

FDA Law Enforcement: Critical to Product Safety

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Sometimes, the strategy proved simple--sampling chocolates and jelly beans to detect substandard ingredients. Other times, the plan was more complicated--paying youngsters to cause a disturbance in front of a store to draw everyone outside long enough for investigators to secretly locate and copy company records. Even more unconventional means sometimes were employed. At one time, a can with a rat in it was used to train investigators to detect, by taste, cream that might have been contaminated by the rodents.



An FDA investigator inspects a fresh catch of salmon.

Health officials involved in enforcing Food and Drug Administration rules and regulations during the early 20th century generally used a variety of tactics--ranging from the ingenious to the heroic--to ensure that companies making products under the jurisdiction of the then Bureau of Chemistry complied with the laws.

"It required great determination on the part of some to push the rat to one side with a grading rod and then taste the cream," said Walter S. Greene, head of the FDA's Microanalytical Laboratory, in 1934. "But probably a dozen or more seizures were made on rat cream in 10 days because of this training."

Today, a law enforcement team operates within a science-based framework that includes rules and traditional methods for ensuring that companies producing FDA-regulated products don't put the public at risk. This team of more than 3,000--made up of investigators, compliance officers, scientists, laboratory analysts, public affairs specialists, and criminal investigators--is directed by the Office of Regulatory Affairs (ORA), the FDA's primary regulatory component.

"We're the eyes and ears of the agency," says Deborah D. Ralston, director of the ORA's Office of Regional Operations. "The idea is that we follow up on anything that needs investigating."

The ORA and its components are responsible for inspecting the full range of FDA-regulated products--both before they are marketed and afterwards. From outside ports of entry to inside manufacturing facilities, on any given day FDA investigators can be found conducting inspections, collecting and analyzing samples, and implementing the FDA's many policies, which impact the regulation of food, cosmetics, drugs, biologics, and medical devices in this country.

Stationed in more than 190 offices, resident posts, and laboratories around the United States and in Puerto Rico, ORA employees work cooperatively with other federal, state, local, and foreign agencies to safeguard the public health and to ensure honesty and fair dealing between regulated industries and consumers.

While some offices within the ORA pursue administrative and civil remedies against violations of public health laws, the Office of Criminal Investigations (OCI) is the organization responsible for conducting and coordinating all criminal investigations related to serious violations of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and related acts, as well as the Federal Anti-Tampering Act (FATA). The OCI's special agents present their investigative findings to U.S. Attorneys' Offices around the country, which have the responsibility for prosecuting those who deliberately produce defective products (adulterate), or misbrand, counterfeit, or tamper with FDA-regulated goods.

Established in 1992, the OCI has a small but highly qualified staff capable of providing the FDA with a vital criminal enforcement component to enhance the agency's inspection, compliance, and regulatory mission. The OCI interacts with the Department of Homeland Security (DHS), the Central Intelligence Agency (CIA), the Federal Bureau of Investigation (FBI), the National Counter-Terrorism Center (NCTC), and others, to assist with terrorism-related threats or acts of terrorism involving FDA-regulated products.

Prior Enforcement Without Boundaries

The crusade against those who do not comply with the laws actually began when the 1906 Pure Food and Drugs Act was passed by Congress after 25 years of debate, and as a result of both industry and consumer complaints about the poor quality and misleading labeling of many food and drug products sold in interstate commerce. The law itself made food and drug adulteration and misbranding a federal offense. Federal offenses, however, required federal inspectors.

"FDA's centennial really marks the anniversary of the creation of the position of federal food and

drug inspector," says FDA Historian Suzanne White Junod, Ph.D. "In 1906, scientists sitting in their labs looking solely at samples would have had difficulty proving their cases based on chemistry alone," she says.

The previously established Bureau of Chemistry became the FDA in 1930. Harvey W. Wiley, M.D., the bureau's chief and founding father, had no well-laid plans for the new inspectors. Having spent 23 years fighting to secure the 1906 law, Wiley would then battle to establish his vision of how the act should be enforced.

