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CHARLES W. CRAWFORD

Commissioner of Food and Drugs

1951 - 1954

It was the only job he ever really wanted—to be a chemist in Harvey W. Wiley's Bureau of Chemistry. Having flunked the stiff civil service examination in 1909, he took it again seven years later and passed. Character, determination, and some unique abilities propelled him from one job to the next, and in 1933 he was given the assignment of handling all matters connected with the legislation which in 1938 became the Federal Food, Drug and Cosmetic Act. How Charles Crawford became commissioner of Food and Drugs, and major events of his four yars in that office, have been compressed in these papers. They include some of the most significant experiences in the history of FDA consumer protection.

— *Wallace F. Janssen*

These articles originally appeared in the *Journal of the Association of Food and Drug Officials* as a four-part series. The first installment was published in the April, 1990 edition of the quarterly, the second in the July issue of the same year, Part 3 in January, 1991, and the conclusion in April, 1991.

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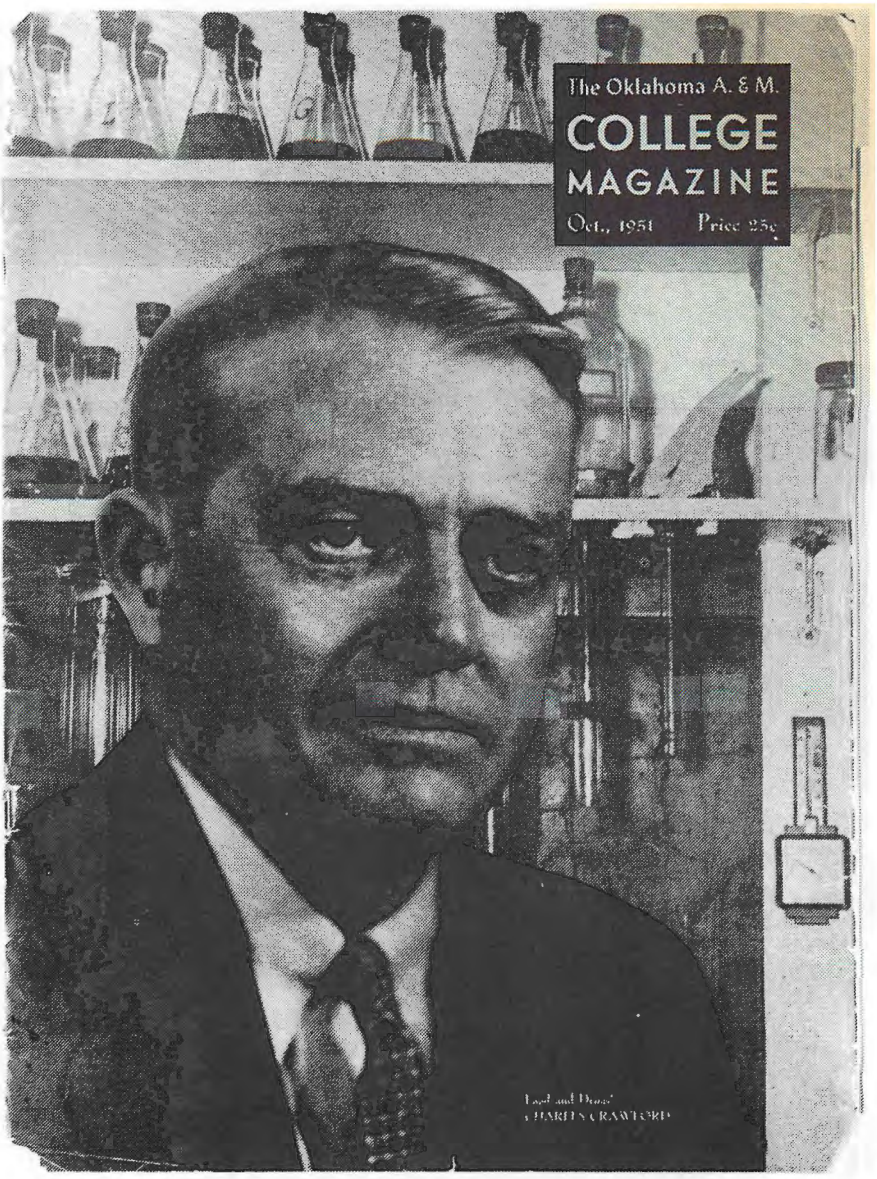
These "Crawford Papers," originally planned as two, evolved into four simply because there was so much to tell about his life and work for FDA. Even so, the result has been a series of unfinished stories about beginnings made during his four years as Commissioner of Food and Drugs. They have been compressed into these articles with the idea of providing background to problems that still confront us.



