittee on Monopoly, 91st Cong., 2nd Sess., January 14, 15, 21-23, 1970.

latitude in both the design of the insert and the information included in it. In terms of the medical establishment, F-D-C Reports commented that the FDA "is particularly sensitive to interference with the MD-patient relationship, and will do all it can to remove the appearance that the patient insert is in any way replacing the information which a patient should get from her physician."²³

By early April, Edwards had already begun back-pedaling on the PPI concept in response to pressure from his superiors at HEW. As a result, the FDA revised the insert placing greater emphasis on the benefits of oral contraceptives than the sample which he had shown Senator Nelson during the hearings. Edwards reiterated FDA's position. "As a consumer protection agency, it was our judgment that we have a responsibility to warn these users of the risk involved and, at the same time, assist physicians in assuring their patients that Oral contraceptives can be used safely."[emphasis added]²⁴

FDA sought to resolve the insert controversy by developing a new approach--a lay language booklet, containing all the important available information, which would be distributed by doctors to their patients as a supplement to a short-form patient insert provided with the package. The FDA received over 800 comments after it published its proposed regulations in the April 10, 1970 Federal Register. In the final rule, FDA concluded "that many patients are not now receiving the needed information in an organized, comprehensive, understandable, and handy-for-future-

²³F-D-C Reports, February 23, 1970, pp. T&G 8-9.

²⁴F-D-C Reports, April 6, 1970, p. 26.

reference form." The safe use of birth control pills required this.²⁵

Cavalierly dismissing the need for a public hearing, which would only delay the implementation of the regulations, FDA concluded that all parties agreed on the need for information, so the only issue was how to provide this. The FDA had already determined that its booklet would be the best way, although there remained some questions about who would produce the insert.²⁶

Not until 1973 did the concept of inserts for all drugs begin to develop support within the FDA. By then the consumer movement had helped push through Congress new regulatory agencies, such as the Environmental Protection Agency and the Occupational Safety and Health Administration, as well as new or amended Freedom of Information and Advisory Committee laws. The FDA had also seen significant change under the tutelage of Edwards and Hutt. Consumers had made it clear that they wanted more information about the products they purchased.

The issues of access to medical information and control over medical decisions, first raised by feminists, began to filter into the mainstream during the 1970s, forcing many people to re-think their opinions about the medical establishment, their doctors, and health in general. The predominant thinking in the post World War II era had extolled the virtues of science and the growth of medical knowledge and technology. From modest postwar beginning, the United States built an immense medical establishment, funded in large part by government grants for research, hospital construction, medical training, and health care for the aged and

²⁵35 Federal Register April 10, 1970, p. ?.

²⁶F-D-C Reports, June 15, 1970, p. 17.

indigent. Federal spending alone on health increased from its minimal level of less than \$1 billion during World War II to \$50 billion by 1979. In 1950, funding for health expenditures accounted for 4% of total federal expenditures, increasing to 8.6% in 1970 and 12% in 1979.²⁷

Moreover, a process of 'medicalization' had enlarged the purview of the physician beyond its original scope of curing or ameliorating disease and illness. Birth and death were no longer natural occurrences, but medical situations requiring extensive professional intervention. "All kinds of problems now roll to the doctor's door," wrote Leon Kass, "from sagging anatomies to suicides, from unwanted childlessness to unwanted pregnancy, from marital difficulties to learning difficulties, from genetic counseling to drug addiction, from laziness to crime." Medicine came to be seen as a panacea for many of the problems facing American society.²⁸

Not only had medicine become big business, it became newsworthy. By the 1970s, most Americans had numerous sources from which to gather health information, according to a Yankelovich, Skelly, and White poll. While 45% reported their doctor and dentist as the main source of information, they also received news and facts from other sources--television programs (31%), columnists and articles in popular magazines (25%), voluntary health organizations (i.e. American Cancer Society) (16%), medical books and encyclopedias (14%), and popular books on health and diet (11%). Newspapers and popular magazines began to feature regular

²⁷Rosemary C.R. Taylor, "The Politics of Prevention," Social Policy, (Summer 1982): 32.

²⁸Leon R. Kass, "Regarding the End of Medicine and the Pursuit of Health," The Public Interest 40 (Summer 1975): 11.

medical columns in which the latest "breakthroughs" or warnings were analyzed.²⁹

The TV and radio industry depended on health or, more precisely on disease, for a large part of its sustenance, suggested physician and author Dr. Lewis Thomas in 1979. "Not just the primarily medical dramas--the Marcus Welbys and Dr. Kildares--but the illness or surgical episodes threaded through many of the non-medical stories in which the central human dilemma is illness." And perhaps exaggerating slightly he saw almost all the commercial announcements, in an average evening, as "pitches for items to restore failed health: things for stomach gas, constipation, headaches, nervousness, sleeplessness or sleepiness, arthritis, anemia, disquiet, and the despair of malodorousness, sweat, yellowed teeth, dandruff, furuncles, piles."³⁰

Americans heeded the message. By the end of the 1970s, they spent 11 cents of every dollar of personal after-tax income on medical care, compared to less than 5 cents 30 years before. An estimated 70 million individuals a year regularly used prescription or over-the-counter drugs. From 1950 to 1974 the average number of dispensed prescriptions rose from 2.4 to 6.6 per capita or approximately 1.7 billion written each year, with perhaps an additional billion prescriptions dispensed by hospital pharmacies.

This huge increase in the use of pharmaceuticals was attributable in part to new and more effective drug products, an aging population, wider health insurance coverage and access to health care services. Just as importantly, pharmaceutical

²⁹Yankelovich, Skelly, and White for General Mills, October, 1978. Roper Center for Public Opinion Research, the University of Connecticut, Storrs, Connecticut.

³⁰Lewis Thomas, The Medusa and the Snail: More Notes of A Biology Watcher (New York: Viking Press, 1979), 46.

houses aggressively marketed their new products to the medical profession through advertisements in leading medical journals and promotions and incentives offered by detail men. But Dr. Kenneth L. Melmon ascribed part of the over-prescribing to physicians who used the prescription pad as an effective 'termination strategy' and to patient who irrationally demanded a prescription.³¹

Many people found their lives improved and enhanced by these "wonder" drugs, but the magnitude of drug prescribing heightened concerns about the misuse or abuse of certain drugs, the occurrence of adverse reactions, and questionable prescribing practices. Antibiotics were often prescribed for trivial complaints or for viral infections, for which they were ineffective. Physicians over-prescribed psychoactive drugs, such as Valium and Librium because of the increased tendency to define social problems--anxiety, malaise, unhappiness--as medical problems.³²

Senator Edward M. Kennedy, in opening remarks at the 1974 Senate Health Subcommittee hearings remarked that the billions of dollars spent on prescription drugs often "went for drugs that were irrationally prescribed, and which in many instances, resulted not in a return to good health, but in the development of additional illness because of adverse drug reactions." Dr. Sidney Wolfe of the Health Research Group joined in the criticism, "The mystique of drug companies, doctors and hospitals

³¹Congress, House, Sub-Committee on Health and the Environment of the Committee on Interstate and Foreign Commerce, Drug Safety Amendments of 1976: Hearings Before the Sub-Committee on Health and the Environment of the Committee on Interstate and Foreign Commerce, 94th Cong., 2d Sess., March 20, March 30, April 1, 1976. 89, 217.

³²Institute of Medicine, Food and Drug Administration Advisory Committees, Richard A. Rettig, Laurence E. Earley, Richard A. Merrill, eds., (Washington, D.C.: National Academy Press, 1992), 17.

has begun to crumble. It is now known that billions of wasted dollars, hundreds of thousands of unnecessary hospitalizations for adverse drug reactions, and thousands of lives needlessly lost are the price society pays for the promotional excesses of the drug industry."³³

The medical profession also came in for its share of disquieting news. Commonly, people expressed great confidence in their own personal physicians, but had become more skeptical of medical authority in general. According to a Harris poll, the proportion of the public having a "great deal of confidence" in medicine declined to 42% in July 1976, down from 73% in 1966.³⁴

Realizing this distrust extended to them, the American Hospital Association (AHA) attacked the issue head-on with its Patient's Bill of Rights, published in 1973 after consultation with hospital administrators, physicians, and consumer representatives. Although not binding on its 7000 members, AHA President John A. McMahon, told a news conference that the Patient's Bill of Rights' "twelve points are subject areas that have always needed to be spelled out to the patient so that he would know what his rights are in the hospital setting." The Bill reflected the needs of a more educated and sophisticated public that demanded information and inclusion in discussions leading to treatment decisions.³⁵

"The right to obtain from his physician complete current information concerning

³³F-D-C Reports, March 4, 1974, p. 5.

³⁴Paul Starr, "Medicine and the Waning of Professional Sovereignty," Daedalus, 107 (Winter 1978): 177-8.

³⁵Historical Documents, 1973, (Washington, D.C.: Congressional Quarterly, 1974), 39.

his diagnosis and treatment in terms the patient can be reasonably expected to understand" followed directly upon the first and most basic right to considerate and respectful care.[Emphasis added] Patients also had the right "to receive from his physician information necessary to give informed consent prior to the start of any procedure and/or treatment," as well as information about the risks of treatment, of not accepting treatment, and alternative treatments. Responding to reports of widespread abuse, the AHA further recommended that a patient had the right to refuse to participate in medical experiments.³⁶

As Americans heard stories about hospital abuses, misuse of drugs, or the rising problems of malpractice, little tendrils of doubt began to creep into the garden of certainty that the medical establishment had so carefully tended. The growing realization that modern pharmaceuticals and medicine had the potential to harm as well as heal piqued a new interest in medical issues. "It is obvious to the physician who is in contact with reality that the era of drug therapy surrounded by a cloud of mystery and patient ignorance is fast disappearing," wrote Drs. Pieter Joubert and Louis Lasagna. "More and more, patients want to know what is wrong with them, what is being done about it, and why; and what the relative risks and benefits of treatment are."³⁷

But before the public could get this information, the FDA needed to change both its attitude and its regulations. A change in the top leadership appeared

³⁶Ibid., 41-2.

³⁷Pieter Joubert and Louis Lasagna, "Patient package inserts. 1. Nature, notions, and needs," Clinical Pharmacology and Therapeutics, 18 (November, 1975): 507.

auspicious for the future of patient package inserts and citizen involvement. After taking office in 1973, the new Commissioner, Dr. Alexander M. Schmidt endorsed patient package inserts as a means for obtaining 'informed patient consent' and indicated his support for FDA's decision on patient inserts in contraceptives. Although acknowledging the controversial nature of the inserts, Schmidt saw the need for information on drugs used to treat chronic diseases. In the course of therapy, additional medical problems often resulted from the long-term use of these drugs. "The patient has an absolute need, not to say a right, to know what these problems might be and if, in fact, he's willing to accept the risk. A good PPI may be the best vehicle for information needed by the arthritic, the diabetic, the psoriatic, and other chronically ill patients."³⁸

Schmidt committed the FDA to exploring the issue of PPIs through the participation of concerned interests. Consumer and patient education advocates had already endorsed the 'right-to-know' principle for all prescription drugs. In August 1973, the Consumer Federation of America (CFA) convention indicated its support for the inclusion of "written information understandable to the consumer" with each prescription. They proposed that an insert "include uses, directions, precautions, and side effects, and also the possible hazard of mixing the prescribed medication with other drugs or food." CFA support was important because the group had 'muscle' in Washington and was known as an old-guard consumer organizations whose

³⁸FDA Commissioner Alexander M. Schmidt, "Dimensions of Change in the FDA," Paper presented at the Pharmaceutical Advertising Seminar, Chicago, Ill., September 17, 1973.

democratic procedures and federation structure barred "shooting from the hip."³⁹

In 1974 the National Food and Drug Advisory Committee, which the FDA used as a sounding board for issues of importance to the public, urged the agency to establish a "Patient Prescription Drug Labeling Project" to explore the prospects and problems involved in a general PPI requirement. The FDA accepted its recommendation and chose Dr. Vincent J Gagliardi, Special Assistant to the Director, Office of Scientific Evaluation to chair a series of meetings with industry, medical, and consumer groups.

In a meeting with the National Association of Retail Druggists on September 11, 1974, William E. Woods, Associate General Counsel, asked if any particular group, for example, drug manufacturers, had pushed the program. Pointing out that PPIs were an FDA-generated activity, Dr. Gagliardi advised them "that the Commissioner had decided to go ahead with the program based upon the Oral Contraceptive precedent.... as well as general input from consumers and an awareness of growing interest in patient education throughout the country."

Mr. Woods concerns centered, of course, on the burden that PPIs would place on retail pharmacists. He reported that his members had not indicated any great demand by patients for drug information, adding "pharmacist-employees are paid an average of \$9.00 per hour and you could not expect them to spend 20-30 minutes explaining things to one patient after a \$2.00 or \$3.00 prescription." Dr. Gagliardi

³⁹Department of Health, Education, and Welfare, Food and Drug Administration, Annual Report 1973, (Washington, D.C.: GPO, 1974), 37. In March 1973, the FDA had received the results of its own survey that reported that nearly half the respondents believed that the inserts should be included with all over-the-counter and prescription drugs. F-D-C Reports, August 20, 1973, p. T&G 2.

explained that FDA's position called for concentrating on maintenance drugs that are frequently refilled and therefore, the pharmacist would not be involved with each purchase.⁴⁰

The Pharmaceutical Manufacturers Association, meeting with Dr. Gagliardi on September 18, 1974, expressed its concerns about liability. In recent years the courts had adopted the concept of strict liability, by which a producer was legally liable for personal injury to a consumer, without regard to negligent conduct, if the injury followed the normal and reasonable use of the product. In the PMA's opinion, 'full disclosure' would not be in the best interests of all patients, yet companies would be in a poor medico-legal position if they did not include a particular side effect about which a patient later sued. In product liability cases drug manufacturers had to prove by expert testimony that warnings given were meaningful and adequate. But, the PMA asked, would any patient feel "adequately" warned if injured by a rare side effect that had not been described in the PPI? In a society that had become increasingly litigious, where jury awards in medical malpractice cases had risen to astronomical figures, this was no small consideration.⁴¹

FDA undertook to assure the PMA that selection of material and disclosure would probably rest with physician groups thus maintaining the industry's liability at its present level. Satisfied for the time being with this explanation, the PMA indicated

⁴⁰Memorandum from Vincent J. Gagliardi, Report of meeting with National Association of Retail Druggists concerning "Prescription Drug Labeling for Patients," October 10, 1974. Food and Drug Administration.

⁴¹Memorandum from Vincent J. Gagliardi, Report of meeting with Pharmaceutical Manufacturers Association concerning "Prescription Drug Labeling for Patients," September 18, 1974. Food and Drug Administration.

its willingness to work with the FDA and print the inserts. From its perspective, the fate of the inserts rested solely in the hands of the two professional organizations whose expertise fitted them to the task, the PMA and the AMA--and of course, the FDA. The consumers' needs and perceptions did not appear in the PMA's calculations.⁴²

The American Medical Association insisted on the need "to protect the physician's right to professional judgment," during its meeting with Dr. Gagliardi and his staff on October 9th. "It is inappropriate to expect that the patient can make a better judgment on the basis of the limited information made available in a package insert." With the reservation in mind, the AMA offered its cooperation, "recognizing the time has come" for PPIs.

Echoing the PMA's position, the AMA saw no need for any input from patients or consumer groups. A process of professionalization which had begun at the beginning of the twentieth century had given greater and greater control over medical treatment to those who bore the proper credentials. Until the 1970s, groups such as the AMA had been successful in their attempts to exclude the lay public from participation in the medical decision-making process. But a more assertive public had begun to challenge this medical exclusivity.⁴³

Although the FDA had clearly indicated its interest in exploring the possibilities

⁴²Memorandum from Vincent J. Gagliardi, Report of meeting with Pharmaceutical Manufacturers Association concerning "Prescription Drug Labeling for Patients," September 18, 1974. Food and Drug Administration.

⁴³Memorandum from Vincent J. Gagliardi, Report of meeting with American Medical Association concerning "Prescription Drug Labeling for Patients," October 24, 1974. Food and Drug Administration.

for patient labeling, consumer advocates and women's groups found the slow progress and lack of tangible results unacceptable. Losing patience with FDA foot-dragging, the Center for Law and Social Policy, a public interest law firm, filed a petition on March 31, 1975 on behalf of a consortium of consumer and women's groups formally requesting that the FDA require more adequate labeling of prescription drugs. Consumers Union, Consumer Action for Improved Food and Drugs, the National Organization for Women, Women's Equity Action League, and the Women's Legal Defense Fund, parties to the petition, contended that many patients received little counseling from their physicians about the drugs they took. Many people, especially those in poor neighborhoods, got their medical care in crowded, busy clinics where explanations or warnings may not be given at all.

The petitioners suggested that physicians may neglect to provide all the necessary information or the patient may not understand the information and be too shy or embarrassed to ask for clarification. At times "the patient is so tense, so overwhelmed with the other information he has been given during the physician's talk about his illness that he can't completely absorb even careful explanations." Later when he or she takes the prescription bottles home from the pharmacist, it is difficult enough to remember what they were for and how often to take them, without trying to remember which one causes dizziness and which one should not be taken with milk. Even patients that retained the information initially might eventually forget warning symptoms if they took the drugs over a long period for a chronic condition. "Therefore, written information--and particularly warnings with respect to adverse side

effects and contra-indications--should be provided to users of the prescription drugs."⁴⁴

The groups presented an extensive literature review highlighting the problem of broad scale non-compliance with medication regimens, which often approached between thirty and fifty percent of patients. Oral communications "may be sufficient if a relationship exists whereby the family doctor, with a broad knowledge of the patient's circumstances, takes time to fully explain and supervise the use of prescribed medication." However, consumer and women's advocates believed that "such a paradigm, whatever truth it once had, no longer comports with the realities of contemporary medical practice." The average patient received fragmented medical care from a number of medical specialists in a rushed, impersonal setting. These physicians often wrote prescriptions without an awareness of other prescribed drugs.⁴⁵

A new field of teratology had begun to investigate which substances crossed the placental barrier to adversely effect the fetus during pregnancy and delivery. The public awareness of the danger that certain drugs presented to the developing fetus began with the thalidomide tragedy in 1962. Neither the public nor the medical community could draw comfort any longer from the idea that the placenta presented

⁴⁴Petition to the FDA to Require More Adequate Patient Labeling of Prescription Drugs. Filed March 31, 1975 by Joseph Onek and Marcia D. Greenberger, Center for Law and Social Policy on behalf of Consumers Union of the United States, Inc., Consumer Action for Improved Food and Drugs, National Organization for Women, Women's Equity Action League and the Women's Legal Defense Fund, pp. 2, 15, Docket No. 75P-0277, vol. 1, Food and Drug Administration.

⁴⁵Ibid., p. 4

an impenetrable barrier to substances ingested by the mother. Pregnant women are now routinely warned to avoid virtually all drugs, from aspirin to alcohol, unless absolutely necessary for their own health. However, in the 1970s, this type of information had just begun to reach the physician and the general public.

