

# The Story of the Laws Behind the Labels

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## Part I: The 1906 Food and Drugs Act

The history of the Food and Drug Administration is also the history of consumer protection as applied to food, drugs, cosmetics, and other products now regulated by the Agency. That history began long before the initials "F," "D," and "A" became household words, as this article points out. Wallace F. Janssen began writing about FDA as a trade journal editor in 1931. He joined the Agency in 1951 as assistant to the commissioner for public information and continued to be its information chief until 1966.

### How old is the FDA?

There are two answers to this frequent question: as a law enforcement organization its 75th anniversary year is 1981, but as a scientific institution it dates from 1862 when Charles M. Wetherill, first chemist of the new Department of Agriculture, set up a laboratory and began at once to analyze samples of food, soils, fertilizers, and other agricultural substances. The first reported project -- a chemical study of grape juice for winemaking -- dealt with, among other topics, the question whether adding sugar to increase the alcohol content would constitute "adulteration." It was concluded that the practice was legitimate. (Forty-six years later the first Notice of Judgment under the new 1906 Food and Drugs Act reported a court ruling to the contrary. Cider made harder by adding sugar was found adulterated.)

Being engaged primarily in agricultural research and development, the early FDA scientists inevitably became involved in matters of food safety. The 1862 report referred also to problems of food preservation and uses of chemical preservatives. The report of 1873 contains analysis of cereals, wine, and opium. In 1874 the adulteration of milk with water and chemicals was discussed, along with experiments on the effects of arsenic and copper pesticides on plants and the possibility of harm to humans.

Federal concern for drugs started with the establishment of U.S. customs laboratories to administer the Import Drugs Act of 1848. The United States had become the world's dumping ground for counterfeit, contaminated, diluted, and decomposed drug materials -- a dangerous situation. American troops in Mexico had suffered from spurious medication for malaria. Pharmacists and the new American Medical Association joined forces to secure the legislation. The mission of the new Customs laboratories was to enforce the purity and potency standards of the U.S. Pharmacopeia, established by trade and professional leaders in 1820. But support dwindled and the program gradually faded away. No organizational connection has been found with the agency now known as the FDA.

The United States was very slow to recognize the need for a national food and drug law. Frederick Accum's "Treatise on Adulterations of Food and Methods of Detecting Them" had been published in London and Philadelphia in 1820, and Great Britain's first national food law was passed in 1860. In the United States a variety of state laws dated from colonial times. Enacted mainly to serve the needs of trade, these laws set standards of weight and measure, and provided for inspections of exports like salt

meats, fish and flour, to promote foreign sales. But there were also local bread inspection laws to insure consumer protection as well as fair competition between bakers.

After the War of Independence the states continued to pass laws that varied greatly, reflecting their special interests. Not until interstate commerce began its great expansion after the Civil War did the need for federal rulemaking become widely realized. The Pure Food Movement -- a grass roots phenomenon that germinated in the 1870's -- was the original and principal source of political support for the Food and Drugs Act of 1906. It was originally a trade movement. Long before Upton Sinclair's *The Jungle* exposed insanitation in the Chicago stockyards; even before Harvey Wiley's arrival in Washington to head the Division of Chemistry, food industry members had begun to advocate a federal law against adulteration. Trade interest arose from two causes: first, competition from a new breed of food products -- glucose as a replacement of sugar, "lard" made from cottonseed oil, and oleomargarine, a threat to butter; and second, intolerable variations in the laws of the states. "As it is now," to quote one food packer, "we have to manufacture differently for every state."

In 1879 Peter Collier, the fifth head of the Division of Chemistry, urged federal legislation to make food adulteration a crime. In 1883 Dr. Harvey W. Wiley, state chemist of Indiana and professor of chemistry at the new Purdue University, was appointed to succeed Collier.

### Chemists on the Move

The staff of the Division of Chemistry is depicted in Figure 1, shortly after Wiley took command in 1883, at age 37 (Wiley is third from right). Eighteen eighty-three was also the year when Robert Koch discovered the germ of cholera and that it was transmitted by water and food. Koch's vaccine could not be obtained quickly enough. "Science," relied on for protection, was rebuked for inaction in this cartoon from *Life*, "Is This A Time For Sleep?" shown in Figure 2.