Cover of the Oklahoma A. & M. college magazine of October 1951 containing an article with reminiscenses by both classmates and Commissioner Crawford himself.

CRAWFORD
I

An Oklahoma farm boy acquires an interest in chemistry—reads about the turn-of-the-century crusade for pure foods and drugs—decides he wants a career in Dr. Harvey Wiley's Bureau of Chemistry. A college senior, class of '09, he takes the tough civil service exam, and flunks. Seven years later, with a master's degree, he repeats the exam and passes. Appointed in 1917 as an analyst at new Orleans, his work on a wartime fraud investigation gets Washington attention. Assigned in 1933 to handle all matters connected with pending legislation, he becomes the leading advisor to authors of the Federal Food, Drug, and Cosmetic Act.

People were always calling him "Doctor," especially after June 1, 1951, when he was sworn in as Commissioner of Food and Drugs. Some of us thought it would be nice if his *alma mater* would give him an honorary doctorate, but we soon learned that Oklahoma A&M College awarded only earned degrees. They wanted to honor him, nonetheless, and proposed that this be done in a special article in the college magazine. It appeared in the October 1951 issue under the title "Watchdog of America's Health—a Collaboration by Friends of Commissioner Crawford."(1) It was comprised of reminiscenses by classmates and Crawford himself, unaware that I was interviewing him for publication.

Which is how the first of these four articles came to be written. The others, compounded from personal recollections and research in FDA's archives, report major events and experiences during the tenure of this employee who deliberately chose an FDA career for his life work and rose from the ranks to be its Commissioner.

Charles Wallace Crawford was born on a farm in McLennan County, Texas, July 21, 1888. His father had come from Arkansas as a boy of 16, shortly after the Civil War, and had worked for years as a cowhand on the old Chisholm trail. In 1890 the family moved to another farm in Hamilton County, Texas. Here Charles' mother taught him to read and do elementary arithmetic and the rudiments of grammar—and here she died when he was 10 years of age. Mrs. Crawford was stricken with acute appendicitis, and on the scrubbed wooden kitchen table she underwent the first appendectomy in all that region. But it was too late. The loss of his mother made a deep impression on Charles. For the rest of his life the odor of chloroform would evoke a tragic memory.

It was rough, frontier country. Only a few years had passed since the last of the Commanche raids, and the land wars between the farmers and the cattlemen were still a topic of everyday conversation. Charles Crawford did all the usual farm chores. He told me he could not remember the first time he picked cotton. Most of his work was with the livestock, especially horses. His first formal schooling began at the age of eight, in the third grade of a one-room school.

In 1901 Crawford's father moved the family to Cleveland County, Oklahoma, and in 1901 he moved again to a farm and horse ranch in Caddo County, formerly Indian territory which had just been opened to white settlement.

Charles attended high school at Apache, Oklahoma, but completed his fourth year of high school as a subfreshman at Oklahoma A&M college. He worked his way in large part. The first two years of college he worked Saturdays on the college farm and did odd jobs such as beating rugs. The going wage was 10 cents an hour. In his sophomore year "Chaz" got an easier job—filling reagent bottles and doing other housekeeping chores around the chemistry lab. In his senior year he won a raise to 12½ cents an hour doing simple analytical jobs for the Agricultural Experiment Station.

It would be a mistake to infer that these extra-curricular activities accounted for Chaz Crawford's interest in chemistry or his future career. But there is no doubt that the personality of Prof. George L. Holter, head of the chemistry department, was a major influence in developing his latent interests. As a boy, such questions as why one stone was different from another, or what made stone different from clay or wood, had often occupied Charles' thoughts. One day he saw a newspaper advertisement offering to furnish the horoscope of anyone who would reply. Trained by his parents to be properly skeptical of such things, young Crawford nevertheless answered the ad, and was informed that his future life would be concerned with liquids, and that he should study chemistry.