American Foundation for Maternal and Child Health President, Doris B. Haire stressed this point at the February 1975 FDA Ad Hoc Consumer meeting as CBS-TV news cameras captured her remarks for the evening news. She urged FDA to require a boxed precautionary statement warning women: "If you are or may become pregnant or are breast feeding, please consult your physician before continuing use." FDA's Dr. Richard Crout expressed "great sympathy" with Haire's work, adding that there has been a "real societal neglect" in this area.⁴⁶

Unlike the FDA, the petitioners had no qualms about interfering with the doctor/patient relationship, especially when doing so protected the patient against erroneous prescribing by the physician. The popular novel, Valley of the Dolls, a thinly-disguised account of Hollywood, had exposed the fact that behind the facade of beauty and success, stars and starlets used tranquilizers and barbiturates to calm down and amphetamines to wake up in a vicious cycle of drug dependence. And they were not alone. "Central nervous system agents are the fastest growing sector

⁴⁶F-D-C Reports, 2/10/75, T&G 8. The FDA amended its regulations in 1979 to require pregnancy warning labels on the package inserts of all systemically absorbed drugs. They must indicate one of five categories of warning ranging from class A--drugs that "have failed to demonstrate a risk to the fetus in the first trimester of pregnancy (and there is no evidence of a risk in later pregnancy)" to class E--drugs that "have demonstrated fetal abnormalities or if there is positive evidence of risk" should be used by pregnant women only if the benefit clearly outweighs any other choice of action. 21 CFR 201.57.

of the pharmaceutical market, now making up 31% of sales," House Health Subcommittee Chairman Paul Rogers told the graduates of the Arnold and Marie Schwartz College of Pharmacy in Brooklyn. "Prescribing of tranquilizers rose by 230% during the 14 years following 1962, a period during which the per capita consumption of liquor rose by 23% and consumption of illegal opiates by 50%...." Millions of patients who thought these drugs harmless needed appropriate warnings of their addictive properties.⁴⁷

The petitioners, along with others in the medical field, wanted labeling to warn of the dangers of combining prescription drugs, especially barbiturates, and alcohol. Most people got their first awareness of the danger of mixing drugs and alcohol through news coverage of the Karen Ann Quinlan case. She had slipped into a permanent vegetative state after combining alcohol with a barbiturate and had been kept alive by artificial means. After a number of years and great soul-searching, her family had asked the hospital to remove her from the respirator and let her die. When the hospital denied their request, they sued in New Jersey Supreme Court. In 1976 the Court ruled in favor of the parents, allowing them to remove her from the respirator if her attending physicians and a panel of hospital officials agreed there was "no reasonable possibility" that she would recover.

The precedent-setting aspect of the case centered on the "right to die" principle and the fears of a medical technology gone awry. However, the tremendous television, radio, and newspaper coverage that the case received made millions of Americans aware of the possibility of adverse drug interactions. As industry, medical,

⁴⁷F-D-C Reports, May 29, 1978, p. 10.

and consumer groups debated the concept of patient package inserts, the specter of Karen Ann Quinlan acted as constant reminder that patients must have more information about the drugs they took.⁴⁸

During the 1970s pharmacologists and medical researchers had begun to realize the extent and seriousness of drug interactions. Critics of the pharmaceutical industry and its promotional practices charged that 60,000 to 140,000 people died each year from adverse drug reactions and that most of these deaths were unnecessary and avoidable. Industry spokesmen called this an outrageous exaggeration but did admit that "perhaps 3,000 or fewer adverse drug reaction deaths are seen each year in patients who were suffering non-lethal diseases, and an additional 3,000 deaths per year occur among patients with severe lethal disease." Even that figure was high if patient information could prevent some of these deaths. Even those interactions that were not fatal could compromise patient health. People needed to be informed that many drugs interacted with foods or other drugs and that the potency of some drugs could be enhanced or decreased in the presence of other medications.⁴⁹

For years, the pharmaceutical companies had received the approbation of the nation for their 'wonder drugs.' Any criticism of the industry had centered on the cost of drugs and pharmaceutical company profits. Questions about the safety of drugs was a new and unsettling factor. Opinion polls had begun to report that the drug

⁴⁸Historic Documents of 1976 Washington: Congressional Quarterly, 1977, p. 197.

⁴⁹Washington Post, July 19, 1974, p. 24.

industry was currently the number two villain among U.S. businesses, second only to oil. Half the public believed drug firms did not provide full product information, especially regarding possible harmful effects, indications of use and effectiveness, and shelf life.⁵⁰ "There are people who are willing to believe that whatever new drug you come out with will do more harm than good," warned New York Times medical editor, Harry Schwartz.⁵¹

Women's and consumer groups met with Dr. Gagliardi on July 14, 1975, three months after they had filed their petition. They expressed their concerns about the tremendous upsurge in drug use in the United States. Joseph Onek, who had filed the petition, contended that, "many drugs taken aren't really needed. Perhaps if the patients knew more about the drugs they were taking they would stop or be more cautious of their use." Ruth Desmond of the Federation of Homemakers claimed that "Americans were over-drugged. If it were any different drug companies would go bankrupt." Opponents of PPIs would later cite this type of argument in their efforts to discredit advocates of the PPIs, claiming consumer and women's groups had little interest in better patient compliance with drug regimens or better consumer information. Rather, they used these arguments to mask their hidden agenda of reducing drug use in the United States to their self-defined absolute minimum.⁵²

⁵⁰Yankelovich, Skelly, and White Survey. January 22, 1977. Roper Center for Public Opinion Research, the University of Connecticut, Storrs, Connecticut.

⁵¹F-D-C Reports, September 18, 1978, p. 3.

⁵²Memorandum from R. Alexander Grant, Director, Consumer Programs, Food and Drug Administration. Consumer Representative meetings on Patient Drug Labeling, July 14, 1975. Food and Drug Administration.

Onek and Desmond's statements reflected the growing influence of a group of writers and intellectuals who had begun to question the success of modern scientific medicine. Critics asked whether medical care made any difference at all in the overall health of society. The nineteenth century doctrine of therapeutic nihilism--the uselessness of existing drugs and therapies--revived in a new form. Its proponents declared that Americans had been duped into believing that scientific medicine and the doctors that practiced it had the answers.

Ivan Illich's influential 1976 book, Medical Nemesis: The Expropriation of Health, presented this contention in its most radical form. Illich attacked not only 'iatrogenesis'--the pain, sickness and death caused directly by doctors, hospitals, drugs-- but the pervasive 'medicalization of life' which made whole populations morbidly dependent upon a dubious--and expensive--system of medical care. Medicalized civilization, he argues, is organized "to kill pain, to eliminate sickness and to abolish the need for an art of suffering and of dying."⁵³

Illich elaborated on Rene Dubos's 1959 critique of a "pan therapeutic society" in Mirage of Health. With Dubos, Illich argued that there is no reason to believe that an increase in medical care is ever significantly related to a decline in the compound burden of disease or a raise in life expectancy.⁵⁴

⁵³Ivan Illich, Medical Nemesis: The Expropriation of Health, (New York: Pantheon Books, 1976), 220.

⁵⁴Rene Dubos, The Mirage of Health, (Scranton, PA: HarperCollins, 1959). In The Role of Medicine: Dream, Mirage, or Nemesis? Thomas McKeown analyzed data from England and Wales to support Dubos' argument for therapeutic nihilism. "If we group together the advances in nutrition and hygiene as environmental measures, the influences responsible for the decline of mortality and associated improvements in health were environmental, behavioural, and therapeutic. They became effective from

"The marginal value of one--or one billion--dollars spent on medical care will be close to zero in improving health," wrote the neo-conservative critic Aaron Wildavsky in a clever essay that gave the title Doing Better, Feeling Worse to an influential volume on health care sponsored by the Rockefeller Foundation. "The best estimates are that the medical system (doctors, drugs, hospitals) affects about 10 percent of the usual indices for measuring health." The remaining 90 percent are determined by factors over which doctors have little or no control, from individual lifestyles (smoking, exercise, worry), to social conditions (income, eating habits, physiological inheritance), to the physical environment (air and water quality).⁵⁵

Many Americans had already decided upon the naturopathic or holistic view

the eighteenth, nineteenth, and twentieth centuries respectively and their order in time was also that of their effectiveness." Thomas McKeown, The Role of Medicine: Dream, Mirage, or Nemesis? (London, Neuffield Provincial Hospital Trust, 1976), 94.

⁵⁵Aaron Wildavsky, "Doing Better and Feeling Worse: The Political Pathology of Health Policy," Daedalus (Winter 1977):

107. Among an outpouring of articles on the relationship between medicine and health see: Rosemary C.R. Taylor, "The Politics of Prevention," Social Policy, (Summer 1982): 32-45; David Banta, "What Is Health Care," in Steven Jonas, M.D., Health Care Delivery in the US, 2d. ed., (New York: Springer Publishing, 1981).

Articles by Amitai Etzioni, "Individual Will and Social Conditions: Toward an Effective Health Maintenance Policy," The Annals of the American Academy of Political and Social Science 437 (May 1978) and Sylvia Tesh, "Disease Causality and Politics," Journal of Health Politics, Policy, and Law, 6 (Fall 1981) argued that placing emphasis on individual responsibility for health was a political ploy to divert attention from both the real socioeconomic origins of disease and the failures of the health care system. Robert Crawford, "Individual Responsibility and Health Politics in the 1970s," in Health Care in America: Essays in Social History, Susan Reverby and David Rosner, eds., (Philadelphia: Temple University Press, 1979): 258 concluded that powerful economic interests had determined that the practical focus of health efforts "should not be on the massive, expensive, politically difficult, or even politically dangerous task of overhauling our work and community environments. Instead, the focus must be on changing individuals who live and work within those settings."

of health, or had taken up the cause of radical hygiene. Just as the idea of eating natural or organic foods had begun to make its way into the mainstream, the ideas of radical hygiene and the wellness movement had started to influence medical thinking. In the inflationary seventies, maintaining health through disease prevention rather than curing illness by expensive medical treatment began to develop a following among those willing to make major changes not only in their lifestyles but in their whole belief systems.

For those not ready or willing to make a leap of faith, but who wanted to improve their health, "The Seven Healthy Life Habits" presented an easy to understand prescriptive. Epidemiologist Lester Breslow and his colleagues at the UCLA School of Public Health had conducted studies to determine how lifestyles effected health and longevity. From an analysis of their data they had distilled seven "rules" for a longer and healthier life: 1) don't smoke cigarettes, 2) get seven hours of sleep, 3) eat breakfast, 4) keep your weight down, 5) exercise daily, 6) drink moderately, and 7) don't eat between meals.⁵⁶

References to the "Seven Healthy Life Habits" turned up in popular magazines and in the health columns of newspapers, often sponsored by health organizations, such as, Blue Cross. The 'baby-boom' generation, which has had such a huge influence on the social mores and popular culture of the country, took the "Seven Signs" to heart--changing their diets, tying on a pair of running shoes, and making fitness centers and equipment a growth industry. Concomitant with this new-found

⁵⁶Lester Breslow et. al., "Research in a Strategy for Health Improvement," International Journal of Health Services, 3 (1973): 7-8.

awareness about health, diet, and medicine, came the realization of the pivotal role that the Food and Drug Administration potentially played in their new lifestyles, for example, by the regulation of labeling of food products or control of vitamin claims.

As the public became more aware of the FDA, the agency took notice of these changing American attitudes toward health. FDA had its own misgivings about the over-use and mis-use of drugs by the medical profession. The petition from the consortium of consumer and women's groups provided a way to explore these issues without the agencies initiating the process. On November 7, 1975, a short time by bureaucratic standards, the FDA published the petition in the Federal Register asking for public comments. Using the same criteria as the consumer petition, the notice limited the scope of inserts to drugs that posed a danger to pregnant and breastfeeding women, widely used hypnotics and tranquilizers, and drugs, such as the antibiotic chloramphenicol, that had been over-prescribed in the past and had serious side effects.

The agency indicated it would give serious consideration to extending its limited policy of requiring patient package inserts, which now included estrogen-based products as well as oral contraceptives, to these classes of drugs. Though the FDA had already gotten feedback from a number of different sources, it now intended to cast its nets wider, and listen to a broader cross-section of the public.⁵⁷

In the Federal Register notice, the FDA commented that it would be helpful in formulating its policy on patient drug labeling to receive comments not only on those aspects mentioned in the petition but "particularly those derived from actual

⁵⁷40 Federal Register 52075, November 7, 1975.

experience and studies." The notice listed seven broad areas for comment including the advantages and disadvantages of labeling, scope and detail of labeling, format, distribution, and priorities for drug selection. Lastly it asked "whether such information should be drafted through open advisory committee hearings, by notice and comment rule making, or through another procedure...."⁵⁸

The FDA tried to get the widest spectrum of opinion by issuing a press release that specifically asked the public to comment on the need for more drug information for patients. The story went out over the Associated Press wires and found its way into the national news pages of local newspapers from Portland, Oregon to Portland, Maine. The Camden, New Jersey Courier Post ran the news story under the headline, 'For drug labels? Let the FDA Know.' The lead paragraph began, "The Food and Drug Administration wants to hear from you, the consumer, about a proposal to print warning labels for patients on certain potentially dangerous drugs." The news article quoted Commissioner Schmidt's statement that with this public feedback, the FDA could assess the best way "to strengthen the agency's program to provide more information on prescription drugs." The story contained the address to which persons could write.⁵⁹

The old-timers must have been shaking their heads in wonder--accepting a petition from public advocates on an important policy issue, holding a dozen meetings

⁵⁸40 Federal Register, November 7, 1975, p. 52076.

⁵⁹Food and Drug Administration press release, November 12, 1975. The Courier Post, Camden, New Jersey, November 13, 1975. A similar story appeared in U.S. News and World Report, December 8, 1975, 98 and other news sources. Docket No. 75P-0277, vol. 1. Food and Drug Administration.

with professional organizations and consumer advocates, asking the public for their personal experiences with drugs and their opinions on patient package inserts. What had happened to the old way of convening a couple of committees within the FDA bureaucracy, making a decision, and sending it up the hierarchy to the Commissioner for his signature? The FDA received 1006 comments on the petition--66 opposed and 940 in favor--over 750 from individuals. In among the form letters and postcards were letters written on personal stationery, pieces of looseleaf paper, and secretarial pads from 246 individuals recounting painful personal experiences that might have been prevented if they had had been better informed.

Certainly one of the most poignant was a hand-written letter from Fred J. Timper of Raleigh, North Carolina, about the loss of his "lovely, otherwise healthy" ten year-old daughter, who died of aplastic anemia caused by "the careless use" of the antibiotic chloramphenicol. The doctor had prescribed it for a common stomach virus, against which antibiotics are ineffective. At no point did the Timpers know that their daughter had been given a drug which was known to cause rare but fatal side-effects. (The FDA kept the drug on the market because it was one of the few drugs effective in treating certain serious illnesses, but once on the market, the FDA had no control over how physicians used it.) "We discovered later that precise warnings did actually exist but only within the limits of the medical society," wrote Mr. Timper. In closing, he hoped that the FDA would require written warnings on all prescription in language the average public could understand.⁶⁰

⁶⁰Letter from Fred J. Timper, December 5, 1975. Comments in response to FDA notice regarding "Labeling of Prescription Drugs for Patients," 40 Federal Register November 7, 1975, p. 52075. FDA Docket No. 75P-0277. Food and Drug

Parents wrote about young children who had been given tetracycline resulting in discolored teeth. They indicated if they had known of the possibility of this effect they would have asked the doctor for a different medication. Other consumers told of getting severe sunburn because no one told them that tetracycline made some patients hyper-sensitive to sunlight. "I am very allergic to salicylates. I very nearly lost my life by taking prescribed pills that contained salicylates," wrote Margaret Lamey of Roseville, California. "This prescription was given to me even after I told the doctor several times that I am very allergic to aspirin." In response to Betty Furness' November 20th broadcast on Newscenter4, Patricia Elliott sent a letter to the FDA. Harkening back to the Karen Ann Quinlan case, she wrote that her husband Michael had been taking Valium 5 for years and had never been warned not to mix it with alcohol.⁶¹

One consumer wrote, "I can't believe it, we, the consumers, are asked to be heard from. It restores my faith in the American way, the F.D.A., to a point...." She went on then to describe a seemingly endless series of illnesses treated with prescriptions that had done more harm than good. Some of the favorable comments agreed in principle with the petition but added qualifications. "I do not want to get a prescription filled and then have the prescription labeling tell me the side effects AFTER I have already purchased the prescription," wrote Ranell Minear. "I want to

Administration.

⁶¹Letter from Patricia Elliott, November 20, 1975. Letter from Margaret Lamey of Roseville, Ca. November 21, 1975. Comments in response to FDA notice regarding "Labeling of Prescription Drugs for Patients," 40 Federal Register November 7, 1975, p. 52075, FDA Docket No. 75P-0277. Food and Drug Administration.

hear it from the doctor to help me determine if the risk involved is worth taking the medicine to alleviate the problem."⁶²

Pharmaceutical associations from Massachusetts and Minnesota sent information about successful patient package information system used in their states. The Boston Association of Retail Druggists had begun a voluntary program called "Rx Info," in conjunction with the Massachusetts College of Pharmacy and Northeastern University College of Pharmacy to increase patient compliance and awareness of potential side effects. The Minnesota State Pharmaceutical Association had organized a similar voluntary patient education program in 1974 for its members. Both program had been initiated after discussions with the medical profession, consumer groups, and member pharmacists. The Massachusetts and Minnesota experiences would be used in subsequent discussions to demonstrate that it was indeed possible to create a leaflet that all groups could accept and that would adequately inform patients. Both groups offered their services to FDA in drafting its PPIs.

The American Pharmaceutical Association (APhA) supported the objectives of both of these programs, although it questioned the value of written information without an educational program to warn both health professionals and the public about the potential dangers in many drugs. The APhA had reservations about implementing a program for PPIs for all drugs. Rather it favored the development of PPIs for only two or three classes of drugs with concurrent evaluation of their

⁶²Comments in response to FDA notice regarding "Labeling of Prescription Drugs for Patients," 40 Federal Register 11/7/75, p. 52075. FDA Docket No. 75P-0277. Food and Drug Administration.

effectiveness in providing information or changing behavior.⁶³

Consumers Union, one of the original petitioners, sent a response stressing the need for consumer input at every stage of the label drafting process and representation on all advisory committees. Consumer representatives could much more easily cut through the medical and scientific jargon, select the most pertinent information, and recommend how to most effectively present this information in a form which could be readily understood by the average patient. "These are matters on which consumers have important expertise the medical professional cannot offer."⁶⁴

Now that PPIs had begun to receive serious consideration, industry and profession organizations began to think through the full ramifications of the proposal. The Pharmaceutical Manufacturers Association, in a lengthy response complete with bibliography, took issue with the proposal. Echoing the APhA, the PMA opted for a limited pilot study to determine the feasibility of this approach and a consideration of alternative means of informing consumers. The PMA again mentioned manufacturer's liability issues and the competitive advantage if different drugs in a class did not have a similar list of side effects.

While accepting the benefits of improved patient knowledge of dosages, side

⁶³Letter from the Massachusetts College of Pharmacy, March 1, 1976. Letter from the Boston Association of Retail Druggists, February 2, 1976. Letter from the Minnesota State Pharmaceutical Association, March 5, 1975. Letter from the American Pharmaceutical Association, March 8, 1976. Comments in response to FDA notice regarding "Labeling of Prescription Drugs for Patients," 40 Federal Register November 7, 1975, p. 52075. Docket No. 75P-0277. Food and Drug Administration.