Figure 1



Figure 2

When Wiley came to Washington to head the Division of Chemistry, its laboratories were in the basement of the 1867 Department of Agriculture building on the Mall (Figure 3) where the white marble USDA Administration Building now stands. The USDA chemist had been located previously at various locations, beginning in 1862 in the Patent Office building, which is now the National Portrait Gallery.



Figure 3



Figure 4

A laboratory fire, during a visit by Secretary of Agriculture Norman J Coleman, prompted him to arrange separate quarters for his chemists in an old house across the street from USDA headquarters (Figure 4). Here, at 14th and B Street (now Independence Avenue), the Division of Chemistry remained from 1890 to 1898. The Division, which was renamed the Bureau of Chemistry in 1901, moved to leased headquarters at 1366 B Street, S. W. (now Independence Avenue) in 1899, its home for the next 11 years. Wiley, wearing his tall, silk, stovepipe hat may be seen in the doorway of that building in Figure 5. Leased buildings at 212-220 Thirteenth Street, S.W. (Figure 6) were the home of the Bureau of Chemistry and its successor, the Food and Drug administration, for the next quarter-century, from 1910 to 1935.



Figure 5



Figure 6

### **Troubling Marketplace**

Conditions in the U.S. food and drug industries a century ago can hardly be imagined today. Use of chemical preservatives and toxic colors was virtually uncontrolled. Changes from an agricultural to an industrial economy had made it necessary to provide the rapidly increasing city population with food from distant areas. But sanitation was primitive in the light of modern standards. Ice was still the principal means of refrigeration. The great pioneers of bacteriology were just starting their string of victories over infectious diseases. Milk was still unpasteurized. Cows were not tested for tuberculosis.

In the same era, thousands of so called "patent" medicines such as "Kick-a-poo Indian Sagwa" and "Warner's Safe Cure for Diabetes" reflected both the limited medical capability of the period and public acceptance of the doctrine that the buyer could and should look out for himself. Medicines containing such drugs as opium, morphine, heroin, and cocaine were sold without restriction. Labeling gave no hint of their presence. Otherwise harmless preparations were labeled for the cure of every disease and symptom. Labels did not list ingredients and warnings against misuse were unheard of. What information the public received came frequently from bitter experience.

The medicine men competed with the circuses, the minstrel shows, and "wild west" performers to entertain the public -- and sell their products. Hamlin's Wizard Oil (Figure 7) had one of the most popular and spectacular of the big touring medicine shows. For minor aches and pains, this liniment continued to be sold for many years after the shows had ceased. A center spread in *Collier's Weekly* for December 1, 1905 (Figure 8), told a pathetic story of the harm done by narcotic "tonics" sold to trusting women.



Figure 7



Figure 8

## Wiley and the Crusade for a Law

While such practices were by no means universal, and many firms were producing reliable and wholesome products, Dr. Wiley's chemists had no difficulty getting material for their investigations and reports. Wiley took their findings to the public, becoming a popular speaker at women's clubs, civic and business organizations. Crusading writers joined in the campaign. National magazines, such as *Collier's Weekly*, the *Ladies Home Journal*, and *Good Housekeeping*, aroused public opinion with their cartoons, articles, and editorials.

Three of Dr. Wiley's most effective supporters: Mrs. Walter McNab Miller, president of the General Federation of Women's Clubs; Dr. Edward F. Ladd, of North Dakota, a leader among the state food and drug officials; and Miss Alice Lakey, of the National Consumers League (shown in Figure 9, left to right respectively). Historians and Dr. Wiley himself credit the club women of the country for turning the tide of public opinion in favor of the "pure food" bill.



Figure 9

In 1902, Wiley captured the attention of the country by establishing a volunteer "poison squad" of young men who agreed to eat only foods treated with measured amounts of chemical preservatives, with the object of demonstrating whether these ingredients were injurious to health (see Figure 10). Overnight the press made the "Poison Squad" a national sensation. Even the minstrel shows had songs about the squad -- officially designated the "Hygienic Table."

"O, they may get over it but they'll never look the same,  
That kind of bill of fare would drive most men insane.  
Next week he'll give them mothballs, a la Newburgh or else plain;  
O, they may get over it but they'll never look the same."

*(Chorus from "Song of the Poison Squad,"  
Lew Dockstader's Minstrels, October 1903)*



Figure 10

Chemicals fed to the young men included borax; salicylic, sulphurous, and benzoic acids; and formaldehyde. The experiments went on for 5 years. Wiley and the public became convinced that chemical preservatives should be used in food only when necessary; that the burden of proving safety should fall on the producer; and that none should be used without informing the consumer on the label -- basic principles of today's law and regulations. William R. Carter (Figure 11), was one of the earliest African-Americans in the history of FDA. He was hired in 1902 as a cook and waiter for the Poison Squad, earned a degree in pharmaceutical chemistry and served 43 years in the FDA laboratories.