Telling me his life story, Crawford strongly denied that this influenced him, offering as proof the fact that he did not originally register for the chemistry course but enrolled in the agricultural course. It was when he came under the classroom spell of Prof. Holter that he changed courses.

Crawford's classmates remember him as a well-rounded student; a member of the track team, with a literary taste that was keener than average. One '09-er recalls that from all indications at the time he might just as well have turned out to be a writer or a teacher of English as head of the Food and Drug Administration. His gift of repartee is remembered—"a dead-eye Dick with barbs of sarcasm" is the description. Ability as a wordsmith might not have seemed important to a budding chemist, but it was later to stand Crawford in good stead.

More significant of later specialization, young Crawford was early aware of the pure food crusade advocating passage of the first federal food and drug law. Magazines and newspapers were full of the pros and cons and Crawford as a boy was one of the readers of the famous "muck-raking" articles appearing in such periodicals as *Colliers Weekly* and the *Ladies Home Journal*. Dr. Harvey W. Wiley, then chief of the Bureau of Chemistry in the U.S. Department of Agriculture, was a national figure and the spearhead of the movement. His chemists had prestige not unlike that of today's astronauts. It was small wonder that during his senior college year Crawford took the Civil Service examination for the job of analyst in the Bureau of Chemistry. To his great disappointment—he flunked!

After graduation, Crawford worked for the Agricultural Experiment station for a year, teaching part time. Then he went to Washington State College where he taught and worked part time on state food and drug law enforcement problems, mainly analytical work. At this stage, the elder Crawford became ill and the son returned home to spend four years at farming.

January 3, 1915, Charles married Relia Brewer, of Illinois, who had attended the Oklahoma College for Women. The couple went to live in Stillwater, where Charles resumed his studies for a master's degree. With that behind him, the persistent young chemist again took the Civil Service examination for analyst, and this time he passed. Appointment did not come immediately, however, and Crawford worked for a year as a chemist for an oil refining company at Cushing, Oklahoma.

In 1917 Crawford finally got the job on which he had set his heart. Appointed as an assistant chemist of the Bureau of Chemistry, he was assigned to the New Orleans station. Most of his work there was routine and prosaic — the lot of analysts generally, but there was one episode in particular which got attention from the "brass" in Washington headquarters.

Two inspectors out of FDA's New York City office inspect a bakery during the period of Commissioner Crawford's tenure. Only much later in the early 1970s was the title changed from "inspector" to "investigator."

A sample of product labeled as Glycerine, USP was found on analysis to be about 80 percent invert sugar syrup. Checking the source in company with an inspector, Crawford found a small but elaborate factory set-up, with an obviously German-born individual in charge. This man claimed that he had succeeded in manufacturing glycerine from sugar. Both commodities were then sky-high and under World War I controls. A number of prominent New Orleanians had invested substantially in the alleged process. Because of the likelihood that the promoter was an enemy alien, the FBI was called into the case. Crawford supervised a demonstration of the process which exposed its phony character, whereupon the owner was jailed on charges of destroying scarce materials.

Changes in the Bureau's administrative organization opened the way for Crawford's transfer to Washington. At a meeting in Chicago he became acquainted with Walter G. Campbell, the new Assistant Chief. Campbell, who later became Chief, had seen the need for channeling all policy statements through the chief's office, so as to avoid conflicting interpretations by the various technical and operating divisions. This necessitated additional people at headquarters to handle correspondence and other duties. Rather than call in a staff of experts who might have acquired bias in their separate fields, Campbell decided to bring in qualified young men who could be trained in administrative work. On a scouting trip he again met Crawford in New Orleans. Crawford attached no extraordinary significance to the meeting, but shortly thereafter he was invited to Washington for a trial month of duty as a member of the headquarters staff. He did not know it, but he had left his first love, the laboratory, for good.

From then on, Crawford's progress was a direct rise toward the top. In due course he handled every kind of administrative problem, but circumstances made him a specialist in a field usually reserved to the legal profession.