⁶⁴Comments of Consumers Union, Inc. on Petition for Labelling of Prescription Drugs for Patients [No. 57P-0277]. Correspondence. Undated. Library of Consumers Union, Yonkers, NY.

effects, and interactions, the PMA envisioned serious disadvantages--beside the obvious interference with the physician-patient and pharmacist-patron relationship. Drug companies might adequately explain the risk/benefit equation to trained medical personnel, but the PMA contended that it would be impossible to present a balanced picture to untrained laypersons. The average consumer would be so overwhelmed by the risks that the benefits of treatment would elude them. In the end, the PPI would not only undermine the patient's belief in the value of the medication but his trust in the physician that prescribed it.⁶⁵

The American Medical Association remained unalterably opposed to the petition, especially its mandatory provisions. The AMA agreed that consumers should receive some information on usage, storage directions, and simple warnings, such as, 'causes drowsiness'. But more information on side effects, adverse reactions, and contraindications they asserted would compromise frighten patients, causing them to discontinue treatment. In its most paternalistic tones, the AMA letter concluded doctors had the right to decide who should receive PPIs because "the physician is the one who is able to ascertain the patient's physical and emotional characteristics and whether a particular patient has need of such information." In an age of feminism and patient rights, this had a quaintly Victorian ring to it.⁶⁶

⁶⁵Letter from the Pharmaceutical Manufacturers Association, March 3, 1976. Comments in response to FDA notice regarding "Labeling of Prescription Drugs for Patients," 40 Federal Register November 7, 1975, p. 52075. FDA Docket No. 75P-0277. Food and Drug Administration.

⁶⁶Letter from the American Medical Association, March 8, 1975. Comments in response to FDA notice regarding "Labeling of Prescription Drugs for Patients," 40 Federal Register November 7, 1975, p. 52075. FDA Docket No. 75P-0277. Food and Drug Administration.

Despite the efforts of physicians to control the doctor/patient relationship through a monopoly on prescribing information, Americans had begun to find sources for drug data outside the doctor's office. More enterprising people wrote directly to the FDA requesting the package inserts that accompanied pharmaceuticals. By mid-1975 the agency received 59 requests a month for these inserts, according to Dr. Vincent J. Gagliardi. The FDA responded favorably to these requests because it believed that patients had a right to this information.⁶⁷

A number of respondents to the consumer petition Federal Register notice mentioned their use of the Physicians Desk Reference (PDR) and other medical reference books. Joy Rogers of Park Forest, Illinois began her letter, "Since I have begun looking up unfamiliar medications in the PDR" Michael J. Motyka wanted every drug store to have a PDR available for the public. Myles King of Long Beach, California thought the PDR was too technical and not impartial, instead he wrote that "without Burack's Handbook of Prescription Drugs and Hyman's Medical Encyclopedia we would be in the dark."⁶⁸

Running over 2,000 tissue-thin pages, the Physicians' Desk Reference (PDR) includes information on more than 1000 of the leading prescription drugs used in the United States. The PDR reproduced the FDA-required "full disclosure" package

⁶⁷Memorandum from Vincent J. Gagliardi. Report of meeting with American Society of Clinical Pharmacy and Therapeutics, Committee on Drug Regulations, concerning "Prescription Drug Labeling for Patients." June 2, 1975.

⁶⁸Letter from Joy Rogers of Park Forest, Illinois, November 16, 1975. Letter from Michael J. Motyka, December 1, 1975. Letter from Myles King, Long Beach, California, November 20, 1975. Comments in response to FDA notice regarding "Labeling of Prescription Drugs for Patients," 40 Federal Register November 7, 1975, p. 52075. FDA Docket No. 75P-0277. Food and Drug Administration.

insert (that manufacturers shipped with its products to pharmacies) in all its technical and scientific "medicalese." Manufacturers chose which of their products to include in the book and used the 350,000 copies of the PDR that they sent free of charge to the nation's practicing physicians as an advertising tool.⁶⁹

The publishers of the PDR never intended it to be used by the general public. The technical language of the package inserts presented a barrier to most consumers, even those with access to a medical dictionary. However, in the 1970s, many people began to use it to supplement the meager information they received from their doctor and pharmacist. Bookstores, such as New York's Barnes & Noble kept several hundred copies in stock and librarians complained that it frequently disappeared from the reference room shelf.⁷⁰

The publishing industry, always on the lookout for an untapped market, realized that there existed a growing need among middle-class readers for books that were less formidable and more easily accessible than the Physicians' Desk Reference. The health section, an increasingly popular and profitable part of the nation's bookstores, began to carry titles such as, The New Handbook of Prescription Drugs, The Essential Guide to Prescription Drugs, and The People's Pharmacy. The latter, written in 1976 by pharmacist Joe Graedon, began "this is a book for people. It is an attempt to dispel the secrecy which surrounds medical treatment today.

⁶⁹Physicians' Desk Reference, Montvale, New Jersey: Medical Economics Data Production Co. Published each year. The 1995 49th Edition is also available on CD-ROM.

⁷⁰Egon Weck, "Look Who's Reading the PDR Now!" FDA Consumer, vol. 13, Nov. 1979, p. 20

People are fed up with being treated as objects by doctors who often do not care about, or can't discuss in easy-to-understand language, the medicines which they prescribe."⁷¹

The FDA had used the consumer petition to further its own objectives and to explore the possibilities and limitations of patient package inserts. The FDA was pleased by the excellent response to its Federal Register notice. In analyzing the over one thousand responses, the FDA tallied a positive response from most of the individual responses, as well as those from consumer organizations, para-professionals, and from people conducting educational programs in community or teaching hospitals. The pharmaceutical industry had adopted a cautious approach, while pharmacists were supportive but pragmatic about distribution problems. The medical profession remained opposed, although academic physicians supported the program in greater numbers than those in private practice.⁷²

⁷¹R. Burack, The New Handbook of Prescription Drugs (New York: Ballantine Books, 1977); Wayne O. Evans and Jonathan O. Cole, Your Medicine Chest: A Consumer's Guide to Prescription And Non-Prescription Drugs (Boston: Little, Brown, and Co., 1978); Joe Graedon, The People's Pharmacy (New York: St. Martin's Press, 1976). The continued sales of these and other titles are a testament to the continued interest of Americans in their health. A quick perusal in any large bookstore will find these titles plus other such as, James W. Long, M.D. and James J. Ryback, Pharm.D. The Essential Guide to Prescription Drugs--1994, 12th ed. (New York: Harper Collins, 1994). H. Winter Griffith, M.D., Complete Guide to Prescription and Non-Prescription Drugs, 11th ed. (New York: Putnam Publishing Group, 1994). U.S. Pharmacopeia, The Complete Drug Reference Book (Yonkers, New York: Consumer Reports Books, 1993). Sidney Wolfe, M.D., Worst Pills, Best Pills II. The Older Adults Guide to Avoiding Drug-Induced Death or Illness (Washington, D.C.: Health Research Group, 1993). There are also a number of books on non-prescription drugs as well as hundreds of health books.

⁷²Marion J. Finkel, M.D., "The Pros and Cons of Patient Package Inserts," Speech to Annual Meeting of the American Medical Association, Dallas, Texas, June 29, 1976. Docket No. 79N-0186, vol. 9, Tab 139. Food and Drug Administration.

After its initial opposition, its belated recognition of the need for PPIs for oral contraceptives, and its bureaucratic foot-dragging in instituting a larger program, the Food and Drug Administration appeared at the point of committing itself to a comprehensive program of patient information. However, the agency made every effort to develop consensus among the interests with which it normally dealt before proceeding with its final rulemaking. At each step in the process interested parties--physicians, pharmacists, manufacturers, consumer groups--used their best arguments and expert witnesses to protect their interests. All parties agreed, at least in principle and in public, that patients had the right to know about the medications that they took. It would take five years from the filing of the original petition to hammer out a set of principles for PPIs with which all parties could at least nominally agree.

To develop the full range of opinions about the inserts, the Food and Drug Administration took the unusual step of co-sponsoring a Joint Symposium with the Drug Information Association, the American Medical Association and the Pharmaceutical Manufacturers Association in June 1976. Since the beginning of the decade FDA had vastly increased the number of sources to which it turned for advice. A project that had begun in-house with the advice of FDA personnel and the National Advisory Drug Committee had been expanded to a series of meetings with professional and consumer organizations and now encompassed a meeting of 700 health professionals, consumer representatives, and members of the press. Dr. Eric Martin, speaking for the FDA, told the audience that the Symposium was strictly a fact-finding meeting to capture attitudes, concepts, ideas and develop research agendas. In his welcoming remarks FDA Commissioner Schmidt mentioned that FDA

did not consider itself the "expert" in deciding if PPI were the best means of providing patients with information. Nor did the agency want to dictate their content. However, since the PPI were considered labeling, the "ultimate stamp of approval" rested with the FDA. No matter how far afield the agency went for information and input, ultimate control remained in its hands.⁷³

The complexity of the issues facing the FDA can be seen by briefly scanning the meeting's agenda. The audience was asked to look at PPIs from the viewpoint of the FDA, the pharmaceutical industry, the physician, the consumer, the community pharmacist, the hospital, and the hospital pharmacist. Symposium participants discussed content, distribution problems, potential effects on patients and the health care system. In the year and a half since the Center for Law and Social Policy had petitioned the FDA, initial enthusiasm had given way to a more wary attitude. Many participants now favored experimentation and evaluation before the initiation of a widespread mandatory program.⁷⁴

Most professional and consumer groups continued to defend their previous positions. The PMA's John Adams expressed his concerns in terms of 'patient default in drug therapy.' In other words, the patient leaves the doctor's office, prescription in hand and then decides not to fill it. Anything that exacerbated this situation, such

⁷³Eric Martin, "Opening Statement," and Dr. Alexander M. Schmidt, "Keynote Address," Drug Information Association/American Medical Association/Food and Drug Administration/Pharmaceutical Manufacturers Association Joint Symposium, Drug Information Journal, 11, Special Supplement (January 1977): S2, S4.

⁷⁴DIA/AMA/FDA/PMA Joint Symposium, S4.

as a PPI overstressing drug risks, would be unacceptable to the PMA.⁷⁵ The PMA continued to support the AMA efforts to maintain control of the doctor/patient interaction in the hopes that doctors would protect manufacturers by restricting information to patients about the potentially dangerous side effects or adverse reaction of certain products. Patients reading about the risks from a certain drug might reasonably ask if another equally effective product was available that did not have these risk.⁷⁶

Marsha N. Cohen of Consumers Union reiterated her group's support for the petition, adding "we do not want to mandate a copy of the PDR in every home.... What we want the patient to receive in information in writing, which could be a matter of life and death, or at least of significant health concern."⁷⁷

Some consumer advocates had reframed the question from how patients could receive more facts about drugs to how the control of information could redress the power balance between patient and physician. The atmosphere of mystery and reverence that had traditionally surrounded the practice of medicine had come at a high price for many patients, who had little choice but to blindly trust their doctors. Their only hope was to arm themselves with information. Advocates hoped that physicians, who had been questioned and challenged by their patients, would turn

⁷⁵ John G. Adams, "The Industry Viewpoint," DIA/AMA/FDA/PMA Joint Symposium, S9.

⁷⁶ Drug Safety Amendments of 1976, 109.

⁷⁷ "What Drug information should the consumer have? a consumer perspective," Marsha N. Cohen, Hastings College of Law, San Francisco, Ca. No date. Files of Consumers Union, Yonkers, NY.

away from drug salesmen and return to the scientific literature, stop prescribing drugs for unproven uses, and more thoroughly weigh the benefits and risks of treatment.⁷⁸

The symposium participants urged FDA to continue its evaluation and maintain "deliberate progress" in instituting an industry-wide program of patient inserts. The FDA could return to its Rockville offices with the knowledge that it had received at least partial support for its position from a widely diverse spectrum of groups and individuals.

It had been over a year since the FDA had received comments in response to the consumer petition. Consumer advocates expressed outrage that the FDA had given no indication that it was ready to move on PPIs. What was FDA waiting for? In FDA's defense, a decision to start a full-scale program of patient package inserts for thousands of drugs at this time would have been a shot in the dark. In reality, the experience with PPIs had been very limited. The FDA looked first at retrospective studies of patient package inserts for oral contraceptives. Besides FDA's own 1974 survey, Lawrence Fleckstein and his colleagues had conducted a survey in 1976 to ascertain how well users remembered information in the PPI. Surveyors asked women if birth control pills ever caused blood clots, the most serious side effect. Even though only sixty-four percent answered correctly, a much higher percentage told the researchers that they had learned important information from the literature, and that they wanted similar information to be furnished with other prescription drugs. Respondents also assured interviewers that the booklets had not affected the

⁷⁸Ralph Nader, Statement on Prescription Drug Information for Consumers, DIA/FDA/AMA/PMA Joint Symposium, S9.

relationship with their doctors. Other studies corroborated Fleckstein's findings.⁷⁹

In truth, the FDA could not prove the effectiveness of the inserts in increasing compliance with dosage regimens, nor even if the public would read them. However, "written information should still be available for those patients who want it and who feel they are benefitting from it," argued Dr. Marion Finkel, Associate Director in the FDA Bureau of Drugs, trying to make her case before a tough audience--an AMA Annual meeting in June 1976. She argued that the case made against drug inserts were analogous to those made against nutritional labeling--consumers were uninterested, they were unable to understand the scientific information, and labeling would raise the cost of food. In actual practice, these proved to be false.⁸⁰

The FDA indicated its ongoing support for patient information in specific, individual situations by updating and strengthen the warnings for oral contraceptives and estrogen products. After consultation with its Obstetrics-Gynecology Drugs Advisory Committee, FDA announced plans to revise the current estrogen package inserts and to produce a new brochure in "lay language" to be given by doctors to

⁷⁹Lawrence Fleckstein et al, "Oral Contraceptive patient information. A Questionnaire Study of Attitudes, Knowledge, and Preferred Information Sources, JAMA 235 (March 29, 1976): 1331-1336. Contractor's Final Report: Survey of Consumer's Perceptions of Patient Package Inserts for Oral Contraceptives, (Washington, DC: Food and Drug Administration, 1975), NTIS, PB248-739. Pierre Joubert and Louis Lasagna, "Patient Package Inserts: 1. Nature, Notions and Needs," Clinical Pharmacology and Therapeutics 18 (November 1975): 507-513.

⁸⁰Marion J. Finkel, M.D., "The Pros and Cons of Patient Package Inserts," Speech to Annual Meeting of the American Medical Association, Dallas, Texas, June 29, 1976, Docket No. 79N-0186, vol. 9, Tab 139. Food and Drug Administration.

their patients.⁸¹

Both Commissioner Schmidt and his successor, Donald Kennedy, viewed estrogens as valuable drugs which had been overused and misused. Using arguments similar to those of the consumer movement, Kennedy argued the majority of estrogen prescriptions were being written for elective post-menopausal indications for which there was no evidence of efficacy, but a known risk elevation for endometrial cancer. "If patients know these risks, we think it will reduce the demand upon physicians to supply the drug for what is clearly an inappropriate use."⁸²

Although not a physician, Kennedy exhibited some understanding of the position that doctors found themselves in as the targets of a billion dollars worth of sophisticated drug promotion a year. "Even physicians convinced of the importance of parsimony in prescribing drugs must find it difficult to resist the multitude of messages about the usefulness of this or that particular drug. While the PPI will not eliminate this kind of drug marketing, it will offer an educational resource of proven neutrality."⁸³

FDA produced a final rule for estrogen labeling on July 22, 1977, without waiting for the completion of its overall program for patient package labeling.

⁸¹Commissioner Alexander M. Schmidt, Press Release, September 27, 1976, Food and Drug Administration.

⁸²FDA Commissioner Donald Kennedy. Speech presented before the Consumer Federation of America, Washington, D.C., January 19, 1978. Docket #79N-0186, vol. 9, tab 150. Food and Drug Administration.

⁸³FDA Commissioner Donald Kennedy, Speech before the Regional Ad Hoc Professional Meeting, Food and Drug Administration, San Francisco, CA, June 10, 1977. Docket # 79N-0186, vol. 10, tab 151. Food and Drug Administration.

Commissioner Kennedy refused to defer the adoption of patient labeling for specific drugs "when the need for such labeling was clearly demonstrated." A model patient label in the Federal Register notice included the sentence, "This leaflet includes the most important information about estrogens, but not all the information. If you want to know more, you can ask your doctor or pharmacist to let you read the package insert prepared for the physician."⁸⁴

The FDA had added this sentence in response to a point raised by Doris Haire at the June 29, 1977 Ad Hoc Consumer/FDA meeting. Patients who had asked for the full disclosure insert were told that it was against the law to give them out. FDA promised to notify pharmacists and correct this misinformation. Responding to continuing pressure from women's and consumer groups, FDA had come down on the side of the consumer and her right to make an informed choice, despite pressure from drug manufacturers, pharmacists, and doctors, and an increasingly hostile response to regulatory initiatives.⁸⁵

The PMA immediately filed suit in Delaware Federal Court on September 2, 1977 seeking a preliminary injunction against FDA's implementation of estrogen PPIs. For the PMA, patient labeling had become a pocketbook issue. Having convinced the doctor of the value of its product, the manufacturer now saw no way of influencing the patient to accept the doctor's dictates. Delaware Federal Court Judge Walter Stapleton rejected the PMA's request for a temporary injunction. The Court of Appeals ruled in favor of FDA in 1980. Although both courts dealt with the narrow

⁸⁴42 Federal Register, July 22, 1977, p. 37636.

⁸⁵F-D-C Reports, July 4, 1977, T&G 3.

issue of estrogen prescribing, the ruling signaled both the medical community and Congress that FDA had the power to require package inserts for all drugs.⁸⁶

While awaiting the ruling in the PMA suit, the FDA sponsored a second major public PPI conference in December 1978. Dr. J. Richard Crout in his remarks to more than 300 delegates, made a distinction between the 1976 meeting and the present conference. At the DIA-sponsored Symposium, participants had gathered to determine if a need existed for PPIs. "If there was a consensus at that meeting, it was that PPIs were a good thing, but a number of important policy, legal, and technical questions remained for us to work on." Two years later, Crout informed his audience, a number of these questions have been resolved, "at least internally within FDA."⁸⁷

The purpose of the conference, therefore, was how best to prepare PPIs--the objectives, contents, style, and the order of priority for this complex, and often emotionally-laden, information. Crout shared with the audience some of FDA's working suppositions: Its legally mandated PPIs would be aimed at the largest possible audience, would present a complete and self-contained message, and would serve as a reminder of the doctor's directions. PPIs must be consistent with practitioner labeling--not a medical text--but including major indications, warnings, and

⁸⁶Pharmaceutical Manufacturers Association v. FDA, 484 F. Supp. 1179 (D. Del. 1980). *Pharmaceutical Manufacturers Association vs. Food and Drug Administration*, 484 F. Supp. 1179. *Pharmaceutical Manufacturers Association vs. Food and Drug Administration*, 634 F. 2d 106.