Figure 11

Strenuous opposition to Wiley's campaign for a federal food and drug law came from whiskey distillers and the patent medicine firms, who were then the largest advertisers in the country. Many of these men thought they would be put out of business by federal regulation. In any case, it was argued, the federal government had no business policing what people ate, drank, or used for medicine. On the other side were strong agricultural organizations, many food packers, state food and drug officials, and the health professions. But the tide was turned, according to historians and Dr. Wiley himself, when the activist club women of the country rallied to the pure food cause.

Final action followed a sensational portrayal of insanitary conditions in the Chicago meat-packing industry. A single chapter in Upton Sinclair's novel, *The Jungle*, precipitated legislation expanding federal meat regulation to provide continuous inspection of all red meats for interstate distribution, a far more rigorous type of control than that provided by the pure food bill. Both measures became law the same day, June 30, 1906. J. F. McPhee's 1906 cartoon (Figure 12) reflected the public's expectations concerning the "Wiley Act." The new law, it was hoped, would put a stop to food adulteration and quack remedies -- the two major evils and targets of a 20-year crusade for federal regulation of foods and drugs.



Figure 12

(from the Wiley Papers, Library of Congress)

## Enforcing the Wiley Act

Administration of the new law was assigned to the Bureau of Chemistry. The young men and women recruited by Wiley and his successors quickly developed an efficient organization. They continued the development of scientific methods of analysis -- the foundation of food and drug protection. They worked out the legal procedures and the techniques of inspection, and applied them in hundreds of hard-fought court cases. And they won scores of judicial decisions which strengthened the law and also uncovered its weaknesses. Many found such satisfaction that they made FDA their life work.

In 1907 Walter G. Campbell (Figure 13, pictured on the left, listening to Wiley) was one of the first 28 food and drug inspectors (over 2,000 took the civil service examination). Selected by Dr. Wiley as chief inspector, he devised the legal process for the first seizure of a violative product (still used), wrote the first Inspector's Manual (1908), and set up FDA's first project system to ensure uniform enforcement while giving top priority to health hazards. Campbell remained in charge of enforcement for 37 years, becoming the first "Commissioner of Food and Drugs" in 1940. A lawyer by training, Campbell was the leading architect of the present Federal Food, Drug, and Cosmetic Act, passed in 1938. He differed sharply from Wiley in his belief that court proceedings were not the only proper way to secure compliance.



Figure 13



Figure 14

The Food Standards Committee, authorized by a 1902 appropriation, was the first FDA advisory committee, and it continued in operation until the passage of the Federal Advisory Committee Act of 1972. The committee met for days at a time, considering the needs and problems of food regulation on a national basis. Members were state agriculture officials and scientists. Figure 14 shows an early meeting of the committee, from the left: M. A. Scovell, Kentucky; H. A. Weber, Ohio; William Frear, Pennsylvania; Dr. Wiley; and E. H. Jenkins, Connecticut.

Wiley's successor, Carl L. Alsberg (Figure 15), was previously a research biologist with the Department of Agriculture. Research, education, and cooperation with state and local officials were basic elements in Dr. Alsberg's policy of administration. For the clever cheaters he sought the full penalties of the law. Retiring in 1921, he became director of the Food Research Institute at Stanford University.



**Figure 15**

The Bureau of Chemistry enforced the 1906 law until 1927 when it was reorganized. Law enforcement functions were separated from agricultural research in order to emphasize and secure better funding for the latter. The Food, Drug, and Insecticide Administration was formed, to be renamed in 1931 as the Food and Drug Administration. In 1940, to prevent recurring conflicts between producer interests and consumer interests, FDA was transferred from the U.S. Department of Agriculture to the Federal Security Agency which, in 1953, became the Department of Health, Education, and Welfare -- now the Department of Health and Human Services.

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## **Part II: The Federal Food, Drug, and Cosmetic Act**

The six-page Wiley law prohibited the manufacture and interstate shipment of "adulterated" and "misbranded" foods and drugs. It enabled the Government to go to court against illegal products but lacked affirmative requirements to guide compliance. Labels were not even required to state the weight or measure -- only that a contents statement, if used, must be truthful. By 1913, food manufacturers, alarmed by growing variety of state weight and measure laws, sought uniformity through the Gould Amendment to the federal law -- requiring net contents to be declared, with tolerances for reasonable variations.