Time and experience had shown that the original Pure Food and Drug Act of 1906, drafted largely by Dr. Wiley, had become inadequate for protecting the American public from dishonest and dangerous products. Court interpretations restricted its application in some situations; ways had been devised to circumvent the intent of Congress. In a generation of industrial progress, legitimate products and practices had changed greatly. As early as 1916 proposals were being drafted to strengthen this inadequate statute, but World War I intervened, and nothing was done. (2)

Inaction, of course, did not solve the problems. Finally, in the first Franklin Roosevelt administration, a new food and drug law became a priority item of the "New Deal" agenda. With other FDA officials Crawford helped the legislative draftsmen of the USDA and Congress in writing the first version of the new law. Immediately a storm of opposition broke out. It became evident that the development of an acceptable law and its passage would take time—possibly years.

Crawford was then given the assignment of handling all matters connected with the pending legislation. As it turned out, he had special talents for this work, winning the respect of lawyers who were experts in legal draftsmanship. His work in advising members of Congress on the intricacies of food and drug problems and the need for new protective features in the law was acknowledged by the "insiders" as an outstanding contribution to the public welfare which could never be fully appreciated. One reason, of course, is that so much of it was on a confidential basis. But there is a clue in the record—the tribute written by Crawford himself to Senator Virgil M. Chapman, who died March 8, 1951:

> Because of Virgil Chapman's great modesty, he did not gain the public recognition he deserved for his vitally important role in enacting the Food, Drug, and Cosmetic Act of 1938. He often told me he felt that this was his greatest contribution during his long career in Congress.
>
> When the bill which eventually became our present law was passed by the Senate in 1935 and went to the House, it was referred to a subcommittee of which Mr. Chapman was chairman. It was loaded with emasculating amendments forced into it by the patent medicine industry over the heroic opposition of Senator Royal S. Copeland, its sponsor in the upper house. The industry group was elated in the belief that they had such command of the situation that they could either compel the enactment of a new law that would give less consumer protection than the Food and Drugs Act of 1906, or at least prevent new legislation of any kind.
>
> But they had not reckoned on facing a man like Chapman. Between sessions of his committee he worked far into the nights reading publications and records and talking with persons familiar with the problems. Industry witnesses before the committee found themselves in trouble when they tried to distort facts or gloss over those unfavorable to their objectives. Always courteous and good-humored, his cross-questioning was as keen and skillfully directed as a surgeon's scalpel. It laid bare for all to see the greed and disregard for human welfare that underlay so much of the opposition to a better law.
>
> This hearing turned the tide. As the facts Chapman had exposed became more generally known, real progress set in. He continued his active support until the measure was finally passed. He was responsible for including a highly important provision during the last committee meeting before the bill went to the floor for passage. This was section 301 (k), which asserts control over articles received from interstate sources until sale to the ultimate consumer. Chapman later aided in writing the Miller Amendment of 1948 which broadened and consolidated this control.
>
> Virgil Chapman's place is secure as a distinguished legislator, statesman, and humanitarian. The public generally, and particularly we who enforce food and drug legislation, owe him an everlasting debt. We, who were privileged to know him and work with him, have lost a dearly beloved friend. (3)

There is no doubt that Charles Crawford was the leader among those "persons familar with the problems" who worked far into the nights in collaboration with Senator Chapman.

In 1939 the basic conflict of interest between FDA, representing consumers, and USDA, representing producers, was resolved by creation of the Federal Security Agency, with FDA as one of its major constituents. Under President Roosevelt's reorganization plan, Walter Campbell, last "Chief" of the Bureau of Chemistry, became "Commissioner of Food and Drugs." In May, 1944, Dr. Paul B. Dunbar succeeded Campbell and in December, 1945, Charles Crawford was made Deputy Commissioner. When Dr. Dunbar retired after 40 years of service, in June 1951, Federal Security Administrator Oscar Ewing followed the FDA career tradition and named Crawford as Commissioner.

CRAWFORD
II

Sworn in as FDA Commissioner in 1951, Crawford calls for expanded FDA resources and a campaign of public education against rampant diet quackery. A National Grain Sanitation Program mobilizes government agencies, growers, and processors in the largest planned food sanitation program in FDA history. Wheat market economics and politics delay the clean-up, but only temporarily.