⁸⁷J. Richard Crout, M.D., Keynote address, "Patient Package Inserts: Content and Format," Proceedings of the Conference Sponsored by the Food and Drug Administration, Washington, D.C., December 11-12, 1978, Docket No. 79N-0186, vol. 2, Food and Drug Administration.

precautions given in the physician labeling.⁸⁸

Patient labeling must reveal all relevant information about a drug but its focus should not be on benefit/risk decision-making by the patient, although the FDA did not rule this out for certain drugs. Crout touched on a thorny problem: were PPIs "health documents" intended to improve patient compliance or "right to know" documents so that the patient could make an informed choice--an issue that had been heatedly debated in previous meetings. Medical ethicist, Dr. Albert Jonsen, speaking to this point, explained that the 'right to know' and 'patient education' concepts pull in divergent directions. The former is built on confrontation and called for the provision of the fullest possible information, stated in the most exact way, so that should there be any untoward event, it will be clear where blame can be placed and accusation refuted. On the other hand, patient education looked to fuller cooperation. By expanding understanding, the communication between the patient and physician can be more lucid, more frank, and more beneficial.

Not supporting one approach or another, Jonsen illustrated the complexities within the simple idea of giving patients information. Doubting that both concepts were compatible in the 'small world of the PPI,' he cautioned those present to decide whether the PPI is about liability and the transfer and distribution of social power or if it is a sort of 'diplomatic communique' which provided the information to allow a person to perform a shared activity--and to then construct a PPI accordingly. Despite his advice, FDA hoped to have it both ways. Its intention not to redress the power relationship between patients and doctors would not prevent it from apprising patients

⁸⁸Ibid.

of serious risk/benefit situations.⁸⁹

Given that FDA saw PPIs as a *fait accompli*, it dispensed with a recitation of the fixed positions of the major interest groups to devote most of the conference to designing sample inserts with maximize readability and comprehension. "There will be no blizzard of paper," FDA's Lloyd Millstein assured his audience in his closing remarks. FDA planned to move slowly, analyzing the results of the symposium before making its final decision on how to implement the program.

Again trying to buttress its decisions with scientific objectivity, the FDA commissioned additional studies. It arranged a long-term prospective study with the Rand Corporation to test the effects of various prototype PPIs on actual drug users. Data samples were taken during the fall of 1979 and the winter and spring of 1980.⁹⁰

While awaiting these long-term results, FDA also asked the Institute of Medicine to study patient package inserts and recommend "research objectives and strategies" that the FDA could use in evaluating the effects of PPIs. The committee did an extensive literature review, covering in depth, again, all the problems and possibilities of the inserts. Their one original contribution documented the lack of

⁸⁹Albert Jonsen, "Medical Ethicist Perspective," in "Patient Package Inserts: Content and Format," Proceedings. Washington, D.C., December 11-12, 1978. Docket No. 79N-0186, vol. 2. Food and Drug Administration.

⁹⁰David E. Kanouse, Sandra H. Berry, Barbara Hayes-Roth, William H. Rogers, and John D. Winkler, "Informing Patients About Drugs: Summary Report on Alternative Designs for Prescription Drug Leaflets," Rand Corporation, Santa Monica, California, August 1981. Food and Drug Administration, Contract No. 223-78-3009.

studies on physician behavior.⁹¹

1979 finally looked auspicious for the beginning of a patient package information program. On July 6, 1979, in one of his last acts as FDA Commissioner before returning to California as President of Stanford University, Donald Kennedy signed the "umbrella" PPI Federal Register proposal. The FDA gave notice that it intended to implement the PPI requirements in two phases--a first phase requiring inserts for 50 to 75 drug classes and after a thorough review of the program, a second phase to cover all prescription drugs.⁹²

In an effort to maximize public participation, the FDA announced its intention to hold three public hearings on the proposals in Chicago, Los Angeles, and Washington, D.C. during September 1979. Although moving two of the hearings out of Washington, D.C. made access easier for some, with slight variations, the same types of organization that had been involved in the process from the beginning again testified. In Chicago, representatives of the Illinois Pharmacists Association spoke, while in Los Angeles, the California State Board of Pharmacy made its case. In each venue, however, a few private citizens expressed their concerns, but these people must have already been involved and had access to the Federal Register to know about the meetings.⁹³

⁹¹National Academy of Sciences/Institute of Medicine, Evaluating Patient Package Inserts. Publication IOM79-05, (Washington, D.C., August, 1979), 13.

⁹²44 Federal Register, July 6, 1979, 40019-20.

⁹³44 Federal Register August 10, 1979, 47104. Proposed Rule Prescription Drug Products, Patient Labeling Requirements and Patient Packaging Inserts. Minutes of Public Hearings before the Food and Drug Administration. September 10, 1979, Chicago Illinois; September 12, 1979, Los Angeles, California; September 14, 1979,

The FDA received 1500 replies to its July 6, 1979 proposal, many of which came on pre-printed forms. Those from individuals mirrored the concerns expressed in 1976. Again Americans wrote of how they had endured unnecessary suffering for a lack of basic information. As opposed to 1976, professional and industry groups were much better organized, perhaps, because they now faced an actual threat to their functioning and autonomy, rather than a theoretical one. According to FDA's Louis A. Morris, a pivotal figure in the agency's PPI program, what had started as mild support from health professionals mixed with skepticism that PPIs could offer a viable solution, became vehement opposition by the time the final rule was ready for publication. "Rather than define the PPI issue as an intervention aimed at the problem of patient education, health professional associations came to see it as an issue of too much government regulation."⁹⁴

In the inflationary 1970s, industry campaigned against PPIs on the basis of their alleged astronomical cost to the consumer. According to FDA's preliminary estimates, the cost to drug manufacturers and pharmacies would be approximately \$90 million a year. Officials of wholesale and retail druggist associations said the FDA made its calculations based on the time it would take a clerk to retrieve the insert, ignoring the time the pharmacist would have to spend answering questions of anxious customers. It put the figure for pharmacists alone at over \$150 million per year.

Washington, D.C. Docket No. 79N-0186. Food and Drug Administration.

⁹⁴"Patient Package Inserts as a Source of Drug Information," Proceedings of an International Symposium on PPIs held in Ghent, Belgium, Sept 26-28, 1988, Marc Bogaert, ed., (NY: Excerpta Medica, 1989): 61.

Robert Bolger, president of the National Association of Chain Drug Stores predicted in an August 20, 1979 letter to President Carter, that prescription drug prices would increase a minimum of 8% to 16%. He expressed amazement that the Carter Administration would propose such an expensive program at the same time as it proposed to control health care costs. FDA countered that the proposed regulation would add a little more than 6 cents to the price the consumer paid for a prescription. More importantly, the FDA felt that in the end health care dollars would be saved by drugs used properly, thereby avoiding further illness or hospitalizations because of side effects or adverse reactions.⁹⁵

Hundreds of Nebraska's registered pharmacists, sent in a form letter objecting to the use of FDA-mandated material, the inflationary cost of the program, and the plans's unrealistic expectations. "Patients must discuss treatment alternatives with their physician," they advised in a heavily paternalistic tone, "and learn to trust the professionals that have been trained to protect their health." Similar form letters arrived from other pharmaceutical associations.⁹⁶

The Cleveland Clinic Foundation sent a letter to its professional staff informing them of the "ill-advised nature of these regulations" and strongly suggesting that they voice their opposition to FDA. The round-robin warned in dire tones that the inserts would not be written by physicians but by contractors. "Generally these people are

⁹⁵"FDA in Hot Water Again Over Cost of Proposed Drug Labeling Rule," National Journal (June 22, 1979): 1568-9.

⁹⁶Letters from the Nebraska Pharmaceutical Association, the North Carolina Pharmaceutical Association, and the Indiana Pharmaceutical Association, Response to 44 Federal Register July 6, 1970, 40019 proposal. Docket # 79N-0186, CHO233. Food and Drug Administration.

sociologists or brand-new lawyers fresh out of school... none of them have ever been sick or have spent a day in their lives in the hospital."⁹⁷

In an atmosphere increasingly hostile to any new regulatory initiative, the Food and Drug Administration published its final rule on patient package inserts on September 12, 1980. Describing the history of patient package insert regulation, the new FDA Commissioner Jere Goyan, who held a doctorate in pharmaceutical chemistry, concluded, "In sum, FDA believes there is ample evidence in the record to support the agency's conclusions that permanent and retainable information for patients about prescription drugs, apart from providing information that patients have a right to have, can significantly improve the quality of health care obtainable from prescription drugs."

Nevertheless, the FDA's final rule signaled a significant retreat on patient information. It established a limited pilot program for just ten drugs or classes of drugs. After a three year period, the FDA would assess the costs and benefits of the program and decide whether to extend, revise or defer the requirements. In a compromise with the medical profession, the FDA ruled that physician may direct the dispenser to withhold the insert "unless the patient specifically requests it." FDA expressed the hope that these situations would be rare.⁹⁸

In self-justification for the limited scope of the program, the FDA cited the

⁹⁷"Newsletter of the Professional Staff of The Cleveland Clinic Foundation," September 10, 1979, Response to 44 Federal Register July 6, 1970, 40019 proposal. Docket No. 79N-0186. Food and Drug Administration.

⁹⁸45 Federal Register, September 12, 1980, p. 60754. The initial classes of drugs chosen were: ampicillins, benzodiazepines, cimetidine, clofibrate, digoxin, methoxsalen, propoxyphene, phenytoin, thiazides, and warfarin.

Institute of Medicine report that favored the inserts but recommended additional research under actual conditions of use. It also mentioned the comments of the Regulatory Analysis Review Group, a federal interagency group created by President Carter to monitor proposed new regulations in an effort to hold down rising costs caused by government regulation. The RARG wanted a limited program to evaluate costs and benefits before proceeding to full implementation.

The final regulations reflected the years of negotiations that had preceded them. The regulations applied only to new prescriptions, not refills. The PPIs would be written in non-technical language, could not be promotional, and should be based primarily on the professional labeling for the product.

In most cases, the changes in the final rule did not significantly affect the overall concept of giving reasonably complete information to the patient, but rather clarified terminology or procedures. For example, in response to one comment PPI would now contain a statement that the patient retain the insert for future reference, especially women patients who may subsequently become pregnant. The FDA also now required that warnings pregnant women and nursing mothers be included under the "cautions" section of the patient labeling.⁹⁹

Despite its decision to forego a full PPI program, FDA's Draft Guidelines for the ten specific drugs indicated that the FDA did not intend to sugar-coat its advice. FDA gave its rationale for choosing each drug and a brief description of the likely content of its PPIs. For example, it chose ampicillins, widely used antibiotics, because serious allergic reactions can occur from the use of the drug. The PPI

⁹⁹45 Federal Register, September 12, 1980, pp. 60766-7.

specifically warned that antibiotics are not useful for treating the common cold. In its suggested insert for clofibrate, a drug to lower serum cholesterol levels, it included "recent data suggest that only a very select patient population use clofibrate, that is, only those people whose cholesterol and triglycerides have not responded to diet, weight loss, exercise, and other measures." In addition, it mentioned a doubling of the risk for gall stones and a statement about the carcinogenic potential of the drug.¹⁰⁰

PPIs were due to go into effect in 180 days. It had been six years since FDA began discussions with industry and consumer groups and five years since FDA had received the consumer petition. The FDA-mandated individual PPIs essentially provided the information for which consumer and women's groups had originally requested. They had visualized PPIs as a way to initiate a dialogue between patient and physician on the risks and benefits of drug treatment for disease. At last, they had the beginnings of such a program, even in severely truncated form.

Considering the limited program FDA finally approved, consumer groups were right in condemning the agency for endangering the public's health by the inordinately long period during which it investigated every possible ramification of the issue. Some might chalk up this delay to FDA's deferential attitude towards industry and the medical profession. But the more likely explanation for the years of delay was bureaucratic self-protection mixed with the inevitable inefficiency and procrastination inherent in a large organization. Patient package inserts were a relatively untested concept, with the exception of oral contraceptives and estrogens. Few bureaucrats

¹⁰⁰45 Federal Register September 12, 1980, pp. 60785-6.

would willingly implemented an across-the-board program costing tens of millions of dollars, in the face of open opposition from the drug industry and the medical profession, without overwhelming evidence of its ultimate success.

The essentially political process of compromise and negotiation, had worked. Public interest groups had claimed a place at the table with FDA's traditional constituent groups in the decision-making process. And then in the blink of an eye, or rather, the turn of an election the whole carefully crafted edifice collapsed. With the election of Ronald Reagan, who had made deregulating the economy a cornerstone of his campaign and the bottom line in his approach to governing, industry and the AMA saw a golden opportunity to press their case to scrap PPIs. President Reagan issued Executive Order No. 12291 on February 17, 1981, requiring federal agencies to review all proposed and existing regulations to determine both their necessity and cost effectiveness.¹⁰¹

The party that controlled the White House had always been part of the political equation in FDA decision-making, not only by its ability to appoint the Commissioner and his staff but also by its involvement in FDA policy-making. However, in the past, the FDA's more restricted mandate had limited political meddling. Within their scientific parameters more FDA decisions now encompassed value judgments and political philosophy. On April 28, 1981, President Reagan's newly appointed FDA Commissioner, Dr. Arthur Hull Hayes, Jr. stayed the implementation of the patient package information regulations in order to review objections from health

¹⁰¹Executive Order No. 12291, 46 Federal Register, February 19, 1981, 13193.

professionals and the drug industry.¹⁰²

In a highly unusual move, the FDA published its proposal to revoke its final rule on patient package inserts in the February 17, 1982 Federal Register. Since the body of FDA regulations have the force of law, it is rare to have the agency issue a ruling and then reverse itself in such a short period of time. In its rationale for revoking the rule, the FDA contended that it no longer believed that it could justify the 10-drug pilot program "based on both new information and on a different view and evaluation of some of the same factors that were present in the decision to implement the program."¹⁰³

Although the agency still believed strongly that informing patients more fully about prescription drugs would significantly improve the quality of their health care, it was no longer convinced that a mandatory program was the best way or only way to reach the program's ultimate goals. The proposal referred to new private sector initiatives that "appear to be accompanied by considerable enthusiasm." This was in direct opposition to its original rule of September 12, 1980, in which it doubted that voluntary programs reached many consumers.

Ciba-Geigy Pharmaceuticals declared that the private sector could do a better job of patient education "if only unleashed from the threat of federal regulations and organized so that a concerted and coordinated effort could be undertaken." It pledged a million dollars to form the National Council of Patient Information and Education (NCPIE), to be headed by former Congressman Paul Rogers.

¹⁰²46 Federal Register, April 28, 1981, p. 23739.

¹⁰³47 Federal Register, February 17, 1982, pp. 7200-1.

The AMA also announced that it was undertaking its own initiative to provide leaflets to physicians. Voluntarism, rather than regulation, was viewed as the primary motivational stimulus for providing patients with information about prescription drug benefits, risks, and usage.¹⁰⁴

In line with the privatizing climate of the 1980s, the FDA pledged to work closely with PMA or others by setting up a Committee on Patient Education "to serve as a catalyst for private sector initiatives." However, it also retained its authority to require future individual PPIs as needed and those already issued for oral contraceptives, estrogens, certain intrauterine devices, and progestational drug products.¹⁰⁵

"This responds to your March 31, 1975 petition" began a May 4, 1983 letter to Marcia D. Greenberger of the Center for Law and Social Policy from Mark Novitch, Deputy Commissioner of Food and Drugs. Without missing a beat, he continued, "I regret the great delay in providing this final response. We are attempting to process petitions received by this agency in a more timely manner." Citing the Presidential Order that resulted in the agency revoking the PPI pilot program, he formally denied her petition.¹⁰⁶

¹⁰⁴Louis Morris, "The FDA's approach to patient package inserts: The Four Phases of PPIs," Proceedings of an International Symposium on PPIs held in Ghent, Belgium, September 26-28, 1988, ed., Marc Bogaert, (New York: Excerpta Medica, 1989): 63.

¹⁰⁵47 Federal Register, February 17, 1982, p. 7202.

¹⁰⁶Letter from Mark Novitch, M.D., Deputy Commissioner Food and Drugs to Marcia D. Greenberger, May 4, 1983. Docket No. 75P-0277, vol. 23. Food and Drug Administration.

Of course, consumer advocates and critics expressed outrage at the FDA's actions. The FDA responded that its authority justified but did not mandate the agency's action. "In that the regulation is a discretionary one, it may be revoked under the same discretionary authority that permitted its issuance."¹⁰⁷

Despite indications that voluntarism was not getting information to patients, the Reagan and Bush Administrations refused to consider reinstating mandatory PPIs. The only way the FDA bureaucracy could have assured that PPIs or any of its other regulations functioned beyond political manipulation would have been for Congress to incorporate them directly into the Federal Food, Drug, and Cosmetic law.

In fact, patient package inserts had been an integral part of a major legislative effort in the 1970s to modernize the Federal Food, Drug, and Cosmetic Act. Just as the old "father knows best" attitude on the part of doctors no longer fit the realities of the last quarter of the twentieth century, FDA's 1938 legal framework hindered its ability to respond to its greatly expanded responsibilities, the complexity and sophistication of modern medicine and science, and the difficult questions of risk and benefit that surrounded so many of its decisions.

¹⁰⁷Ibid.

CHAPTER 9

"QUO VADIS, FDA?"

"Interestingly, not one person who has discussed the bill with me over the last two months has suggested the existing drug law is appropriate or that the status quo should be maintained. I think there is all but unanimous agreement that the existing law is archaic and badly in need of revision." Representative Paul G. Rogers.¹

"The major problems that confront us in drug regulation lie in the basic statute under which FDA operates," HEW Secretary Joseph A. Califano, Jr. told Ralph Nader's Public Citizen Forum on October 5, 1977. "The law has not kept up with scientific advances or with the changing needs of society. It highlights irrelevant historical distinctions [between classes of drugs] and perpetuates time-consuming, repetitive processes that are closed to effective public review. It unnecessarily increases the prices we pay for drugs. It keeps from consumers information necessary to participate in the decisions on whether they need drugs." The time was ripe to retool and refit the Food and Drug Administration for the last quarter of the twentieth century. The agency had gone as far as it could under the constraints imposed by the 1938 Federal Food, Drug, and Cosmetic Act. Secretary Califano announced that the Administration would be sending its drug regulation reform bill up

¹Congress, House, Subcommittee on Health and the Environment of the Committee on Interstate and Foreign Commerce, The Drug Regulation Reform Act of 1978, H.R. 11611: Hearings Before the Subcommittee on Health and the Environment of the Committee on Interstate and Foreign Commerce, 95 Cong., 2nd Sess., June 6, 1978, p. 2. [Hereafter cited as House Hearing, Drug Regulation Reform Act]

to Capitol Hill.²

The beginning of 1978 seemed a most auspicious time for congressional action on drug regulation. Years of accumulating discontent on the part of consumers, industry, and the FDA itself, had convinced Congress that serious efforts to reform the agency had become politically tenable. Science magazine called the FDA "a hot, popular issue." Gregory Spence on Senator Edward M. Kennedy's staff remarked to the reporter that "all the ingredients for a major drug reform are here: Senate awareness, well-considered proposals, the interest of the Administration, and some industry willingness to change."³

F-D-C Reports, the drug industry newsletter reflected the same sentiments. It found that senators were attuned, sympathetic, and knowledgeable about the issues. The Carter Administration had committed itself to new and innovative proposals to change the Food, Drug, and Cosmetic Law, as well as to revamp the FDA. Since there was also some positive movement within the pharmaceutical industry, "all of the important ingredients for major drug legislation are present." Moreover, lawmakers and interest groups alike recognized that a missed opportunity now might doom further efforts for decades.⁴

"Nothing less than a comprehensive rewrite will suffice," FDA Commissioner Kennedy advised a late 1977 meeting of the Institute of Medicine. "More patchwork

²HEW Secretary Joseph A. Califano, Jr. Speech to Public Citizen Forum, October 5, 1977. Doc. #79N-0186, vol. 9, tab 132, Food and Drug Administration.