When the first 28 inspectors met in Washington, D.C., in 1907, their instructions on how to collect and mechanically prepare samples were short-lived. Wiley's assistant sent the trainees off two by two to gather samples, providing each man with a woven fiber shopping bag used by women of the day. They had to cross the Mall from C Street to Pennsylvania Avenue to reach their destinations. FDA documents state that Walter G. Campbell, who eventually became the chief inspector, looked at his shopping bag, winked at his partner--who replied in kind--and without a word, both tossed their bags under some nearby shrubbery. They would conduct the inspections their way.

Although there were no hard and fast rules about personal appearance, Campbell, in his role as chief inspector, insisted that inspectors look neat. Those on the road stayed in respectable hotels, and the average per diem, at the time, was \$4 for a night's stay. Since the act neither permitted nor prohibited anyone the right to enter a factory or a store and to examine the premises or peruse the records, new inspectors were taught how to be resourceful as part of their basic training.

From sample snatching to a Sherlock Holmes approach to enforcing the laws of the time, inspectors used all of their senses to poke and prod, taste and smell, inspect, examine, and observe suspect food and drug products. In the early years of federal food and drug enforcement, inspectors began to work together with bench chemists to police the marketplace.

For example, an enterprising Baltimore inspector enlisted the help of a New York chemist to detect adulterations in pepper. The chemist devised a quinine solution, which the inspector injected into bags of spent pepper shells that he suspected were being used to adulterate pepper. When lab results from marketed pepper showed telltale signs of quinine, the company was successfully prosecuted and fined. Even today, investigators' senses, awareness, intuition, inquisitiveness, assertiveness, and objectivity remain among their most valuable tools to accomplish their jobs.

Back then, as now, the courts had the final authority to enforce the provisions of the food and drug law. Often inspectors were able to convince food processors and drug manufacturers to make necessary changes in their operations. If they did not, a case was brought to court. Local juries were not inclined to punish local businesses and business owners in the earlier years; however, over time, legal precedents were established in courts around the country that made for more uniform, more reliable, and speedier law enforcement. As scientific methods for detecting food and drug adulteration and misbranding improved, they became more convincing to judges and juries.

For the drug manufacturer's part, the then-new laws applied mostly to what was said on a label, not what was actually contained in a bottle. Any statements made on the label about the contents had to be true. The manufacturer, though, also could choose to state nothing on the label. The 1906 law provided a list of 11 dangerous ingredients, including marijuana, alcohol, opium, cocaine, morphine, and a few poisons, which, if they were in the product, had to be listed on the label. Therefore, a bottle could contain a poison not on the list, and if the label were blank, there was no way the government could stop the public from swallowing the contents. Even the weight and measurement of the contents didn't have to be disclosed until 1913. Nor did the law apply to advertisements or any other promotional material.

Food, meanwhile, had a few more rules: it could not be missing a key ingredient or be filthy, decomposed, or putrid, and food processors could not try to disguise violations. However, there were no enforceable standards of identity for foods.

Change Was Inevitable

By 1933, the United States was overwhelmed with all sorts of products, from cosmetics to pesticides, that had not been anticipated in 1906 and, therefore, clearly had not been regulated. Meanwhile, mysterious miracle cures and phony food products were still being peddled.

In 1938, the Federal Food, Drug, and Cosmetic Act (FD&C Act) was signed into law. Deficiencies in the 1906 act led the FDA, with a blessing from the White House, to begin drafting this new federal food and drug statute. The Elixir Sulfanilamide disaster--whereby more than 100 people, many of them children, died in agony after consuming the product in liquid dosage form, and which contained a solvent that was a cousin of radiator antifreeze--forced a stalled congressional bill to be converted under public pressure into the new food and drug statute. Nearly the entire field force of the FDA was deployed to help retrieve Elixir Sulfanilamide from stores and homes across the country, making this incident one of the major investigative initiatives for the agency.

Public and congressional outrage over the incident, fueled by the agency's inability to charge the company with anything more serious than misbranding its product, helped push this revised and strengthened food and drug bill through Congress.