Although it was Paul Dunbar who recruited me to be FDA's information chief, there is no doubt that Charles Crawford and George Larrick were consulted and concurred in the action. As a food and drug industry journalist for some twenty years I had come to know this triumvirate of professionals who succeeded Walter Campbell as Commissioners of Food and Drugs. All three shared a fundamental belief that the majority of industry was law-abiding, being convinced that this was good business for their companies as well as their customers. And all three believed that accurate information was the key to problem solving. My employment by FDA meant that the agency was planning to step up its educational activities to promote compliance and consumer protection. The FDA staff was informed of this in an announcement from Commissioner Dunbar—accounting, I believe, for the warm welcome and cooperation that I received from all hands. (1)

The new job gave me more of an insider's view of the institution and activities I had been covering since 1931. I had worked under Dunbar only a few months when Crawford replaced him. It was a completely smooth transition. No commissioner could have been more innovative and deliberate than Crawford in his use of education and information to reach important objectives. This was illustrated by the statement and press release issued on the occasion of his swearing in as Commissioner. (2) Crawford and I saw this as an opportunity to say things that needed to be said. The ceremony took place in the office of Federal Security Administrator Oscar R. Ewing, who said: "Mr. Crawford's appointment recognizes not only his outstanding qualifications, but is in line with the distinguished tradition of the Food and Drug Administration as one of the career services of the Federal Government. Food and drug law enforcement is a highly specialized activity. Today more than ever the interest of the American consumer requires that this work be kept in experienced hands."

After the oath taking Crawford made a statement contrasting the resources of the Agency with its responsibilities: "The purity and truthful labeling of foods, drugs, and cosmetics, for which the public now spends more than $50 billion each year, or one fourth of the total consumer income, is in the hands of a small organization. FDA has about 250 inspectors in the field, and a total of just over 1,000 for its scientific and enforcement work."

Already Charles Crawford was thinking about how to break out of FDA's fiscal rut, with Congress appropriating less than $5 million a year. Later he would find a way — the first Citizen's Advisory Committee on the Food and Drug Administration.

Turning to current affairs, Commissioner Crawford called "the false teachings of diet quacks the FDA's most troublesome current problem." Consumers were being ripped off by armies of door-to-door sales agents for irrational mixtures of vitamins, minerals, and dozens of unrecognized ingredients. Posing as "nutrition experts," much of their sales ammunition consisted of attacks on the nutritional adequacy of the American food supply and the policies of the Food and Drug Administration. Hitting diet quackery, Crawford said that "a vigorous campaign of spreading the truth, as well as law enforcement, is needed." The truth, he said, is that "America, far from suffering malnutrition, has the most abundant and nutritious food supply in the world and is enjoying the best health of any nation in history." He pointed out that most of the nutritional nostrums then being promoted by food quacks did not have any false claims on their labels, often making legal action extremely difficult.

There was an immediate response to Crawford's call for a campaign of spreading the truth about nutritional quackery. The national magazines, particularly, assigned investigative reporters and published hard-hitting articles debunking the health food frauds. And on the enforcement side, FDA's investigators and lawyers won case after case against varieties of misbranding previously thought to be immune from legal action.

Charles Wallace Crawford, Commissioner of the Food and Drug Administration, was one of the chief drafters of the 1938 Food, Drug, and Cosmetic Act.