³R. Jeffrey Smith, "FDA Reform: An Idea Whose Time Has Come," Science, (October 21, 1977) 177: 272-3.

⁴F-D-C Reports, December 12, 1977, p. 10.

efforts to make 1938 concepts fit contemporary science and a modern health care system will only further amplify the inconsistencies and contradictions that now encumber our work."⁵

The 1938 food and drug law, with a few amendments, had served the FDA adequately for almost twenty-five years because the agency for which it had been designed had remained essentially the same in its scope and structure. In 1962, the Kefauver-Harris Amendments, that had legislated a major expansion of the FDA's responsibilities for all aspects of prescription drug regulation, should have caused a profound transformation of the agency. But it did not. Instead, the FDA spent much of the decade reacting first to the resignation of George Larrick, the last of the FDA Commissioners to come up through the ranks, and then to a number of his short-term replacements. It weathered the chaos of major and minor bureaucratic reshuffling, while it tried to figure out how to implement the massive drug re-evaluation and other criteria that the 1962 law demanded.

It was not until the beginning of the 1970s that the FDA began to come to terms with its new mandate, with the consumer movement's demands for public inclusion, and with the scientific changes affecting the food and drug industries. By 1978, ten years of rethinking, restructuring, and responding to pressure from industry, Congress, and the public had produced a scientifically-based agency that was better organized, more open and accessible, and more cognizant of the needs of industry and consumers. Edwards, Hutt, and their successors had taken the agency as far

⁵FDA Commissioner Donald Kennedy, Speech to the Institute of Medicine 25th Annual Meeting, Washington, D.C., October 10, 1977. Docket #79N-0186, vol. 10, tab 153. Food and Drug Administration.

as possible using regulatory rule-making. However, to respond to the needs of a swiftly changing technological society that was also experiencing profound and complex changes in its value system required a reformulation of the fundamental law under which FDA operated.

The Drug Regulation Reform Act of 1978 was an amalgam of bills submitted by Senators Edward M. Kennedy and Jacob Javits, Representative Paul Rogers, the Carter Administration, and bits and pieces of other legislation that had been introduced and considered over the previous five years. In part, legislators drew on their experience with the Medical Device Amendments of 1976, which had given the FDA much more effective control over these devices than it possessed under provisions of the general drug law. The committee intended to build on its lengthy device hearings to determine whether provisions within that act should be extended to the rest of the agency's functions.⁶

Other issues had been explored during Representative Paul Rogers' hearings on the Drug Safety Amendments of 1976, the first legislative hearings to take a broad overview of drug regulation since the 1962 Kefauver-Harris Amendments. "We cannot afford to continue to criticize the inaction of FDA when it has insufficient authority with which to act or when it is forced to act only by bending the law and essentially legislating by regulation or when it doesn't have sufficient manpower and resources," Rogers had noted in his opening remarks at the hearings.⁷

⁶Medical Device Amendments of 1976, P.L. 94-463, 86 Stat. 539, (1976).

⁷Congress, House, Subcommittee on Health and the Environment of the Committee on Interstate and Foreign Commerce, Drug Safety Amendments of 1976: Hearings Before the Sub-Committee on Health and the Environment of the Committee

Officials at both the FDA and HEW were not unmindful of problems facing the agency. HEW Secretary Caspar Weinberger had established an outside committee, known as the Secretary's Review Panel on New Drug Regulation, in February 1975 to apprise him of FDA shortcomings. The immediate impetus for the Panel were allegations made by over a dozen disgruntled FDA employees, popularly referred to as 'conscientious objectors,' who had appeared on August 14, 1974 before Senator Kennedy's Joint Subcommittees on Health and Administrative Practices and Procedures. Their highly charged testimony recounted pressure by upper echelon agency personnel to force them to approve drugs about which they had reservations. When they failed to do so, FDA officials transferred them without proper procedures, excluded them from meetings, or subjected them to other forms of harassment.⁸

on Interstate and Foreign Commerce. 94th Cong., 2d Sess., March 20, March 30, April 1, 1976, p. 1. Hereafter cited as "Drug Safety Amendments of 1976."

⁸Congress, Senate, Subcommittee on Health of the Committee on Labor and Public Welfare and the Subcommittee on Administrative Practices and Procedures of the Committee on the Judiciary, Investigation of the Drug Industry: Joint Hearings before the Subcommittee on Health of the Committee on Labor and Public Welfare and the Subcommittee on Administrative Practices and Procedures of the Committee on the Judiciary, 93rd Cong., 2nd Sess., August 15, 1974. In his testimony before the Senate Committee, newly-appointed FDA Commissioner Alexander M. Schmidt promised to conduct a complete review and issue a report. In November 1975, after a year of delays and procedural quibbling on both sides, the FDA produced the 906 page Commissioner's Report, which basically exonerated the FDA on almost all counts. Schmidt later admitted that it was a mistake to have initiated the investigation in house. Not only did it take an inordinate amount of his time, but in the end any report that FDA issued looked like a whitewash. In its review the Panel concluded that the report did not adequately resolve many important allegations and recommended that the Secretary hire Justice Department lawyer, Frank E. Schwelb to complete the investigation. The probe continued for two more years eventually finding that FDA used improper procedures. Commissioner Kennedy ended up apologizing and reinstating the 'conscientious objectors,' as well as changing FDA personnel policies.

The Panel, swamped in the minutiae of charges and counter-charges, eventually gave over these responsibilities to a special investigator and concentrated its efforts on studying the broader and more important question of FDA policies and procedures for the approval of new drugs. In 1977, the Panel, chaired by Professor Norman Dorsen, a New York University law professor, issued "The Final Report of the Review Panel on New Drug Regulation." Panel members found "the system of new drug regulation that requires governmental pre-clearance of prescription drugs, based on evidence of safety and effectiveness" fundamentally sound, but needing substantial improvement to ensure that the system operated smoothly and efficiently. They proposed a wide range of legislative, administrative, and procedural reforms concentrating on four major areas: making the drug review process more open and accountable to the public, increasing FDA's scientific capabilities, improving the standards and procedures for pre-market approval of new drugs, and increasing FDA's authority in the post-market period.⁹

Endorsing the principle that government actions should be open to public scrutiny, the panel found an FDA drug approval system closed to public review and participation. They blamed this in part on a trade secrets policy which prohibited disclosure of most scientific data submitted to the agency in support of drug applications. They urged Congress to amend the Federal FD&C Act to provide that safety and effectiveness data did not constitute trade secrets for the purposes of the federal prohibitions against release of confidential and privileged information. To

⁹Department of Health, Education, and Welfare, Final Report of the Review Panel on New Drug Regulation, May 1977, (Dorsen Report), 2.

mitigate any possible adverse effect on drug innovation, the new law should provide that scientific data, while available for public scrutiny, could not be used by another drug sponsor to support an Investigation New Drug application or New Drug Application for five years without the consent of the original drug sponsor.¹⁰

Openness in government is a hollow promise if those who wish to participate cannot afford to do so. For years, public advocates had lobbied for reimbursements to public interest groups for the costs of attorneys and expert witnesses at regulatory hearings. Congressional committees investigating the problem had determined that agencies had the power to do this, although they refrained from making this mandatory. The Dorsen panel advised extending the reimbursement policy to those who filed petitions. The Panel reasoned that "FDA withdrawal of new drugs seldom occurs as a result of a hearing; thus the most likely form of public involvement is by petition. Moreover, a petition which awakens FDA to a previously unknown problem is at least as beneficial to the public interest as participation at a hearing."¹¹

"To promote public confidence in the agency, it is essential that FDA maintain a relationship with its regulatees which is impartial both in fact and appearance." The Panel found "no justification for much of the informal contact" between staff and industry personnel. Drop-in visits and decisions made on the telephone left an impression of improper industry influence in the review process, as well as precluding

¹⁰Dorsen Report, 4.

¹¹Dorsen Report, A-16. See Congress, Senate, Committee on Government Operation, Public Participation in Government Proceedings Act of 1976--S. 2715: Hearings Before the Committee on Government Operation, 94th Cong., 2nd Sess., June 24, 1976.

a written record of agency decision-making.

Although the committee recommended better salaries and training for FDA personnel, it endorsed the decision made by Commissioner Edwards to bolster FDA's scientific capabilities by using standing advisory committees. The advisory committee system furnished "FDA with valuable advice on technical and policy questions and afford FDA staff an opportunity for dialogue with experts in drug therapy." The panel reiterated the need for a broadened selection process and questioned FDA's conflict of interest policies. The Panel gave its unqualified support to the FDA's policy of opening all advisory committee meetings and deliberations to the public. The report recommended the inclusion of a voting public interest representative on each advisory committee "so that consumers will have a voice in deciding whether the social benefits of new drugs outweigh their risks." Believing that Americans needed as much information on these potent pharmaceuticals as they could find, the Panel also endorsed the use of patient package inserts.¹²

As FDA, the scientific community, and the public had done for most of the 1970s, the Dorsen Committee grappled with the concepts of 'safe' and 'effective.' It found these to be "imprecise because no drug is absolutely safe or always effective." It recommended that the statutory standard should be amended to reflect the fact that assessing the value and ultimate approvability of a new drug entailed weighing its risks against its overall benefits. "The complete assessment of the risk and effectiveness of a new drug cannot be limited solely to data generated about the product. Other factors, such as the severity of the disease to be treated, the

¹²Dorsen Report, 5, A-9.

availability of alternative remedies, and the drug's public health implications, should be considered."

Reflecting a decade of debate over the significance of scientific methodology, Panel members recommended that efforts should be made to determine "the value and limitations of current scientific methods for assessing safety and efficacy." Participation in the judgment of benefits should be broadened to include interested individuals from many sectors of society. Committee members realized that FDA decision-making had moved from the realm of purely scientific data to one that encompassed political considerations. Five years earlier, participants at the National Academy of Science forum, "How Safe Is Safe?" thrashed out the same issues and came to similar conclusions.

Significant changes needed to be made at both ends of the drug approval process. They favored accelerated approval of new drugs in certain exceptional cases, such as those involving a drug that represented a major therapeutic breakthrough. The Dorsen panel advocated giving FDA the power to require post-marketing surveillance of drugs. Once a drug was approved for marketing, FDA had almost no control over the conditions under which it was used. During the 1970s, the medical and scientific community had become more aware of the danger of drug interactions and adverse reactions. A drug shown to be safe and effective on 2000 volunteers in a controlled clinical trial might present a surprisingly different picture when used over the course of weeks or months or years by two hundred thousand or two million patients in uncontrolled situations. The FDA needed the means to require manufacturers to do additional research or initiate follow-up studies in

exchange for approval.

The drug chloramphenicol presented another type of regulatory problem for the FDA. Useful for treating very specific diseases, it caused dangerous and unacceptable side effects in general use. FDA had no authority to restrict its use to specific diseases or its distribution to particular settings, such as a hospital, or to specially-trained practitioners. The FDA's only choices were to allow its uncontrolled use in any situation in which a doctor deemed it appropriate or to completely remove it from the market.¹³ Unlike most government reports, this one did not end up languishing in an obscure folder in some warehouse outside of Washington. FDA Commissioner Kennedy pronounced the Panel's recommendations "thorough, thoughtful, and well balanced" as well as "fair and reasonable." Because of the importance and potential impact of the Dorsen Report's administrative and legislative recommendations, Commissioner Kennedy invited the public to comment. The Agency announced in the Federal Register that it would hold a public hearing on September 29th, 1977. "To emphasize the importance we attach to public comment on the recommendations," Kennedy informed HEW Secretary Califano, "I wrote to approximately 50 organizations and individuals whose knowledge and experience would make their views particularly valuable to us." The FDA utilized this information as well as presentations made at the hearing in the preparation of its report to the Secretary on the Dorsen Report.¹⁴

¹³Dorsen Report, 8, A-8.

¹⁴Department of Health, Education, and Welfare, Report by the Commissioner of Food and Drugs on Findings and Recommendations of the Review Panel on New Drug Regulations, March 1978.

Based on the Panel's recommendations, Califano instituted those changes that did not require new legislation. These included strict new guidelines governing meetings between Agency officials and industry representatives, the development of a rudimentary drug adverse reaction reporting system, the inclusion of consumer representatives as voting members of advisory committees, increased recruitment and better use of professional personnel, and improved communications with physicians and other health professionals. These signified major changes and commitments on the part of HEW and FDA officials. They could proceed no further, however, by rule-making and internal procedural changes.

The Panel recommendations became the basis for the Carter Administration Drug Regulation Reform bill, which Califano had announced on October 5, 1977. "At your request we have worked with the General Counsel to draft legislation for your consideration in time for submission to the Congress in this session," Commissioner Kennedy had written to Califano. "In developing our proposals, we have been guided by close consultations with congressional staff involved in the development of existing proposals for drug regulatory reform and with executive agencies, public interest groups, and industry and professional associations."¹⁵

Senator Edward M. Kennedy announced the Drug Regulation Reform Act of 1978 on the Senate floor with all the fanfare that a once-in-a-generation piece of legislation deserved. He hoped that the 228-page bill, which would bear his name, would change the face of drug regulation until the end of the twentieth century. The

¹⁵Memorandum from FDA Commissioner Donald Kennedy to HEW Secretary Joseph A. Califano, Jr. March 16, 1978.

bill was the culmination of years of hearings, negotiations, and legislation put forth by himself as well as Senators Jacob Javits, Gaylord Nelson, Claiborne Pell, Harrison Williams, Representative Paul Rogers, and the Carter Administration. The mark-up sessions preceding the final bill, which included congressional staff members of all the principals, had extended for months as participants pressed their points, bargained for advantage, traded off provisions, and modified specific clauses. "It is a consensus bill," Kennedy advised his Senatorial colleagues. "As such, no single sponsor endorses every single aspect of this legislation.... but by and large, we agree that this legislation provides the basis for sound, comprehensive, legislative reform of the drug provisions of the Food, Drug, and Cosmetic Act."¹⁶

Legislators had reason to believe that they had a unique opportunity to modernize the forty-year old Federal Food, Drug, and Cosmetic Act. The proposal envisioned a top to bottom re-writing of the law. The provisions of the omnibus bill divided into four major areas: 1) changes that affected internal operations of the FDA or its ability to regulate various types of drugs; 2) efforts to respond to charges that the United States had experienced a "drug lag" that had kept Americans from using beneficial drug products already on the market in other industrialized nations; 3) means to encourage competition in the pharmaceutical industry by allowing generic firms to produce cheaper versions of popular drugs while at the same time protecting

¹⁶Congress, Senate, Subcommittee on Health and Scientific Research of the Committee on Human Resources, Drug Regulation Reform Act of 1978, S. 2755: Hearings Before the Subcommittee on Health and Scientific Research of the Committee on Human Resources, 95 Cong., 2nd Sess., March 17, 1978, p. 3. Floor statement of Senator Edward M. Kennedy introducing the Drug Regulatory Reform Act of 1978. [Hereafter cited as Senate Hearings Drug Regulation Reform Act]

the interests of the original firm and encouraging drug innovation; and 4) procedures to increase public participation in the FDA drug approval process and provide drug information to the public.

From FDA's perspective, a major thrust of the proposed law placed all drugs, no matter when they had been approved, under one standard and one form of regulation. HEW Secretary Califano testified that "there is no reason that the standards for drug approval, continuing marketing or withdrawal should vary by historical accident; the time or circumstances of introduction to the market says nothing to us as consumers." FDA wanted to end anomalies in the law that applied different standards to new drugs, 'grandfathered' drugs--those in use before 1938, drugs approved between 1938 and 1962, antibiotics, and insulin. The FDA sought to extend the re-organization that Peter Hutt had applied to the agency's procedural regulations to its legal framework.¹⁷

Senator Kennedy's bill carried over the concept of relative safety and effectiveness from the Review Panel on Drug Regulation recommendations. The bill defined safety as an acceptable benefit in view of the risks that the drug entailed. In acknowledging that few absolutes existed in the modern world, the FDA predicated its regulation philosophy on the concept that "there are always risks associated with drug use but that the benefits the drug provides can outweigh these and that is the condition for marketing a drug."

In determining the safety of a drug, the FDA's task was made more difficult by the fact that FDA law for the most part imposed constraints prior to granting

¹⁷Senate Hearings Drug Regulation Reform Act, 238.

permission for drug marketing. Decisions had to be based on the type of pre-marketing studies that were feasible. Animals studies were useful but could sometimes be misleading. Using current animal testing techniques, both aspirin and penicillin would probably be rejected as unsafe, but thalidomide's ability to cause birth defects may well have gone undetected (it causes similar effects only in rabbits if given during the first trimester).

The number of patients that could be enrolled in clinical trials within the constraints of time and cost limited human testing. With a few thousand patients, it is difficult if not impossible to assess rare side effects. The regulatory structure encourage FDA to exhibit a high degree of caution in approving new drugs. The agency knew, and knows to this day, that while the American public may grumble about the slow pace of new drug development or the costs that result from excessive regulation, it is unforgiving of an agency that allows another thalidomide to slip through, even through no fault of its own.¹⁸

Once approved, a drug may be given to millions of people, who take it anyway they want, as often as they remembered, in conjunction with any other food or medication. Under the 1978 bill, any drug, old or new, could be subject to post-marketing surveillance for a period of five years, if the Secretary determines that there was a public health reason to do so. Data on post-market surveillance would be collected and published annually in the Drug Experience Assessment Report. "Because all new drugs will be tightly monitored, we will be able to allow them on the market more rapidly than the process allows today," Commissioner Kennedy testified.

¹⁸F-D-C Reports, April 10, 1978, B-1.

Ironically, the lack of post-marketing surveillance also limited the FDA ability to approve certain drugs. "Because it is difficult to remove a drug from the market," Secretary Califano argued, "our only responsible course has been to be extraordinarily conservative in the approval process." The drug reform bill gave FDA powers to remove a drug without having to declare it an imminent hazard to public health, a device it had used only once.¹⁹

Industry had chafed at the regulatory restraints imposed by the 1962 Kefauver-Harris Amendments efficacy requirements and what it believed to be excessive FDA regulation in the early 1970s. For a number of years many in the pharmaceutical industry, as well as prominent members of the scientific community, had charged that the United States experienced a "drug lag" in the introduction of new drug entities vis-a-vis other industrialized nations. Stricter safety requirements in the United States coupled with a lack of post-marketing surveillance explained part of the lag but the FDA's inertia and bureaucratic bungling had also contributed to the problem.²⁰

¹⁹Senate Hearings Drug Regulation Reform Act, 263. The FDA had removed phenformin, a drug to treat diabetes.