### **Problems with the 1906 Act**

False therapeutic claims for patent medicines had escaped control in 1912 when Congress enacted an amendment outlawing such claims but requiring the Government to prove them fraudulent; i.e., that the promoter intended to swindle his victims. A defendant had only to show that he personally believed in his fake remedy to escape prosecution -- a major weakness in the law for 26 years.

Food adulteration continued to flourish because judges could find no specific authority in the law for the standards of purity and content which FDA had set up. Such products as "fruit" jams made with water, glucose, grass seed, and artificial color undercut the market for honest products.



Economic hardships of the 1930's magnified the many shortcomings of the 1906 act and brought a new consciousness of consumer needs. The book *Your Money's Worth*, by Stuart Chase and F. J. Schlink, signaled the start of a new consumer movement. Most important, the 1906 law became obsolete because of the technological changes which were revolutionizing the production and marketing of foods, drugs, and related products.

### **Movement for a New Law**

In 1933, a few days after the inauguration of Franklin D. Roosevelt as President of the United States, the chief of the Food and Drug Administration, Walter Campbell, seized an opportunity to discuss the food and drug situation with Rexford Tugwell, a member of the President's "brain trust," who had been named Assistant Secretary of Agriculture. The same afternoon Campbell was again called to Tugwell's office. "Mr. Campbell," said Tugwell, "since I saw you this morning I have talked with the President. I repeated our conversation to him, and he has authorized a revision of the Food and Drugs Act."

To help illustrate the many shortcomings of the 1906 law, FDA assembled a collection of case studies to present to the public in several venues and to the Senate on why new, improved protections were necessary. Chief Inspector George P. Larrick, later FDA commissioner, is shown in Figure 16 in front of this collection of marketplace atrocities, dubbed by a member of the press as the "Chamber of Horrors." Ruth De Forest Lamb (Figure 17), FDA's chief educational officer, helped organize consumer support for a new law and wrote *The American Chamber of Horrors*, which employed and elaborated on the collection of problematical products assembled by the agency.



**Figure 16**



**Figure 17**

The "Tugwell bill," introduced in congress a few weeks after the Campbell-Tugwell meeting, was a legislative disaster. The opposition of industry and advertising interests to this New Deal legislation was total and overwhelming. When the smoke cleared away the Senate sponsor, Royal S. Copeland, M.D., of New York, aided by FDA officials, consumer-minded Congressmen, attorneys, and staff members, began the laborious process of fashioning a bill that could be enacted, yet not surrender essential consumer protection. A bitter 5-year legislative battle began. Again, organized club women provided most of the public support. Trade leaders

made positive as well as negative contributions. Again public opinion was aroused by a shocking disclosure -- the deaths of more than 100 people from a poisonous "elixir of sulfanilamide." On June 25, 1938, President Roosevelt signed the Federal Food, Drug, and Cosmetic Act.

Many compromises had to be made to secure passage, but still the new law was a major improvement. The following is a list of some of the substantive changes which altered the law to fit the new conditions.

- Drug manufacturers were required to provide scientific proof that new products could be safely used before putting them on the market.
- Cosmetics and therapeutic devices were regulated, for the first time.
- Proof of fraud was no longer required to stop false claims for drugs.
- Addition of poisonous substances to foods was prohibited except where unavoidable or required in production. Safe tolerances were authorized for residues of such substances, for example pesticides.
- Specific authority was provided for factory inspections.
- Food standards were required to be set up when needed "to promote honesty and fair dealing in the interest of consumers."
- Federal court injunctions against violations were added to the previous legal remedies of product seizures and criminal prosecutions.

### **The Preventive Amendments**

The new law, and World War II, greatly expanded FDA's workload. Wartime demands had stimulated the development of new "wonder drugs," especially the antibiotics, which were made subject to FDA testing beginning with penicillin in 1945. Fortunately there was a law requiring clearance of new drugs prior to marketing, but consumers continued to be guinea pigs for a host of new chemical compounds of unknown safety. The law prohibited poisonous substances but required no showing that food ingredients were safe. It provided for exemptions and safe tolerances for unavoidable or necessary poisons such as pesticides, but when FDA attempted to set a pesticide tolerance an adverse court decision showed that the lengthy procedure required by law was unworkable. FDA could stop the use of known poisons, and did so in numerous cases, but the vast research efforts needed to assure that all food chemicals were safe was clearly beyond all foreseeable resources.