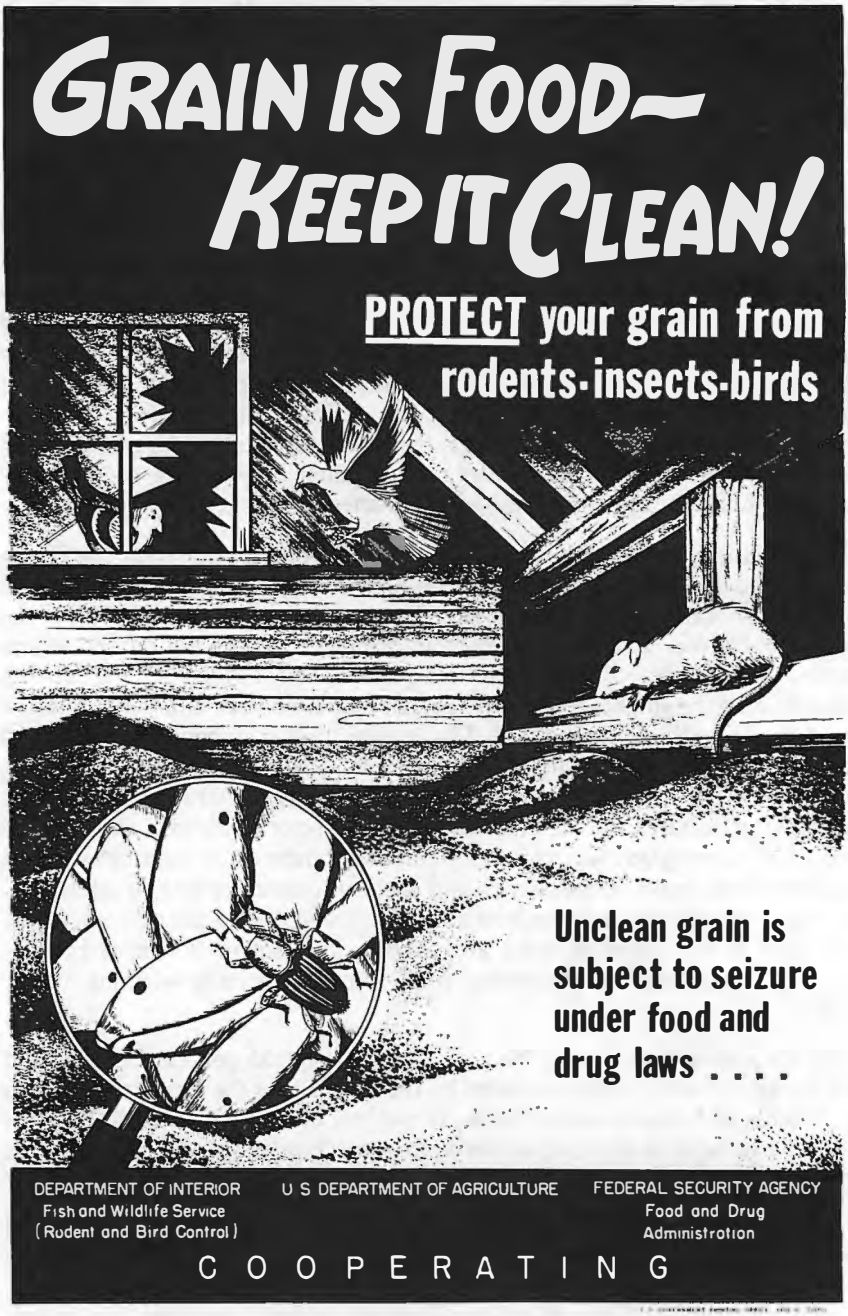
One of the most serious weaknesses of the 1906 Food and Drugs Act was its lack of any enforceable sanctions against products made, shipped, or stored under insanitary conditions. Section 402(a) of the 1938 Act gave FDA the power to enforce sanitation through inspections and court action. Supported by industry, this provision made food establishment sanitation a high priority objective, particularly where health was involved, as with seafoods and dairy products.

Efforts to keep flour and bakery products free from filth began with actions against stored lots of flour, then against insanitary conditions found by FDA inspections in flour mills and bakeries. Industry leaders and their trade associations joined effectively in the clean-up programs, and substantial improvements brought the majority of establishments into satisfactory condition. But a 12-month study of the sources of contamination showed that filth-free flour and baked goods required protection of the basic material—food grain—from insect, rodent, and bird contamination. Based on its previous successful experience promoting sanitation with industry cooperation backed by enforcement, the FDA launched the largest planned compliance program in its history, a campaign to promote the sanitary handling and storage of milling wheat, America's largest food crop.