²⁰F-D-C Reports, March 29, 1978, A-1. Describing the drug lag became a cottage industry in the 1970s. A partial bibliography includes: Clement Bezold, The Changing Environment for New Drugs (New York: John Wiley and Sons, 1981), Rita Ricardo Campbell, Drug Lag: Federal Government Decision Making, (Stanford, CA: Hoover Institution Studies, 1976), Peter Temin, Taking Your Medicine: Drug Regulation in the United States, (Cambridge, MA: Harvard University Press, 1980), William Wardell, ed., Controlling the Use of Therapeutic Drugs: An International Comparison, (Washington, DC: American Enterprise Institute, 1978), William Wardell and Louis Lasagna, Regulation and Drug Development, (Washington, DC: American Enterprise Institute, 1975). Wardell and Lasagna were among the first to write on the drug lag in articles for the journal, Clinical Pharmacology and Therapeutics. Interestingly, many of the books and articles about the drug lag came out of conservative organizations, such as the American Enterprise Institute and the Hoover Institution, attempting to counter the growing government regulation of the economy

The bill's sponsors sought to speed up the drug approval process in general but especially for 'breakthrough' drugs. A New Drug Application averaged 34 volumes in the 1970s and cost millions of dollars to complete. Each had to be painstakingly reviewed by FDA medical officers, who often demanded clarification, more information, or more testing--the process could run from six to eight years. FDA officials complained that under the law they had no way of differentiating an important new drug from a "me-too" drug, a slight variation of a currently marketed drug. The agency needed a regulatory mechanism to identify and expedite "breakthrough" drugs, innovative products that offered new or substantially improved treatment for a disease. While FDA had begun to use computers to track applications and had initiated new procedures to review applications more expeditiously, HEW and members of Congress hoped that changes in the law would be an additional factor in improving FDA productivity.²¹

These provisions were not without their critics. Fred Wegman, speaking for the American Association of Retired Persons, expressed the fears of many that speeding drugs through the approval process would mean unsafe drugs reached the market. Decisions made under this section of the law could easily be made for political or economic rather than health reasons. Wegman charged that drug companies and physicians could use "calculated leaks to the media and pressure on

in the 1970s. In the late 1970s Representative Steven Symms (R-Idaho) authored a bill which would have repealed the 1962 efficacy amendment. It eventually had 115 members of Congress as co-sponsors. Although it never got out of committee, FDA took the threat seriously.

²¹HEW Secretary Joseph A. Califano, Jr., speech to Public Citizen Forum, October 5, 1977.

patients to demand premature release of inadequately proven drugs."²²

The FDA vehemently denied that approval of breakthrough drugs would compromise safety. FDA wanted the authority to be able to put drugs for major diseases, which had met all safety regulations, that had very good preliminary evidence of effective but had not completed all clinical trials on the market more rapidly. The company would then continue to monitor the drug. There was nothing the FDA could do under the law to allow this type of drug to be given to desperately ill patients that needed it.²³

Many critics pointed to FDA's handling of the epilepsy drug, sodium valproate, as an example of what FDA could do to expedite drugs under its present regulatory parameters. Doctors treating children who had not responded to other forms of treatment joined with the Epilepsy Foundation to pressure the agency to allow them to use valproate. The FDA approved limited distribution of the drug, which had been marketed in Europe for years, in 90 days under a compassionate NDA after Abbott Laboratories had submitted its application. However, FDA ruled that the prescribing of valproate was limited to two patients per doctor because of safety questions. FDA Commissioner Kennedy stressed to the congressional committee that this was "a very, very limited mechanism. It depends heavily on doctors being in the know, on the inside track--the system just does not get the drug to large fractions of the population immediately."²⁴

²²Senate Hearings Drug Regulation Reform Act, 924.

²³F-D-C Reports, March 20, 1978, A-7, B-6.

²⁴Senate Hearings Drug Regulation Reform Act, 254.

The bill also ran into a buzzsaw of criticism from the American Medical Association and related medical groups for trying to place restrictions on physician prescribing. Physicians feared that the FDA's actions would pit local hospitals against university medical centers, general practitioners against specialists, and rural versus urban medical establishments, eventually weakening the power of them all. It revived the arguments of physician autonomy and raised fears of encroaching federal regulation of medical practice. The AMA testified that the bill would "grant unbridled authority to the Secretary" who could establish any restrictions.²⁵

One of the most important components of the 1978 bill was the drug monograph system. Under the drug approval system then in place, the innovator firm submitted a New Drug Application which included all manufacturing information on its drug, as well as the required animal and clinical studies demonstrating safety and efficacy. If approved, the manufacturer then had exclusive rights to market this drug until its patent ran out. In reality, however, the innovator firm had rights into perpetuity for that drug because for another manufacturer to market the product would necessitate conducting the same animal and clinical trials as the original firm. Few companies were willing or able to invest the millions of dollars needed to repeat the experiments to compete with a drug that already had a market niche. Critics contended that the system stifled competition. Equally important, repeating clinical trials that had already confirmed the drug's safety and efficacy placed human subjects of these experiments at risk or gave them a placebo instead of the proven product.

²⁵Senate Hearings Drug Regulation Reform Act, 420.

Under the 1978 bill, legislators proposed that the pioneer manufacturer submit a petition establishing a monograph for its drug including manufacturing information and the required safety and efficacy data. The pioneer firm would have exclusive use of the monograph for five years or until the patent expired. Subsequent manufacturers who wanted to market the drug only needed to show that their product was bioequivalent and furnish evidence of adequate manufacturing controls.

Protection of human subjects was important, but the real impetus behind this proposal was the desire to get cheaper drugs on the market. In the double digit inflation of the 1970s, drug prices had sky-rocketed. The growing dependence on pharmaceuticals to treat many medical conditions, an aging population which purchased 25 percent of prescription products, and a federal government that spent billions of dollars on drugs propelled the demands for generic drugs that would be sold at a fraction of the cost of the original patented products.

If any section of the bill could be considered a deal breaker, it had to be this one, especially when coupled with another part of the bill that required the release of safety and efficacy raw data after approval of the NDA. HEW Secretary Califano had reminded Ralph Nader's Public Citizen Forum that the secrecy surrounding the drug approval process prevented disclosure of information to the public. "This procedure denies FDA's decision-makers the fruits of scrutiny by other interested reviewers, and closes from view proceedings of vital and legitimate interest to the public."²⁶

²⁶HEW Secretary Joseph A. Califano, Jr. speech to Public Citizen Forum, October 5, 1977.

The bill, by requiring a public hearings, "will involve a broader scientific community in the process of commenting on and criticizing both the quality of the data that the sponsor brings in and the quality of FDA's decision," FDA Commissioner Kennedy observed. "I do not believe that the prospect of public scrutiny and second-guessing by the scientific community at large, or by the public interest community--asking the scientific community to help it--is likely to do anything except improve the quality of [drug] submissions."²⁷

But pharmaceutical companies had no intention of revealing valuable trade secrets. C. Joseph Stetler, PMA spokesman, told the Senate and House committees that premature disclosure of safety and efficacy data would discourage drug research because the fruits of the innovators' efforts would be available to imitators, both foreign and domestic. Scientists did not want this information, he charged. In actuality, companies that did little research were the ones that really wanted it. "With this [data] they can see "what blind alleys have been pursued, what analogs explored, what research routes led to significant findings, what serendipitous findings were made and what long and short term animal investigations revealed."

Since the public will be well represented on advisory committees and at each public hearing, Stetler argued, the drug approval process would be open, orderly and responsible without unduly penalizing the monograph applicant. "These laudable objectives [openness in government and FDA'S justification for its decisions] can be achieved without the disclosure of valuable data, through the release of scientific

²⁷F-D-C Reports, April 10, 1978, p. B-4.

summaries and public participation in the approval process."²⁸

Anita Johnson, who had always disparaged the value of summaries to scientists, now saw more sinister reasons in manufacturers' refusal to disclose raw safety and efficacy data. She openly questioned the adequacy and honesty of data submitted by drug companies. "As long as drug tests are performed by the very parties that stand to benefit the most by a finding of safety and effectiveness, open data will be necessary to provide adequate incentives for careful and honest practices. The companies must know that their tests can be gone over with a fine tooth comb by all scientific comers." Small wonder, she concluded, that this obvious measure has been opposed by industry for years.²⁹

Bill supporters did not feel that the monograph system and the data release would dramatically alter the current drug approval process. However, Senator Richard Schweiker, who had taken up the cudgel in support of the pharmaceutical industry, wrote to Senator Kennedy on May 26, 1978 to inform him that the release of raw safety and efficacy data "appear to me to be so serious for the future of drug development in this country that they constitute an insurmountable obstacle to my support of any drug law revision legislation."³⁰

Industry supporters also had problems with Title II of the bill, which authorized the establishment of a National Center for Clinical Pharmacology. The legislators had given the HEW Secretary broad discretion for the Center's responsibilities and its

²⁸House Hearings Drug Regulation Reform Act, 1974.

²⁹House Hearings Drug Regulation Reform Act, 1985.

³⁰F-D-C Reports, June 12, 1978, p. T&G 5.

research projects. Backers envisioned it doing research in areas where private funds and private incentive had been clearly shown to be inadequate, such as treatments for rare diseases. Representative Rogers championed the Center because "we have no real technique, no machinery, for seeing the drugs that may be needed for small segments of the population be developed where there may not be a market potential for a drug company to develop that drug and bring it on the market." Despite the fact that private industry had forsaken this market, PMA's Stetler, opposed any government effort in competition with private industry.³¹

The Washington Post in its March 22, 1978 editorial explored what was at stake in this bill and the enormous hurdles that it needed to clear if its sponsors ever expected to see it signed into law. On the positive side, pharmaceutical companies would have fewer obstacles to surmount in putting new drugs on the market, the FDA would have more power to take dangerous drugs off the market, and consumers would be furnished with more information about drug side effects, the editorial concluded. "Given the fact that each of those aims is something the group benefitting from it has been seeking for years, you might think the bill would be regarded as a wondrous example of consensus legislation."

But the conflict between the parties was so great that reconciliation appeared unlikely. Thus, some drug companies and consumer groups had already denounced various aspects of the legislation. The editorial, however, ended on an optimistic note. "Our impression of Mr. Califano's proposal is that it balances the competing interests quite carefully..... [I]t seems to us that the outline is there for a new law--an

³¹F-D-C Reports, December 19, 1977, p. 11.

improved law that will keep the essential new drugs coming while giving the public the necessary reasonable assurance of safety."³²

Unfortunately, the Washington Post's confidence was not warranted. The bill, which suffered the fate of many omnibus bills, was too ambitious, too complex, and encompassed too many controversial topics that adversely affected too many constituencies. Despite months of hearings, backpedaling by sponsors, and bitter, extensive negotiations, a grand over-arching design for drug regulation in the United States was not to be--the bill did not even reach a vote.

Kennedy tried to pass a bill again in 1979. The mammoth 1978 Drug Regulation Reform Act had replaced, modified, or revised virtually every drug related provision of the Federal FD&C Act. Senator Kennedy's rewrite of the bill, the result of an agreement between Kennedy and Senator Richard S. Schweiker (R-PA) on a block of industry-backed amendments, was a much more limited bill that selectively amended the 1938 Act in order to implement a limited number of new drug policies.

The new bill kept many of the important elements of the original bill, including expedited approval for 'breakthrough' drugs, patient package inserts, post-marketing surveillance and the FDA research center, now called the National Center for Drug Science. To gain industry support, the new law abandoned the monograph system, permitted drug companies to submit summaries--instead of raw test data--on safety and effectiveness testing of drugs for which they sought approval, permitted the export of drugs that did not meet US safety and efficacy standards in certain circumstances, and weakened criminal liability standards for drug company

³²Washington Post, March 22, 1978, p. 16.

executives.³³

As an indication of how desperately Senator Kennedy wanted passage of the bill and how minimal were its chances, he brought it up for a voice vote on September 26, 1979 with only four senators on the floor. The bill that had been the subject of more than five years of hearings, which produced 38 volumes of testimony, slipped quietly through the Senate with virtually no debate. Critics may have been caught napping but when his outraged opponents woke up on September 27 the press releases flew. The bill was denounced by all interests--the Pharmaceutical Manufacturers Association, the American Medical Association, the Center for Law and Social Policy and any other constituency that could buttonhole a reporter. Kennedy may have snuck the bill passed the Senate, but it would never see the light of day in the House.³⁴

In the past substantive changes in the food and drug law had come only in the wake of a tragedy, such as the 100 deaths from Elixir Sulfanilamide which led to the 1938 Federal Food, Drug, and Cosmetic law and the near disaster of thalidomide which resulted in the enactment of the 1962 Kefauver-Harris Amendments. No such tragedy or public health emergency arose to give the needed impetus to pass this bill. After a decade of debate and discussion it had become clear that many possibilities for reform existed, but each had its price. What tragedies had done in the past was to sweep away the consideration of cost and tradeoffs by presenting the situation in the starkest terms. Now, however, the issues were being considered on their own

³³F-D-C Reports, May 14, 1979, p. B-3.

³⁴Washington Post, September 28, 1979, p. A-9.

merits. The various committees had become mired in the complexities, in weighing such issues as scientific testing, economic benefits, levels of risk, and conflicting risks. In 1979, the positions of the different parties in the drug field were so antithetical that reconciliation was impossible.

But having said that, it should not be construed that this was an exercise in futility, that Congress and the Administration threw up their hands and accepted the fact that no means existed for the FDA to regulate drugs in a complex world of competing interests and contested values. The food and drug laws that had been adequate to guide a small, obscure government bureaucracy with limited duties and restricted responsibilities had become a strait-jacket limiting FDA's ability to respond to either its new or old challenges. After the dust settled and the realization sunk in that an all-encompassing legal framework was out of the question, the principals began the tedious work of implementing what appeared feasible.

Some elements of the bill became part of FDA's functions through its regulatory rule-making. In 1979, as prospects for implementing patient package inserts by law dimmed, the FDA published a notice of rule-making in the Federal Register, held hearings, evaluated comments, and issued its final rule in 1980. FDA bureaucrats thought they had secured the rights of patients to be informed of the risks and benefits of prescription drugs. The quick life and death of the inserts certainly must have underscored for many bureaucrats the value of protecting its programs from meddling politicians by enacting them into law. Lost for the time being with Drug Regulation Reform Act was the right of patients to be informed of the risks and benefits of the drugs prescribed for them.

Efforts to accelerate the drug approval process continued to be a high priority goal for the agency, especially in the time of AIDS. To answer charges that the drug approval was too capricious during its investigational stage and too rigid during its approval stage, the FDA instituted regulations to make the process more predictable by encouraging drug companies to seek advice from FDA about testing plans, protocols, and methods. Bureaucratically, the agency had evolved philosophically over the decade from the "Gotcha!" adversarial stance many of its bureaucrats had taken toward industry to a more cooperative attitude in which agency personnel cooperated with industry in establishing NDA requirements.

FDA embraced the concepts of 'breakthrough' drugs, post-marketing surveillance, and limited distribution to expedite the approval process for important drugs and over time, the approval time for these important drugs has continued to shorten. But FDA's need to protect itself from charges that it has allowed dangerous drugs to enter the market because of its lack of vigilance has undermined its efforts to speed the introduction of new drugs except for fatal diseases, such as AIDS. Despite a 1995 GAO report that the average approval time in 1995 has shrunk from 33 to 19 months, FDA Commissioner David Kessler was still called on the carpet to defend his agency before a Senate committee that threatened to privatize the approval process.³⁵

During the 1980s, major portions of the bill eventually were enacted into law, although sometimes emerging in barely recognizable forms. The research-based

³⁵Congress, Senate, Committee on Labor and Human Resources, Hearings on S. 1477 Before the Senate Committee on Labor and Human Resources, 104th Cong., 2nd Sess., February 28, 1996.

pharmaceutical companies had the clout to defeat the monograph system but not the need for cheaper generic drugs. Ironically, the FDA already had a procedure, the Abbreviated New Drug Application (ANDA), to approve generic equivalents for drugs approved before 1962, but lacked the ability to extend this to post-1962 drugs. For pre-1962 drugs, generic drug company conducted tests that showed that the generic drug were bioequivalent to the pioneer drug and that their drug would be properly manufactured and labeled.

In the late 1970s, FDA Deputy Director Dr. Marion Finkel created the "Paper NDA" by internal memoranda as way of extending the ANDA process to post-1962 drugs. After the pioneer company's patent expired, the second company presented a literature search documenting toxicology, pharmacology, safety and efficacy data on the drug. Just as in an NDA, it submitted full data on its chemistry, manufacturing, and quality control procedures plus evidence of the bioequivalence. If FDA accepted the data, the second company had approval to market the drug. While this allowed the marketing of some products, FDA estimated that satisfactory scientific literature was not available for 85% of all post-1962 drugs. All involved realized that this was a stop-gap measure.³⁶

In extraordinarily bitter negotiations, even by Washington's standards, passage of a generic drug law came down to what kind of concessions the PMA could wring out of Congress in exchange for its acceptance of generics. Representative Henry Waxman (D-Calif) conducted the intense and difficult negotiations between the

³⁶House Report (Commerce Committee) No. 98--857(I), June 21, 1984 [to accompany H.R. 3605], p. 16.

research-based pharmaceutical firms that created brand-name drugs and the generic drug makers, consumers, the elderly, and organized labor. A dozen research-based firm fought against the negotiation efforts of their trade association, the PMA, doggedly insisting on further concessions. The fight was so bitter that top PMA officials resigned abruptly.

The name of the new law, the Drug Price Competition and Patent Term Restoration Act of 1984, often called the Waxman-Hatch Act, spelled out the terms of the deal. In exchange for allowing generic firms to produce some competition in the pharmaceutical field, the pioneer firms would get extensions on its original drug patents. Because of the enormous cost of reproducing safety and efficacy data, the net result of FDA's present rules "has been the practical extension of the monopoly position of the patent holder beyond the expiration of the patent," Waxman argued. A generic drug would produce competition in the drug field and lower prices. Proponents argued that 150 drugs approved after 1962 were off patent and had no generic equivalent, among them five best sellers: Motrin, Valium, Inderal, Dyazide, and Lasix. The Federal government alone spent \$2.4 billion in 1983 on drugs. "The availability of generic versions of pioneer drugs approved after 1962 would save American consumers \$920 million over the next 12 years."³⁷

In testimony before Congressional committees, pharmaceutical firm representatives claimed that the effective patent term of their drugs had been shortened by years while the NDA worked its way through the laboriously slow FDA

³⁷Drug Price Competition and Patent Term Restoration Act, P.L. 98-417, 98 Stat. 1585, (1984). Congressional Quarterly--1984 Chronology (Washington, D.C.: Congressional Quarterly, 1985), .

approval process. The new law compensated for this by extending the patent for a period not to exceed 5 years (the period of patent extension when added to the patent time left after approval of the product could not exceed 14 years). Most observers believed that this gave the pioneer company a tremendous advantage, but proponents of the legislation urged its adoption as the best possible compromise between two competing economic interests. On the day the law went into effect, generic manufacturers submitted over 200 ANDAs.³⁸

The Orphan Drug Act was the second offspring to emerge from the wreckage of the Drug Regulation Reform Act. In the 1978 bill Congress had proposed a National Center for Drug Science, which amongst its other duties, would have conducted research on drugs for rare diseases. However, in the 1980s, when the party in power had popularized the slogan, "get the government off our backs," the idea of the federal government engaging in drug research in direct competition with private industry was anathema. But in a system driven by profits, in which millions of dollars had to be committed for research and testing before a drug can be marketed, companies were not willing to commit these resources unless they had a likelihood of recouping their investment. The answer put forth by the Reagan Administration was to offer economic incentives to private industry to produce these drugs.