In 1949, FDA Commissioner Paul B. Dunbar took the problem to a friend in Congress, Rep. Frank B. Keefe of Wisconsin. Mr. Keefe introduced a resolution to investigate chemicals in food, and later, cosmetics. The hearings, chaired by Rep. James T. Delaney of New York, went on for 2 years. From the committee's work came three amendments that fundamentally changed the character of the U.S. food and drug law: the Pesticide Amendment (1954), the Food Additives Amendment (1958), and the Color Additive Amendments (1960). As these changes to our food laws were being implemented, the November 1959 cranberry recall gave cartoonists an opportunity to poke fun at both regulators and politicians (Figure 18). Between Thanksgiving and Christmas the FDA chemists worked 24 hours a day, testing the entire crop for contamination by a carcinogenic weed killer.



Figure 18

With these laws on the books, it could be said for the first time that no substance can legally be introduced into the U.S. food supply unless there has been a prior determination that it is safe. By requiring the manufacturers to do the research, a problem of unmanageable size was made manageable. Preventing violations through clearance before marketing gave consumers immeasurably better protection than merely prosecuting the few violations which could be proved by investigating after injuries were reported.

Very significant was a proviso in the food and color additive laws that no additive could be deemed safe (or given FDA approval) if found to cause cancer in man or experimental animals. Known as the "Delaney Clause," the section was initially opposed by FDA and by scientists who agreed that an additive used at very low levels need not necessarily be banned because it may cause cancer at high levels. Proponents justified the clause on the basis that cancer experts have not been able to determine a safe level for any carcinogen. This was the underlying basis in 1959 for a nationwide FDA recall of cranberries contaminated by the weed killer aminotriazole. Notwithstanding publicity critical of FDA, this action has beneficial results, particularly in convincing farmers that pesticides must be used with care. Other important and controversial FDA actions stemming from the Delaney Clause will be mentioned later.

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### Part III: The 1962 Drug Amendments and After

The trend toward preventive lawmaking continued. A drug tragedy in Europe, the births of thousands of deformed infants whose mothers had taken the new sedative thalidomide, focused public attention on pending U.S. legislation to further strengthen the Federal Food, Drug, and Cosmetic Act. Frances O. Kelsey, M. D., the FDA medical officer who relied on the 1938 "new drug" law to refuse approval of that drug for marketing in the United States, received the

Distinguished Federal Civilian Service Award from President John F. Kennedy on August 7, 1962 for her key role in protecting America from widespread death and injury (Figure 19).



**Figure 19**

The Drug Amendments of 1962, passed unanimously by the Congress, tightened control over prescription drugs, new drugs, and investigational drugs. It was recognized that no drug is truly safe unless it is also effective, and effectiveness was required to be established prior to marketing -- a milestone advance in medical history. Drug firms were required to send adverse reaction reports to FDA, and drug advertising in medical journals was required to provide complete information to the doctor -- the risks as well as the benefits. In the years since 1962 literally thousands of prescription drug items have been taken off the U.S. market because they lacked evidence of safety and/or effectiveness, or they have had their labeling changed to reflect the known medical facts.

Preventing harm again was the goal of amendments passed in 1976, to insure safety and effectiveness of medical devices. federal authority to regulate therapeutic devices was first provided in the FDC Act of 1938. As a result, hundreds of quack machines and gadgets were taken off the market. The growth of medical technology, however, soon made the 1938 act obsolete in regard to legitimate devices. Spectacular growth also occurred in the related field of medical diagnostic aids. Anticipating the need for better regulation in both areas, and FDA Bureau of Medical Devices and Diagnostic Products was officially created in February 1974. Years of study and many drafts of proposed laws developed by FDA and Congressional staff workers and industry experts culminated in the Medical Device Amendments of 1976, signed by President Gerald Ford on May 28. To avoid excess regulation the new law provides for classification of devices for controls appropriate for each class. Critically important devices, such as heart pacemakers or surgical implants, must be proved safe and effective before they can be marketed.