"The National Grain Sanitation Program" (its official title) was the FDA's major enforcement activity when I joined the agency and when Charles Crawford became its Commissioner. Through this interagency project the Government was providing detailed information on the conditions which needed to be corrected, the means of correction, and the legal measures being taken to stop the shipment of filthy, rodent contaminated, and insect infested grain to the nation's flour mills. The information was being disseminated to elevator operators and farmers by the grain trade itself, and by cooperating government agencies, particularly the Extension Service of the U.S. Department of Agriculture, and the predator control director of the Fish and Wildlife Service. The program was being explained at hundreds of meetings of farm organizations, grain cooperatives, and elevator operators by FDA speakers, and was the subject of hundreds of articles in the agricultural and rural press, especially in the grain growing areas. Using the slogan "Grain is Food—Keep it Clean," all this educational publicity was virtually without cost to FDA.

FDA's preliminary survey had shown that over 35 percent of all wheat was contaminated. It was estimated by the USDA that the loss of grain eaten by rodents and insects amounted to 10 percent of the total crop. If this loss could be reduced only one half through protective action it would save as much as $100 million a year in wheat alone!

A particularly difficult part of the grain sanitation problem was internal insect infestation. FDA scientists had done a monumental study correlating data from wheat and flour samples to establish reasonable "action levels" for enforcement. (3) Although originally scheduled for "long range" consideration, the prospect of enforcement action against weevil infested wheat was



One of the educational posters used in the interagency program.

having an impact on the wheat market. It was this, rather than rodent contamination, that particularly caused the Senate Committee on Agriculture to challenge the continuation of the grain sanitation program as scheduled by the FDA. Hearings were held March 10-11, 1953. Six questions were on the hearing agenda, all involving one major economic and political issue — the losses which the USDA's Commodity Credit Corporation (CCC) might incur on loans to farmers on wheat "from which weevils have not yet emerged in substantial numbers." Would the CCC have to revise its grain standards? What percent of wheat did the FDA estimate would be subject to seizure? Were there practical methods for determining the degree of insect infestation? Answers to such questions were needed by the Committee in planning price support programs and quotas. As the hearing developed, however, it dealt broadly with the entire history of FDA's clean food program. (4)

Vermont Senator George Aiken, chairman of the Committee, presided, but Senators Milton Young of North Dakota and Andrew Schoeppel of Kansas led the questioning. Commissioner Crawford avoided attempting to present the FDA position, requesting permission for this to be done by Deputy Commissioner George Larrick, "because of his intimate knowledge" of the program which he had supervised from its beginning. Larrick's presentation and his skilled answers to dozens of technical trade questions amply justified the "intimate knowledge" attributed by Commissioner Crawford. But the same questions also raised another — whether enforcement of the Grain Sanitation Program was moving too fast for compliance to catch up with it. The trade, at all levels, was in favor of clean grain, but not yet adjusted to all that this involved.

Association representatives related experiences of members illustrating the difficulties and confusion caused when U.S. marshals began court-ordered seizures of carloads of wheat — a new experience to shippers unfamiliar with such events. Handling grain as a food rather than merely a bulk commodity was a new way of life. Notwithstanding the massive educational program, the changes needed in such things as storage facilities, testing, and grading, had not yet become general and routine.

What should be done? The American Farm Bureau Federation made it specific: "The proposed regulations of the Food and Drug Administration dealing with insect infestation in grain should be postponed for at least one year. We believe that, if this program is put into effect as scheduled on July 1, 1953, it will greatly disrupt the movement of grain and will cause grain dealers to adjust their prices to compensate for possible condemned grain under this regulation." The Farm Bureau recommended that, during the period of postponement, the FDA and USDA should "develop simple tests" for farmers and grain dealers to determine the extent of damage by insects and thereby avoid condemnation of grain after it leaves the farm or local grain elevator.

They also recommended continuation of an "intensive educational program" by the land grant colleges and the Extension Service, and promised

continued cooperation by the Federation. Concluding, the letter said, "Due to the progress made during recent years, we believe this situation can be corrected. All information we have indicates that this problem is on the decrease rather than on the increase . . . With large stocks of grain that will be turned over to Commodity Credit about May 1, 1953, we believe that to put into effect the FDA program would add an additional burden under the existing loan program."