FDA officials indicated not only their support for the bill, but their intent to react favorably to orphan drug applications and facilitate their approval. "FDA has a

³⁸House Report (Commerce Committee) No. 98--857(I), June 21, 1984 [to accompany H.R. 3605], pp. 14, 17.

longstanding policy of approving NDAs on the basis of studies with relatively few patients when the disease in question is rare and the benefit-risk considerations are favorable." If the studies were well done, the drug would be approved. FDA would further ease the regulatory barriers for orphan drug approval by informing companies of precisely the tests it required for approval.³⁹

After much debate a compromise bill authorized tax credits and grants to promote the development of these rare disease drugs. It also authorized seven years of exclusive marketing rights for unpatentable rare disease drugs. Despite objections to the tax credit provisions of the bill from Treasury officials, President Reagan signed it into law on January 4, 1983.⁴⁰

Much of what Senator Kennedy and other supporters had envisioned in 1978 eventually came to pass in one form or another. What got lost along the way were the provisions that offered greater openness and public participation in the drug regulatory process. By the end of the 1970s consumerism was on the defensive, blamed for high costs, red tape, and an intrusive government. For many, the Sidney Wolfes and Anita Johnsons had ceased to be determined warriors protecting the health and safety of the public but extremists and obstructionists. Industry beat back efforts to include the public in the evaluation of New Drug Applications. It kept a tight lock on raw data documenting safety and efficacy, although FDA-vetted data

³⁹House Report (Energy and Commerce Committee) No. 97-840, September 17, 1982, [to accompany H.R. 5238], pp. 11-12.

⁴⁰Orphan Drug Act, P. L. 97-414, 96 Stat. 2049 (1982). The FDA produces a listing of Orphan Product Designations and Approvals every three months. The listing that covers drugs through March 31, 1996 has over 400 products listed.

summaries became available to the public after an NDA had been approved.

For non-profit groups the ability to participate in hearings would continue to depend on how much money they could raise. The idea that government would reimburse consumer advocates for the cost of attorneys and expert witnesses who would then expose agency shortcomings no longer held favor. Although the Medical Device Amendments required the use of advisory committees that had consumer representatives, the FDA would have to continue and extend this practice by regulation. Although never balancing industry and academic influence on advisory committees, the FDA did try to develop diversity and include more fully consumer and patient groups on its advisory committees.

Even with the loss of particular sections of the bill, the forces dissatisfied with the transformation of the FDA could no more reverse the changes that had been made in the 1970s than they could stop the tides. The 1978 Drug Regulation Reform Act was a direct reflection of factors that had transformed the Food and Drug Administration and American attitudes toward drugs, health, safety and risk. In the breadth and sweep of its provisions, it demonstrated as clearly as any institutional flow chart or annual report the complexity of the organization and the problems it had begun to deal with on a regular basis in the 1970s.

As much as the old-timers might lament it, the old FDA was a product of a time that has since past. Even if the consumer movement, the media, and the congressional investigating committees were to diminish in importance, the pre-1970 FDA could not be recreated. The old FDA functioned in a Norman Rockwell time of dining room tables heaped with a wondrous array of brimming dishes assumed to be

safe and nutritious. A time in which housewives tried products marked "NEW" because they promised to make their lives easier or added variety to their cooking or because "new" meant progress and store-bought meant clean and scientifically produced.

The old FDA operated in a time when old Doc Jones knew the whole family, had brought most of them into the world, and offered sympathy when the old left it. He knew what illnesses his patients had and what medicines they were taking. If Doc Jones thought this medicine might work, that was good enough. His patients gratefully took the samples he handed out or filled the prescription down at the drug store, a fixture in the community. The neighborhood pharmacist, like the family physician, personally knew all his customers, their medical history, and the drugs they took. After a comment about the doctor's handwriting, and perhaps the cost of the prescription, few patients asked any questions about the medicine given them.

The old FDA had a specified period in which to decide whether test results and information submitted by the manufacturer demonstrated the safety of a new product. Unless the FDA issued an order finding that such safety had not been established, the manufacturer could proceed to market the drug. In most cases, the FDA rubber-stamped its approval. Did it work? The company provided data to back up its claims, but it could be anecdotal, a testimonial from Doc Jones about the wonderful results he had gotten prescribing it for his patients. Neither the patient nor the FDA nor consumer advocates asked whether the drug was effective. Or whether other drugs on the market did the job as well or better. Or if taking a powerful drug like this had any serious risks or side-effects that the patient should know about.

In the old FDA, there was little the public could do even if it had chosen to try to influence FDA decision-making. Much of the agency's time and effort was taken up inspecting manufacturing plant and ruling on labeling. Either the plant met cleanliness standards and specifications, or it did not. Its materials met assay requirements, its antibiotics were up to potency, and its labeling contained all the information specified in the regulations or they did not. The parties involved might argue about the particulars--whether the plant should be cleaner, there should be less dirt or rodent hairs in food products, or the level of particulate matter in the antibiotic should be lower. But these are not the risk/benefit questions that the FDA began to face in the late 1960s and 1970s and that continue to the present. Nor do they involve inimical positions based on philosophical values that are incapable of definitive resolution as are many of the contemporary disagreements that the FDA confronts.

Critical events in the 1960s--the passage of the Kefauver-Harris Amendments, the resignation of George Larrick (the last Commissioner to come up through the ranks), the bureaucratic reshuffling, and the problem with cyclamate--gave clear indication to everyone concerned that the FDA needed fundamental changes. FDA needed a new vision, a re-conceptualization of how to meet its prime responsibilities of ensuring that the nation had safe drugs and pure food. An agency that had been held together by the bureaucratic equivalent of chewing gum and baling wire could no longer function under the strain of an expanded mandate, inadequate resources, a new visibility, and outsiders demanding a voice in the increasingly value-laden decisions that the FDA had to make. However, in the seven years between the

Kefauver-Harris Amendments and FDA's confused, disorganized, and hasty response to the 1969 cyclamate fiasco, the agency had managed to do little more than spin its wheels and tinker with a system that could not meet the demands placed on it. For the FDA to fulfill its new legislative mandate, respond to the changing scientific environment, and reflect the goals of an open and accessible government it needed leadership willing to re-build the agency, create the bureaucratic channels necessary to implement its expanded programs, and respond to the needs of consumers and industry.

Commissioner Charles Edwards, FDA General Counsel Peter Hutt and their successors sought to recreate the FDA as a modern administrative agency. Hutt believed for the FDA to effectively exercise its complex responsibilities all parties needed to be cognizant of the parameters under which FDA operated.

During the early 1970s under Hutt's legal leadership, FDA began to use the Federal Register to propose regulations and solicit comments. The FDA then published its final rules, with their "Peter's Preambles" which explained FDA's reasoning and responded point by point to comments about specific aspects of the regulation. Not satisfied with these accomplishments, Hutt revamped the agency's disorganized and often unwritten procedures. As a result, FDA became better organized, better managed, and more predictable in its actions. FDA hoped that this would facilitate greater compliance by manufacturers and lessen tensions between the agency and the regulated industries. Undoubtedly these changes worked to the benefit of the food and drug companies, but consumer organizations or public advocates used these same procedures as points of access into the regulatory

process. Nowhere was this more true than in the Freedom of Information regulation. The need to bring FDA's FOI regulations in line with new national standards produced great anxiety in both the agency and industry. They imagined consumer advocates demanding access to rooms full of documents. Instead, industry made eighty percent of the requests as it combed agency files for reports and data about competing firms. One should not dismiss, however, the use that the consumer and health groups made of FOI regulations or the other procedural revisions that FDA officials instituted in the 1970s. These reforms gave the public access to FDA material, the right to petition the FDA for changes in its policies, and the ability to comment on proposed regulations. As a result a previously impenetrable federal agency opened to public scrutiny.

However, those outside the agency or industry had little involvement in the actual deliberations of the agency. That opportunity came through Commissioner Edwards efforts to strengthen the scientific expertise of the FDA. He hoped to deter criticism of FDA's regulatory decisions by grounding them on scientific principles. In doing so, FDA allowed certain "outsiders" to influence its policies and decisions on drugs, medical devices, and biologicals. Although at first membership on the committees was restricted almost entirely to those affiliated with the university-based, academic medical community, they nevertheless contributed to opening up the agency to a greater diversity of opinion.

Because many of the decisions that the FDA made were not based on a mere determination of scientific facts, but rather were predicated on certain underlying beliefs about risk versus benefit, patient rights and control, or government control

versus personal freedom, FDA needed procedures that brought to bear a variety of perspectives. Before the 1970s there was little or no recognition on the part of the FDA of the necessity or desirability of these procedures.

Under pressure from consumer activists and the provisions of the federal Advisory Committee and Government in the Sunshine Acts, the FDA slowly began to broaden the representation on its committees to reflect more closely the pluralistic nature of American society. Many charged that the FDA's dependence on an "old boy" network of consultants excluded women, minorities, and younger scientists thereby undermining its efforts to achieve diversity. Critics also pressured the agency to include technically qualified, consumer-nominated individuals and representatives of patient groups as voting members of its drug and biologics committees. With a certain amount of reluctance, the FDA opened its committee system to a multiplicity of voices.

Each advisory committee worked in a specific pharmaco-therapeutic area evaluating data submitted by pharmaceutical companies or advising the agency about scientific or medical problems germane to that specialization. But in the course of their deliberations they also considered larger, more fundamental policy issues. For example, what was the value of human epidemiological studies versus animal bioassays and short-term in vitro laboratory tests in assessing drug risks? How did animal studies extrapolate to humans, especially when high-dose testing was used on laboratory animals? Did the susceptibility of a highly heterogeneous human population to carcinogens differ from the susceptibility found in the small number of homogeneous laboratory animals used?

In their discussions, the committees pondered the level of risk inherent in particular chemical substances, whether these risks had been underestimated or overestimated, and in light of these assessment whether they had been properly regulated. As consumer groups pressured the FDA for representation on the advisory committees, public advocates argued that although FDA deliberations are frequently based upon a core of scientific information, the decisions themselves ultimately reflected the value judgments of the decision-makers. As Marsha Cohen, Counsel for Consumers Union observed. "One need not be biologist or economist to weigh all these factors and to make a legitimate decision worthy of respect by all, including experts in the field affected by the judgment."⁴¹

Sidney Wolfe and Anita Johnson of the Health Research Group, Michael Jacobson of the Center for Science in the Public Interest, Barbara Seaman and the National Women's Health New and others like-minded groups took advantage of the new procedures to monitor FDA's activities. They and public health groups, such as the Epilepsy Foundation or the American Heart Association, tracked the FDA's relationship with industry, its decisions, or its lack of progress on certain issues. They were quick to mobilize their members to organize letter writing campaigns, attend hearings, and to convey their findings to the media.

However, even the prodigious efforts of these consumer and health advocates would have been little noticed were it not for a new-found interest and concern about

⁴¹Statement of Marsha N. Cohen. Counsel, Washington Office of Consumers Union. "Obtaining Consumer input into Food and Nutrition Deliberations of the NAS-NRC Food and Nutrition Board. 1/11/74.

health and wellness in the 1970s. People have always worried about their health and the fragility of life. In the past, they gave themselves over to fate, to medicine men, to religious leaders, and to physicians. In the twentieth century most people put their faith in modern medicine, celebrating the 'wonder drugs' that had cured infectious diseases, controlled the manifestations of mental illness, and ameliorated a host of other conditions.

However, in the 1970s, the major killers--cancer, heart disease, and stroke--had not succumbed to such magic bullets. Americans, while not losing faith in the ability of their doctors or modern medicine to find a cure for these diseases, began to respond to another message, which had two components. The first came neatly encapsulated in the "Seven Signs," which shifted responsibility for health back to the individual. Those of us who smoked, drank in excess, never exercised, skipped breakfast, ate the wrong foods, and burned the candle at both ends had only ourselves to blame when that candle was prematurely snuffed out.

The second part warned that personal responsibility for health required knowledge. Dr. Lewis Thomas fretted that Americans had become "a nation of health hypochondriacs, living gingerly, worrying ourselves half to death." But the public had reason for some alarm. In the 1970s Legionnaire's Disease and Toxic Shock Syndrome, diseases that hitherto had not existed in the medical lexicon, added to the public's fears for its health and to the fear that medicine's triumph over disease still had large and painful gaps.

Environmentalists, consumer advocates, and science writers discovered previously unrecognized dangers to health and safety. Not knowing if the air and the

water had been polluted by dangerous chemicals or if the food grown on America's farms had been contaminated by pesticides aroused deep fears in many Americans. Until consumer advocates told them, few people knew that most food additives had never been adequately tested for safety. Saccharin and Red No. 2 had been around since the turn of the century, but questions about their safety arose only in the 1970s. If food or color additives had been tested at all, it certainly had not been with the new, highly sensitive, and sophisticated toxicologic equipment then coming into use. When Congress enacted the Delaney Clause in 1958 to ban all cancer-causing material from the food supply, it regarded 50 parts per million as the practical equivalent of 'zero' contaminants. With such techniques as gas chromatography and mass spectroscopy, scientists could detect particles at the rate of one part per trillion.

To protect their health consumers, who were more and more dependent on pre-packaged foods, needed labeling to inform them what manufacturers had added in processing. Health and weight conscious shoppers wanted to know not only about food and coloring additives but also nutritional information.

Many patients also demanded information in order to make their own risk/benefit decisions about the powerful pharmaceuticals their doctors prescribed in ever increasing numbers. It was only in the 1970s that the public began to realize that those widely touted wonder drugs had risks as well as benefits. The Karen Ann Quinlan case made Americans aware of the dangers presented by mixing prescription drugs and alcohol and numerous news stories documented adverse effects from widely used drugs. At a very minimum, patients needed an awareness of danger signals, instructions for accurately taking drugs, and contraindications.

Consumer activists and health advocates found a receptive audience for their information. Consumer organizations funneled information about the FDA to the media, which gave it coverage on the evening news or prominent space in the newspapers thus increasing the number of people aware of the FDA and its activities. The fact that conflicts about the safety and effectiveness of food and drugs continue to arise and that answers to these questions rest as much on ethical, philosophical, and political values as on science has sustained interest in the FDA and continued to make its pronouncements and decisions newsworthy.

The confluence of a heightened interest in personal health, changing public attitudes about safety and risk, a more open and responsive government, and a new leadership that both understood and could respond to the swiftly changing world in which the FDA operated, made the 1970s pivotal to the transformation of the Food and Drug Administration. In describing that change, one would want to draw on the time-worn imagery of ugly ducklings becoming graceful swans or the metamorphosis that would produce an elegantly conceived administrative agency out of the chrysalis of an inept little bureaucracy. In reality, the FDA evolved from a organization in danger of extinction to a stronger and larger agency that adapted to a changing social and political environment thus allowing it to function in a complex and often hostile world.

CHAPTER 10

"EPILOGUE--STILL FRONT PAGE NEWS"

Dr. Michael Jacobson, his dark hair turned gray, but just as thin, feisty, and outraged as in 1970 when he demanded the inclusion of consumers in a Food and Drug Law Institute forum, stood before the television cameras on October 25, 1995 denouncing the pending FDA approval of Proctor & Gamble's new product, Olestra. On television news shows across the nation, Jacobson, the head of the Center for Science in the Public Interest (CSPI), raised serious objections to Olestra. An artificial product which acted and tasted like fat, it passed unabsorbed through the digestive tract, thereby adding no calories to the diet--a dream come true for a public only too eager to grasp any advantage in the Sisyphean battle of the bulge. But with almost humorless fervor, Jacobson dashed these hopes. He charged that Proctor & Gamble had known from its own testing that Olestra caused diarrhea and blocked the absorption of fat-soluble vitamins. The media savvy Jacobson came equipped with computer-generated graphics to demonstrate the way in which Olestra leached out vitamins A, D, E, K, and blood carotenoids. Of course, the news stations also had a spokesperson from Proctor & Gamble, who charged CSPI with misinterpreting the data.¹

The next day both national and local newspapers gave the story prominent coverage. In these reports CSPI buttressed its allegation by drawing on the credentialed expertise of two Harvard experts. Jacobson quoted Dr. Walter Willett,

¹"Live At Five," News Show, WNBC-TV, October 25, 1995, taped interview. "11 O'Clock Action News." WABC-TV, October 25, 1995, taped interview.

chairman of Harvard's Department of Nutrition, and Dr. Meir Stampfer, a professor of epidemiology and nutrition, that "the evidence is clear that olestra causes dramatic reductions in blood carotenoids." The professors cited studies showing that diets rich in these compounds are associated with a lower risk of cancer, heart disease, stroke, and macular degeneration.

As in so many previous health controversies, the public found itself trying to judge the competing claims of scientific authorities. Nutrition columnist, Marian Burros' New York Times story included reports of a Dutch study indicating that consuming just six olestra-fried potato chips resulted in a sharp reduction in carotenoids. She also reported that Proctor & Gamble intended to fortify olestra with the fat-soluble vitamins, as if indicating that it had already agreed with the points made by Jacobson, Willett, and Stampfer. Burros' article included statements from Proctor & Gamble scientists detailing the safety data on the product. The Gannett-Westchester newspapers had company scientist, Dr. Christopher Hassall, objecting that Jacobson "has shown great creativity in combing through the extensive olestra data to find colorful and potentially alarming information that is simply not true." Proctor & Gamble claimed that it had spent more than \$200 million testing olestra for 25 years on more than 8,000 people, "unprecedented for a food ingredient," to prove that it was a safe way for Americans to lower their fat intake.²

Jacobson had forcefully insert himself into the regulatory approval process again. The CSPI had found over the years that it got more mileage out of its limited

²New York Times, October 25, 1995, p. A-16. The Mount Vernon Argus, a Gannett Westchester Suburban newspaper, October 25, 1995, p. B-2.

non-profit dollars by selectively targeting problems than by trying to cover the full panoply of FDA issues. In recent years CSPI had garnered enormous amounts of publicity by its attacks on the fat content of Italian, Chinese, and Mexican foods, movie popcorn, and deli sandwiches. In a strategy that had been honed in many food wars, CSPI held its fire until the last moment when final approval of Olestra seemed imminent. Before this, either problems inherent with the product or FDA doubts about its safety might have kept it from reaching the market. After it had been approved, it would have been much more difficult to force its removal. By reading the Federal Register and FDA calendars and attending advisory committee meetings, CSPI kept track of its progress through the regulatory machinery.

Despite the last-minute campaign by Jacobson and his fellow scientists, FDA approved the use of olestra on January 24, 1996. However, their efforts were not in vain. FDA warned consumers that olestra can cause such gastrointestinal side effects as diarrhea and "can literally wash out of the body certain nutrients...." Products that use olestra will have to carry a warning about possible side effects and be fortified with vitamins A, D, E, K, and carotenoids. Although the FDA contended that the nutritional effects appeared not to be "medically significant," the FDA required that Proctor & Gamble study olestra's long term dietary effects and report the results within 30 months.³

The battle will probably not end there. Dr. Walter Willett, of the Harvard School of Public Health, doubted the adequacy of the warning label "because it

³Gannett-Westchester Suburban Newspapers, January 25, 1996, B-1.

doesn't mention the possible consequences of cancer, heart disease, and blindness." Calling olestra a 'public health time bomb,' Michael Jacobson said his group might sue to remove olestra from the market.⁴

Jacobson fully appreciated the taste that Americans had acquired for charges that industry, driven only by its desire for profit, displayed little regard for the health and safety of the consumer. Jacobson's charges put FDA in its usual no-win situation. If it ignored Jacobson, its consumer critics would say it caved in to industry. If it gave due consideration to his allegations, the approval schedule would be halted, all submitted data would have to be reviewed again, more information might be needed from Proctor & Gamble, and the agency would have to use scarce staff time to justify its position. Industry critics in turn would say that it had succumbed to the outlandish charges of a self-promoting publicity-seeker out to frighten the public.