Settling Old Scores

Plans to implement the new act got under way in earnest a few months before the laws actually went into effect. FDA officials made it clear in their meetings with industry during this period that they were going to insist on the broadest and strictest interpretation of all sections of the law. Although most of the new provisions of the law would not go into effect until a year after it was signed, some important sections, such as the one requiring manufacturers to show that new drugs were safe prior to marketing them, went into effect immediately.

Many of the earliest seizures carried out under the 1938 act were attempts to settle old regulatory business. According to Junod, the first drug seizures were intended to take action against drugs

containing the deadly ingredient dinitrophenol--a manufactured chemical once used in diet pills. But all of these products quickly disappeared from the market just prior to the signing of the new act. Instead, the government acted against other obesity products such as Marmola, which contained thyroid extract, a potent drug that the agency had been unable to take action against under the 1906 act. Pain relievers and headache remedies containing aminopyrine and cinchophen and a mixture of acetanilide and bromides were soon seized based on misbranding charges.

Because the 1938 act contained many new sections that applied to the food industry, Junod says that the early inspectors recall they spent a lot of time in the field taking industry surveys. On the one hand, they were looking to see what kind of violations existed. On the other, they were gathering information. Besides problems with spray residues and occasional food poisoning reports, most of the work did not involve dangers to health, but rather, economic cheats and less serious problems with sanitation. A sample of sauerkraut that was collected resulted in the first Notice of Judgment under the new act.

The first cosmetic seizures under the new act were for Lash Lure, "the new and improved eyebrow and lash dye," which had blinded at least one person and injured many others. By mid-1939, the FDA had accomplished over 65 seizures of lash and brow dyes containing the dangerous para-phenylenediamine chemical.

The agency did not have a timetable for enforcing the provisions of the new 1938 act, other than those dates when the provisions actually became effective in the act. The FDA preferred to start out by educating industry, interpreting for them the provisions of the act, and promoting voluntary compliance, wherever possible. Those cases the agency selected to take to court involved new authorities covered by the act and were taken in order to establish strong precedents under the new laws.

For example, in a 10-week period during the 1959 cranberry crisis in which the 1957 crop was contaminated with a carcinogenic pesticide, FDA chemists examined 3,653 samples representing over 33,000,000 pounds of cranberries or cranberry products, so that people could enjoy this holiday favorite at Thanksgiving. To save the nation's traditions, Junod says that the FDA and industry quickly developed a program to test all holiday berries for contamination. "For the only time in its history," she says, "FDA allowed cleared berries to carry an agency endorsement."

The cranberry crisis, for the most part, had diminished by Christmas 1959, but Junod says that the FDA continues to test cranberries regularly because Congress asks about them every 10 years or so.

The 1938 FD&C Act dramatically changed the nature and scope of the food and drug inspector's work. The ORA has seen marked changes over the years. But even as new schemes were devised by shrewder proprietors, the long arm of the agency has responded with new tools and inspection techniques, as well as with legal approaches.

Consumer Confidence

Based on the assumption that informed consumers require less protection, the FDA began recruiting candidates for consumer representatives for the field in February 1952. These consultants would serve as liaisons between the agency and the public on a wide variety of consumer problems, says FDA Historian John P. Swann, Ph.D., but most notably they would represent the consumer viewpoint in the ongoing food standards hearings.

Later in 1952, the FDA Commissioner announced the appointment of 16 women as the first consumer consultants. Many were married and had children, a few were educators, some had formal training in home economics, and still others were active in local women's organizations. "But the abiding tie between them," says Swann, "was a breadth of knowledge of consumer habits, expectations and preferences, such as the sort of information important on a food label."

Consumer consultants reported on consumer opinions about the FDA's work as revealed in the press. They collected items of interest to the FDA from local newspapers about companies regulated by the FDA, related accounts of food poisoning, and conveyed complaints about products with deceptive packaging, misleading labeling, or filth contamination.

Overall, consumers had limited protection until the 1950s and early 1960s. The ORA consumer consultants were part of a larger movement concerned with defective products, misleading advertising, and other issues. In his 1962 speech to Congress, President John F. Kennedy outlined four basic consumer rights, which later became known as the "Consumer Bill of Rights." The United Nations has since endorsed this document, expanding it to cover more consumer rights.