Preventing harm is again the purpose of the newest amendment of the basic Food, Drug, and Cosmetic Act, the Infant Formula Act of 1980, drafted by Congress to insure minimum amounts of essential nutrients in commercially prepared baby foods, and to establish safety and quality standards for such foods. The Congressional action followed reports during 1979 that over 100

infants had been made seriously ill because of the lack of chlorides in two soy-based formulas. The new law authorizes FDA to adjust nutritional standards for such foods to conform with the best available scientific knowledge. Manufacturers are required to periodically test their products and report promptly to FDA when they do not meet the official specifications.

## Major Trends and Developments

At the start of the 1950's the resources of FDA were seriously deficient. Appropriations and staff, never adequate, remained at approximately the levels prevailing in 1938 when Congress passed the present basic Federal Food, Drug, and Cosmetic Act, greatly increasing the Agency's responsibilities. In 1954, Commissioner Charles W. Crawford won approval by Nelson Rockefeller, undersecretary of the department, for the appointment of a representative Citizens Advisory Committee on the FDA, to study the adequacy of enforcement. The committee, adopting recommendations drafted by a distinguished industry lawyer, Charles Wesley Dunn, recommended a three-to fourfold increase in funds, to be accomplished in 5 to 10 years. The budget makers and the Congress were impressed by the committee's report, and a spectacular increase in FDA appropriations has since occurred -- from a \$5 million budget in 1955 to over \$320 million in 1980, with a staff increase from less than 1,000 to over 7,000.

Equally striking in the last quarter century has been the increase in FDA's scientific capability to detect and measure substances in foods, drugs, and cosmetics. FDA chemist Paul A. Clifford and physicist Brooks Brice developed the visual spectrophotometer shown in Figure 20 in the early 1930's. This was the forerunner of equipment that has increased the sensitivity of FDA analytical methods approximately a million fold -- the difference between 10 parts in a million in the 1940's and less than one part per billion today.

FDA scientists have always been outstanding for their skill in analytical chemistry, leading to a new arsenal of spectrographic and chromatographic techniques in which contaminants can be measured to parts per trillion. Today automated instruments can even print out the results of sample analyses in minutes, a procedure which once would have required weeks of laboratory benchwork. The increase in sensitivity of methods, by roughly one million times, revolutionized food and drug regulation. The continuing revolution in analytical techniques is typified by the high-resolution, double-focusing mass spectrometer in the FDA Washington headquarters laboratories seen in Figure 21. This advanced unit is used to identify food toxicants ranging down to one part per billion. It is in this context that scientists must now decide such questions as where to draw the dividing line between consumer risk and benefits.



Figure 20



Figure 21

## **Programs Transferred**

From its beginning, FDA's mission has been consumer protection. As a consequence the Agency has initiated several major consumer protection programs now administered by other agencies, and today includes consumer programs transferred to FDA from other agencies.

A great chapter in FDA history came to an end in 1968 when the FDA Bureau of Drug Abuse Control was merged with federal narcotic law enforcement in the Department of Justice. On its own initiative FDA has pioneered in the 1940's the federal effort to curb abuse of nonnarcotic drugs, by prosecuting dealers who sold barbiturates and amphetamines without prescriptions. The advent of the dangerous hallucinogenic drug LSD in the 1960's magnified the problem. Working with inadequate law, unarmed, and with little experience in criminal investigation, FDA inspectors went undercover as drug peddlers and secured the conviction of hundreds of racketeers and pushers. When stronger drug abuse control amendments were passed in 1965, a new FDA Bureau of Drug Abuse Control was established, with a nationwide field service and over 300 trained agents. Anticipating ultimate consolidation with the Federal Bureau of Narcotics, FDA Commissioner George Larrick planned the new bureau as a separate establishment. With the transfer, FDA lost many experienced employees, and criminal investigation became a relatively minor field of activity.

Safety of household chemical products, appliances, toys, and other consumer goods is another area of consumer protection pioneered by FDA. The Caustic Poison Act, lobbied through Congress in 1927 by Dr. Chevalier Jackson and the American Medical Association, required labels to warn parents and protect children from accidental injury and death caused by lye and 10 other caustic chemicals. In 1960 thousands of other chemical products for home use came under FDA control when the Hazardous Substances Labeling Act was passed with strong industry support. To administer this law and subsequent amendments which expanded it, FDA developed an effective consumer safety program. With the passage of the Consumer Product Safety Act, in 1972, the FDA Bureau of Product Safety became the operating organization of a new independent Consumer Product Safety Commission.