Michael Jacobson and the Center for Science in the Public Interest Olestra campaign illustrates the impact that a determined, focused individual or group can have on the regulatory process. But more than interest, even passionate interest, in a product or cause is required. Knowledge about FDA policies and procedures, from the Federal Register notices of advisory committee meetings to open calendars, from Freedom of Information regulations to petition requirements is fundamental. Access to sympathetic experts to frame arguments, challenge data, and appear before advisory committees is crucial. Dogged persistence, sometimes over many years,

⁴Marian Burros, "U.S. Approves Fake Fat For Use in Snack Foods," New York Times, January 25, 1996, p. B-1.

is essential. A member of Congress willing to hold hearings on an issue that engages the public's interest or concerns can contribute significantly to the final outcome. But fulfilling all these requirements is no guarantee of success.

Non-industry groups confront the awesome resources of the corporate world with its six-figure lobbying budgets and access to high-priced legal talent, researchers, and consultants. Industry also employs those who have taken advantage of the revolving door at federal agencies. In any contest, industry's superior resources present a formidable obstacle to consumer interests. As a result, these groups often limited their participation to rule-making proceedings, primarily in the form of submissions of relatively brief written comments on proposed agency regulations. The public interest comments may be easily swamped in a sea of submissions from individual firms and their trade associations. One of the few advantages that consumer activists have is that agency officials may accord special weight to positions advocated by public interest groups as a way of redressing the imbalance.

In the 1970s, Robert Mayer reported, the ratio between business and consumer resources was about 300 to 1.⁵ If anything the situation is more unbalanced in 1996. Sally Squires of the Washington Post described the scene at an important FDA advisory committee meeting evaluating two genetically engineered drugs by the Centocor and Xoma corporations. At stake was a \$1 billion market, the prestige of the biotechnology companies, and investor returns. In the standing-room

⁵ Robert N. Mayer, The Consumer Movement: Guardian of the Market Place, (Boston: G.K. Hall, 1989), 55.

only FDA hearing room, drug company officials, **financial analysts**, scientists, and reporters listened to the deliberations of an 11-member **advisory** panel, which had its own advisory panel. Each company brought its own TV **crews** to record the event, CNN had its crew, the news media and the trade journal **reporters** "scribbled notes with one hand and held tape recorders in the other," **while** financial types and executives using "compact cellular phones ... **whispered the latest word**" to their offices as the panel evaluated the well-rehearsed **presentations** of each company. In this kind of high-stakes game, it would seem **impossible** for the public interest to survive at all. Logic suggests they should have **packed up shop** years ago.⁶

In fact, many political analysts predicted that the **election** of Ronald Reagan in 1980 would mark the end of the consumer **revolution**. In terms of new governmental bureaus, new consumer laws, extensive **new** regulation of industry, they were correct. However, in terms of influence, **Michael Jacobson**, Sidney Wolfe, Consumers Union and other consumer advocates still **command** attention from both the public and the regulatory agencies. As the historian **Eric Foner** has written, "the tide of change rises and then recedes but leaves an **altered** landscape."⁷

Neither the proponents of the Reagan Revolution **nor** those that followed in its path have been able to undo changes wrought by a **decade** of consumer activism. The philosophy of openness, access, and accountability **that** fundamentally changed the way the federal government operated has not been **reversed** and has trickled

⁶Sally Squires, "At an FDA Panel Hearing--Lights, **Cameras**, Action!" Washington Post, October 1, 1991, Health Section, p. 12.

⁷Eric Foner, Reconstruction, 1863-1877 (New York: **Harper & Row**, 1988), 602.

down to state and local governments. The Freedom of Information, Federal Advisory Committee, and Government-In-the-Sunshine Acts have remained on the books. Each year the Federal Register consumes a small forest printing the rules, regulations, proposals, and announcements that document the activities of the myriad executive branch agencies. For those willing to peruse its tens of thousands of three-column pages, it is a font of information and provides a point of access for those trying to influence the government.

Recently, those who decried the over-bearing presence of the federal government have struck a responsive chord. Speaker of the House Newt Gingrich's 1994 Contract With America expressed the frustration of many Americans with a federal government grown too large and intrusive and proceeded to revamp the federal government, making the Food and Drug Administration one of its first targets. But the public did not respond as expected. They had come to rely on the FDA to provide a modicum of protection on health and safety issues. There were powerful reservations about allowing these items to become bargaining chips in a free enterprise free-for-all. The challenge to FDA was quietly put on the back burner.

Since the 1970s, the specifics may have changed, but interest in the issues overseen by the Food and Drug Administration has remained. "We are, perhaps uniquely among the earth's creatures, the worrying animal," the philosopher-physician, Lewis Thomas wrote in 1979. Every story about hundred-year-olds as the fastest growing demographic cohort is countered by another that ominously warns about decreasing longevity from cancer, excess weight, or lack of some vital component in our diet. Questions about the safety of the food supply, the purity of

cosmetics, the effectiveness of drugs or medical devices and the largely untested field of biotechnology are unlikely to diminish in the foreseeable future.⁸

In the 1970s the media discovered an almost unlimited public interest in medical topics. It fed this appetite through columns and features in newspapers and magazines, health reports and medical correspondents on television. Many of the stories hyped new 'breakthroughs' in treatments or the latest 'wonder drug' on the market of course. But other stories revealed dangerous food, cosmetics filled with untested ingredients that caused irritation or worse, and ineffective or dangerous drugs. The techniques of expose journalism that had become so potent and fashionable in political reporting, worked equally well on health issues. These stories warned readers that even the highly touted 'wonder drugs' had the potential for causing adverse side effects and dangerous drug interactions. Each story ended by urging FDA to act or castigating it for its lack of action.

Since the late 1960s, the Food and Drug Administration has functioned in an environment of intense, unending public scrutiny. By contrast, the historian James Harvey Young recalled that during the five years of negotiation and debate leading to the passage of the massive 1938 Federal Food, Drug, and Cosmetic law, "the story made the front page of the New York Times only once, and that was when there was a disturbance in the gallery."⁹

⁸Lewis Thomas, "On the Science and Technology of Medicine," Daedalus 106 (Winter 1977): 46.

⁹Dr. Daniel Banes, retired Director of the Office of Pharmaceutical Sciences, Interviewed by Professor James Harvey Young, June 17, 1980, transcript, p. 46, Oral History Project, Food and Drug Administration.

In the 1970s the FDA needed to re-invent itself in a way that would allow it to function in the "glass house" it now inhabited in Rockville, Maryland. At the same time, it had to find a means to protect itself from the missiles fired at it from all sides-- industry, consumers, the media, and Congress. Better still, it needed to establish a way to bring these people inside and make them part of the process. FDA, for its part, had to demonstrate to all those interested in or affected by its actions that its decisions were not arbitrary and capricious but were the end product of an open, orderly, scientific process of regulation.

The FDA had spent decades developing a working relationship with the industries that it regulated. Years of interaction had resulted in an understanding of the rules of the game, and in some cases, shared expectations. But to concede this should not lead to the conclusion that the FDA necessarily capitulated to business. Gabriel Kolko's idea of "capture" of regulated bodies by the industries they have been created to regulate is a important but oversimplified argument.¹⁰

The 1906 Pure Food and Drug and Meat Inspection Acts pitted ethical pharmaceutical manufacturers against patent medicine makers, companies that used saccharin against those that used sugar, the dairy industry against oleomargarine producers, and huge meat companies, like Swift and Armour, against smaller, local producers. These intra-industry battles have continued to the present. Sugar interests fought against artificial sweetener producers again in the 1970s. Generic manufacturers battled for years to gain a foothold against the large pharmaceutical

¹⁰Gabriel Kolko, The Triumph of Conservatism, (New York: The Free Press of Glencoe, 1963).

houses. After a year of torturous negotiations, in 1984 they and consumer groups hammered out the specifications of the Drug Price Competition and Patent Term Restoration Act, which gave legitimacy to generic drugs.

The dichotomy of industry and the FDA on one side and consumer interests on the other does not do justice to the complex, often competing, interests which FDA has had to balance. Physicians have been vociferous, personally and through the powerful American Medical Association, in denouncing any infringement on their prerogatives or the doctor/patient relationship by FDA action. Although they usually cast their lot with industry, there have been significant divergences. In the 1970s they campaigned against patient package inserts even when manufacturers tended to accept the general concept. During hearings on the 1978 Drug Regulation Reform Act, the medical profession brought out its big guns to blast the idea of restricted or limited distribution for approved drug products, fearing that this would benefit university-affiliated medical centers over local practitioners.¹¹

The long and arduous path to a pilot program for patient package inserts revealed the complexity of balancing the requirements of a number of vested interests. Besides the medical profession and industry, the FDA had to consider the requirements of pharmacists, wholesalers, chain stores, pharmaceutical associations, even the demands of private organizations that wanted to sell their own inserts. Each group had its own turf to protect, and its own legal liabilities to consider.

It also highlighted the pros and cons of operating in a highly politicized

¹¹Paul J. Quirk, "Food and Drug Administration" in James Q. Wilson, ed., The Politics of Regulation (New York: Basic Books, 1980), 198.

situation. The Reagan administration decided to revoke the FDA's control of inserts, returning the production of PPIs to the private sector. Despite the efforts of a number of medical and industry drug information programs, surveys in the 1980s indicated that few patients were receiving more than the minimal facts about prescription drugs and this usually constituted usage instructions. The voluntary education program was not a compromise between FDA and the provider groups to achieve jointly agreed upon goals, according to Rosalind Kendellen, who studied FDA's patient package information program, but rather a means to effectively dispense with government regulation at any cost. The lack of a mandatory PPI program maintained "the status quo, i.e., the traditional doctor-patient relationship in which the doctor, in control of information, shares little with his patient; the drug manufacturer's duty to disclose information runs only to the 'learned intermediary;' and the duty of the pharmacist is to fill prescriptions and refer questions to the physician."¹²

However, in 1982 when FDA lost control of the PPI program, it made sure it retained the right to issue them for specific situations or if voluntary programs failed. It took a dozen years, and an administration with a different political philosophy, for the FDA to exercise its option. On August 24, 1995 the FDA issued a 70-page proposed rule for prescription drug product labeling. Using a carrot-and-stick approach, the agency told drug manufacturers that it was "proposing performance standards that would define acceptable levels of information distribution and quality, and [it intended to] to assess supplied information according to these standards."

¹²Rosalind M. Kendellen, "The Food and Drug Administration Retreats from Patient Package Inserts for Prescription Drugs," Food, Drug, and Cosmetic Law Journal, 40 (1985): 186.

With the advent of computers and prescription software the possibility existed for patients to get up-to-date, complete information about their prescriptions, but few received more than the minimum facts, if that much. "Therefore, in concert with Healthy People 2000, FDA is proposing that private sector initiatives meet the goal of distributing useful patient information to 75 percent of individuals receiving new prescription by the year 2000 and 95 percent ... by the year 2006."¹³

FDA reminded industry that during the 1982 hearings that led to the withdrawal of the PPI regulations, promises were made by representatives of the pharmaceutical, medical and pharmacy communities that if FDA withdrew the PPI regulations, the private sector would meet the goals of the proposed PPI program. "These promises have not yet been fulfilled." If industry did not meet these goals, FDA would implement a mandatory comprehensive Medication Guide program, or seek public comments on whether the comprehensive program should be implemented. Regardless of the outcome of a general program, FDA would institute "a mandatory Medication Guide program limited to instances where a product poses a serious and significant public health concern requiring immediate distribution of FDA-approved patient information would be implemented within 30 days of publication of a final rule based on this proposal."¹⁴

Over time, the FDA had learned to predict with some regularity the position likely to be taken by industry, the medical profession, and its political bosses in the

¹³60 Federal Register, August 24, 1995, pp. 44182.
"Prescription Drug Product Labeling; Medication Guide Requirements" Proposed Rule. Docket No. 93N-0271.

¹⁴60 Federal Register, August 24, 1995, p. 44183.

White House and Congress on most issues. Putting a finger on the public pulse of a large pluralistic nation often seemed impossible. Who was the "public" and who spoke for it? A politician with a cause, or a grudge, might claim that honor, but so would a consumer leader who has spent years developing a grassroots organization that supported his principles. A health organization, such as the American Heart Association, speaking out for product labeling could argue that this information benefitted all Americans interested in their health. Occasionally, the general public spoke for itself. However, as FDA found in the 1970s, public concerns were often scattershot, episodic, and aroused by the latest health threat or a new health theory that received major coverage in the media.

Did the "public" want a stronger FDA, one that would take products such as Red No. 2, off the market? It would have seemed so in 1976. But that same year, the public sent a message to Congress to rein in the power of the FDA. Legislators obliged by passing a law that prohibited the FDA from regulating vitamins as drugs. A mere two years later, the public in an increasingly anti-regulatory mood pressured its representatives to pass a Moratorium bill that prevented the FDA from banning the carcinogenic artificial sweetener, saccharin. In an end run around FDA regulations, laetrile supporters convinced 21 state legislatures to legalize the sale of the alleged cancer cure.

When the FDA began to deal with the consumer and health groups in the 1970s, the relationship for the most part was adversarial. As can be seen from the interaction between Michael Jacobson and the FDA over olestra, this still remains the norm in many circumstances. However, in recent times, consumer advocates and

health groups have developed other ways, which are often more effective, to negotiate with the FDA. The Gay Men's Health Crisis, Project Inform and other AIDS activist groups have developed sophisticated methods for interacting with both the FDA and industry. For example, their efforts to gain approval for saquinavir, a member of a new class of drugs used to treat AIDS called protease inhibitor, is indicative of the new methods by which consumer and health organizations push their agendas. AIDS groups spent two years negotiating directly with the drug maker Hoffmann-La Roche on the design of the clinical protocols.

They were particularly concerned about expanded access, that is the ability of patients to get the drug before the clinical trials have been completed or as they are being conducted. AIDS groups negotiated these points with Hoffmann-La Roche, but any decisions made with the pharmaceutical company in terms of clinical trials and access would have to be approved by FDA under the Investigational New Drug application filed by Hoffmann-La Roche. So in essence, they negotiated the terms of the clinical trials with FDA itself.¹⁵

AIDS groups also brought pressure to bear directly on the FDA. Although no consultants from GMHC sat on the advisory panels, representatives of GMHC made presentations during the public comment part of the advisory committee meetings. Leading AIDS organizations petitioned the agency to implement an expanded access program for saquinavir. At a September 12, 1994 FDA Advisory Committee meeting,

¹⁵David Barr, Spencer Cox, Gregg Gonsalves, Mark Harrington, Derek Link, Michael Ravitch, and Theo Smart, "Problems with Protease Inhibitor Development Plans," prepared for the National Task Force on AIDS Drug Development, February 23, 1995, Bethesda, Maryland, p. 3.

FDA Commissioner David Kessler responded, "The FDA would strongly welcome expanded access for saquinavir." The FDA position thus put added pressure on Hoffmann-La Roche to enroll more patients in studies.¹⁶

The FDA had cooperated with both the advocacy group and the pharmaceutical company in expediting the approval of saquinavir. "These drugs, in the right combination with other drugs, have potential that we have not seen before," FDA Commissioner David Kessler predicted. The Washington Post commented that "such a positive statement by the usually cautious Kessler--who rarely comments on a drug before an advisory panel considers it--is a clear signal that the FDA expects to move expeditiously on getting protease inhibitors to market." In fact, the FDA approved the drug in 97 days after the company applied for licensing and one month after its advisory panel urged FDA approval.

However, this should not indicate that conflicts between the agency, industry and advocacy groups have disappeared and produced an 'Era of Good Feeling'. AIDS groups initiated a series of meetings with FDA to raise concerns about cross-resistance between different protease inhibitors. There were some indication that resistance to one of these drugs would cause resistance to others in the class. By choosing to use one of these new and not fully tested drugs the patient might foreclose the use of another drug which was subsequently developed. This was a new complicating factor in drug therapy and it was not clear how serious the danger was or even if it did in fact exist. GMHC had asked the FDA to consider the issue of cross-resistance at its November 6, 1995 Antiviral Drugs Advisory Committee

¹⁶GMHC Treatment Issues, November 1994, p. 7.

meeting.¹⁷

However, the agency chose not to do this. In response, GMHC and Project Inform set up their own forum on the Sunday before the FDA advisory committee meeting at which they brought in experts in the field, representatives of pharmaceutical companies, and others to explore issues of resistance and cross-resistance. Ben Chang, manager of the information department for Project Inform said "We're not saying stop--I think that what we're saying is the companies have an obligation to continue looking at [resistance issue] rather than just get the drug on the market and forget about it."¹⁸

Public access to FDA decision-making has become a much more complex process. It is no longer a matter of groups or individuals attacking the FDA in the newspaper, testifying at congressional hearing, or appearing at an advisory committee meeting lecturing FDA for its failure to protect the public. Now highly sophisticated groups, such as Project Inform or GMHC "work both sides of the street," using whatever leverage they have to pressure both the pharmaceutical companies and the FDA. If they fail to accomplish their ends, they have the option of going public, using their high visibility and public sympathy to further their demands.¹⁹

¹⁷Derek Link, Gay Men's Health Crisis, November 30, 1995, personal communication.

¹⁸John Schwartz, "FDA Sees Promise in New Anti-AIDS Drugs. Commissioner Indicates Agency Will Move Swiftly to Approve 'Protease Inhibitors' for Market," Washington Post, November 4, 1995, p. A-4.

¹⁹Derek Link, Gay Men's Health Crisis, November 30, 1995, personal communication.

The process is not one sided. Pharmaceutical companies can work with patient groups to prod the FDA into moving faster in approving their drugs. The FDA, in turn, can pressure companies worried about liability to expand their trials or move faster in completing paperwork. While AIDS activists are unusually well-organized and scientifically astute, their access and success has not been unique. In the 1980s patient groups worked with congressional representatives, the pharmaceutical industry, and the FDA to set up the parameters for the Orphan Drug Law that encouraged research and development of drugs for rare diseases. Patients, in general, are so effective as lobbyists that some lobbying organizations have hired them as full-time employees. Companies "realize that it's important to build alliances with patient groups, to enhance their image and to be more effective politically." Samuel D. Turner, a lawyer for the Coalition for Cancer Survivorship, which gets 1/3 of its \$700,000 budget from drug and biotechnology firms, observed.²⁰

The Gay Men's Health Crisis and other similar organizations have shown what a well-organized, focused, medically sophisticated group can accomplish. David Kessler, Commissioner of the FDA, in a recent interview on the CBS television program, "60 Minutes" spoke of the changes that health groups, such as AIDS activists, had brought to the FDA. Those, who had once been placard carrying protesters, now sat on Advisory Panels where they provided expert medical testimony. From this vantage point, they pressured FDA to change its "business as usual" attitudes, streamlined the approval process, and expanded clinical trials so that more infected

²⁰New York Times, March 4, 1996, A-14.

individuals might benefit from still experimental drugs.²¹

It is only fitting that the agency that came into being at the beginning of the century largely because of the efforts of Dr. Harvey W. Wiley, a one-man lobbying organization for the Pure Food and Drug Act, should end the century forced to respond to the demands of other consumer and health activists, as deeply committed, tenacious, and focused as Wiley.

²¹"60 Minutes," CBS Television Network.

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