By 1964, the agency began hiring full-time consumer "specialists," as the position became known. But by the 1970s, confusion over the meaning of "consumer specialist" prompted a change of title to first, Consumer Affairs Officer, and later to the title used today, Public Affairs Specialist.

Impact on Public Health

During an average year, the FDA and those states under contract to or in partnership with the agency conduct about 43,000 establishment inspections in the country, and the FDA alone conducts about 900 inspections abroad. The FDA reviews about 12 million imported goods, conducts 110,000 import field examinations, and analyzes about 46,000 product samples annually.

It's a big job, to be sure, monitoring products accounting for more than 20 percent of all consumer spending, or 1 trillion dollars' worth of goods. FDA-regulated products today are produced and distributed by 128,000 domestic establishments, including 62,000 food companies, 37,100 medical device firms, 18,900 human drug companies, and 11,800 firms that make and sell animal drugs and medicated feeds. By comparison, this level of activity is twice the number it was in the early 1990s.

Ralston says besides taking various criminal, civil, and other enforcement actions, such as product recalls and import refusals, against violators, the ORA continues to offer education and

technical assistance to industry, states, health professionals, and consumers to encourage the safe use of products and compliance with the laws that the FDA administers.

The ORA's Increased Strength

The ORA has made dramatic advances over the past quarter century--allowing it to meet the unprecedented challenges the FDA has faced. In 2005, for example, the agency celebrated an important milestone: the 10th anniversary of the first mammography facility inspection under the Mammography Quality Standards Act (MQSA) of 1995. The scope, diversity, and complexity of the products the ORA regulates have grown along with its responsibilities.

"Each and every day the products and industries we regulate become more complex; the technologies we are responsible for evaluating become more sophisticated; and the science upon which the products we regulate are based becomes more advanced," says Associate Commissioner for Regulatory Affairs Margaret O'K. Glavin. "Likewise, the risks that are posed by these products and scientific advances are also increasing."

The ORA has seen a 12-fold increase in the number of regulated imported goods--more than doubling in the past five years alone. Other challenges include those posed by product tampering, drug counterfeiting, the sale of prescription drugs over the Internet, and situations involving potential terrorism threats.

The ORA's ability to protect the public health has been enhanced by additional resources and authority granted by Congress in the aftermath of the Sept. 11, 2001, terrorist attacks. The FDA hired 655 new ORA employees, the majority of whom either were stationed at border locations or were assigned to work on imports to help ensure the safety and effectiveness of FDA-regulated goods that are imported into the United States from countries around the world.

The attacks emphasized the need to ensure that the FDA has additional tools to help prevent food-related bioterrorism events or other public health emergencies. One of the authorities afforded the FDA as a result of the Bioterrorism Act includes mandating that prior notice of imported food shipments be submitted to the FDA before the food enters the United States.

To implement the prior notice requirement, the ORA established and staffed a first-of-its-kind activity--the Prior Notice Center (PNC)--which operates 24 hours a day, seven days a week, to accommodate the global economy. Working cooperatively with the U.S. Custom Service and Border Protection, the FDA has gained critical new tools that help identify shipments containing potentially dangerous foods and prevent them from entering the country.

For example, the FDA now knows in advance when and where specific food shipments will enter the United States, what those shipments will contain, the countries and entities from whom they originate, and the facility where the food was manufactured. This advance information, along with other information from the intelligence community, allows the agency to more effectively target inspections and to ensure the safety of imported foods. Nearly 20 percent of all imports into the United States are of food and food products that are consumed daily by the American public.

Glavin says in the future, the ORA will build upon its current and past strengths to maintain the critical role it plays in protecting and advancing public health. She says the ORA will do this by "always cultivating our skills, especially in the application of risk management principles to our inspection and enforcement programs." She adds that with all the new capabilities, the ORA in the 21st century is becoming a more agile and effective force for safeguarding the American people and for ensuring that FDA-regulated goods are safeguarded.

While some enforcement cases make headlines, most of the ORA's work is without much publicity. People, Glavin says, have simply come to expect that their food and drugs will be safe.