## **Programs Added**

Important health programs were merged with FDA as a result of a 1968 departmental reorganization. By transfer from the Public Health Service, FDA became responsible for activities to:

- Assure safe milk supplies through cooperation with state and municipal milk control authorities;
- Assure that shellfish are harvested from unpolluted waters and handled in a sanitary manner;
- Assure safe food, water, and good sanitary facilities for travelers on trains, planes, ships, buses, and the interstate highways;
- Promote sanitary practices in restaurants and other food service facilities;

- Protect victims of accidental poisoning by providing poison control centers with information needed for emergency treatment.

The health hazards of radiation have been known since the discovery of radium and the x-ray. Before World War I, FDA was taking action against quack drugs and devices claimed to be radioactive -- some of them highly dangerous. About 1913 the Public Health Services became concerned with workers who contracted cancer from luminous paint they applied to watch dials. Overdosage with diagnostic x-rays increased greatly, becoming a major public health problem. Following World War II both PHS and FDA were involved in monitoring contamination of food, milk, and public water supplies due to radioactive fallout from open testing of atomic weapons. Meanwhile, electronic technology developed a host of new products -- television, microwave ovens, lasers, etc., which could emit harmful radiation. In 1968 a comprehensive Radiation Health and Safety Act was passed, and in 1971 the product-related activities of the PHS Bureau of Radiological Health were transferred to FDA, while its environmental activities were shifted to a new Environmental Protection Administration.

One more important health program was assigned to FDA in July 1972, from the National Institutes of Health -- the regulation of biological drugs. This, the oldest continuing federal drug control program, was begun in 1902 to insure the safety and effectiveness of vaccines, serums, antitoxins, etc., by setting standards and licensing both the producers and their products. The transfer immediately strengthened control by applying provisions of the Federal Food, Drug, and Cosmetic Act as well as the licensing controls previously in effect. More effective regulation of blood banks has been a major accomplishment of FDA's new Bureau of Biologics.

From its beginning, the law defined food and drugs as products "for man and other animals." But livestock feed and veterinary drugs were left largely to state regulation until World War I made it important to increase food production. One way was to crack down on quack veterinary medicines, especially the numerous "cures" for hog cholera. For years the Bureau of Chemistry and FDA waged war against such products, saving farmers uncounted millions in livestock losses as well as the cost of worthless drugs. Today the law for animal products closely parallels the regulation of products for humans, and FDA's Bureau of Veterinary Medicine is as much involved with the health of human consumers of animal products as it is with the animals which produce them.

### **The Trend Toward Prevention**

There are many ways to write FDA's history. It can be a story of the laws which Congress enacted, a story of famous cases to enforce those laws, a story of the organization and the people who built it, or a story about the changing technology and the scientific controversies, some settled, others still unsolved. And it can be all of these, but not in a few pages.

If there is one dominating theme it is the change from a law that was primarily a criminal statute, protecting consumers through the deterrent effect of court proceedings to a law that is now dominantly preventive through informative regulations and controls before marketing.

The laws requiring approval prior to marketing made important changes in FDA's methods of

control. They specifically required the Agency to issue regulations explaining the requirements and procedures. The 1962 Drug Amendments called for Current Good Manufacturing Practice Regulations to set standards for plant facilities, maintenance, laboratory controls, etc., to prevent errors or accidents which could harm consumers. The idea was too good to be restricted to drugs, and in 1969 the first GMP's for food establishments were issued. All such regulations are based on actual industry practices. Today FDA inspectors especially look for GMP violations, as well as product violations.

The American public has little knowledge of the routine work of FDA, important as it is to every consumer. Much better known are its efforts to deal with scientific problems that make the news. A succession of these, beginning with the cranberry recall of 1959, has greatly affected the Agency's work as well as its public image.

Those who read the papers or watch TV know FDA in terms of such topics as cyclamate in soft drinks, the food color Red No. 2, saccharin, nitrite, and caffeine. Chemicals and cancer are the great public health concerns of today. Much more is known about such matters than just 20 years ago, yet uncertainty about the risk of borderline carcinogens continues to hamper decisions. Generally a great deal of money is involved -- both for the users and the regulators who must seek scientifically valid answers. At the same time an inflexible law (the Delaney Clause) leaves little room for the exercise of judgment.

Fortunately, the regular business of consumer protection goes on as usual. Millions of times a day people in factories, warehouses, drugstores, and hospitals do things to comply with the food and drug law -- yet never give it a thought! Consumer protection happens because so many people do things the right way.