Some six weeks after the Senate hearing the Secretaries of Agriculture and the newly created Department of Health, Education and Welfare issued a joint release announcing their intention to start over with "a plan to promote improvement in the harvesting, transportation, storage, and processing of grain," to be developed with representatives of the grain growers, handlers, and processors. Buried in the fifth paragraph was the news that the Departments had agreed to "set aside temporarily certain enforcement aspects of the program," pending further study and a report by a committee representing land grant colleges in the wheat states, the grain industry, and the government agencies. Essentially the departments had adopted the recommendations of the Farm Bureau Federation.

The "certain enforcement actions" to be set aside temporarily had been spelled out earlier (April 3, 1953) in a Memorandum of Understanding signed by Agriculture Secretary Ezra Benson and Oveta Culp Hobby, then serving as Federal Security Administrator. Under this agreement FDA was to continue enforcement action against insanitary storage conditions and against wheat contaminated by rodents, but would not initiate action against wheat held by the Commodity Credit Corporation. (5)

It was at this point that the clean grain program, previously confined to agricultural and grain trade media, finally became news to the general public. The story broke May 18, 1953, in Drew Pearson's *Washington Merry-Go-Round:*

> WASHINGTON — One of the most amazing backtracks of the Eisenhower Administration took place very quietly a few days ago when it reversed a program for keeping rat droppings and weevil waste out of wheat and other grain sold to the American housewife. The rat cleanup program had begun last fall, Oct. 15, 1952, under the Democrats, and on April 6 was widened by the Food and Drug Administration under the Republicans. It was then extended to weevil infested grain. However, one of the first official acts of Mrs. Oveta Culp Hobby, after she became a full-fledged member of the Eisenhower cabinet was to suspend this grain cleanup program by an order issued May 1. The Food and Drug Administration is under her. Simultaneously Secretary of Agriculture Benson, who was cooperating in the grain cleanup, also dropped the program.
>
> The sudden reversal came after 45 carloads of wheat had been seized for having an excess of rat droppings . . . The Government's grain cleanup actually got under way with the encouragement of many millers and all the bakers. With their cooperation the FDA last fall set standards

> whereby grain containing more than one rat dropping per pint of grain was condemned for human consumption but classified as O.K. for animal consumption. Likewise grain containing more than 20 surface weevils or other insects, dead or alive, per 1,000 grams of wheat would be declared unfit for human consumption, but could be used for animal food.

According to Pearson's "inside story" grain trade pressure on the Agriculture Department and the White House even included a demand that Commissioner Crawford and his Deputy George Larrick and two associates, John L. Harvey and Malcolm R. Stephens, be fired for their refusal in 1952 to back down on enforcement actions.

Inspection of terminal and country elevators for sanitation continued through fiscal year 1953 and brought many improvements on storage facilities. Meanwhile the two departments proceeded as planned to establish their study committee representing the government agencies, agricultural colleges, grain producers and dealers, millers, bakers, and sanitarians. Further work on sampling cars of wheat was stopped pending the report of the committee, but the sanitation inspections and educational program continued. Inspection time formerly given to the baking and confectionery industries was reduced because of continued improvement resulting from industry sponsored sanitation programs. (6)

On January 5, 1955, the Secretary of HEW issued a 5-line press release announcing that the Food and Drug Administration had been "directed to start immediate sampling of cars of wheat and to institute legal action under the federal pure food laws against lots of wheat contaminated by rodents or damaged by insects." Based on the grain committee report, Secretary Oveta Culp Hobby had "concluded, after discussion with the Secretary of Agriculture, that the responsibility for enforcement of the Food, Drug, and Cosmetic Act could not adequately be discharged without an enforcement program against rodent contaminated and insect-infested grain." (7)

True, the action levels for seizure were raised—wheat containing more than two rodent pellets per pint or two percent or more of weevil-damaged kernels—but the Department of Agriculture announced that wheat not meeting the requirements would not be accepted under the Government's loan program and if found in possession of the Government would be diverted from human food channels. Twelve carloads were seized between January 1 and June 30, and 15 carloads voluntarily diverted from human use.

The clean grain program was good economics and good business for all concerned. Better knowledge on how to keep grain clean was reflected in the fact that fewer carload lots were seized in the entire fiscal year 1956 than in the 6 months of the previous fiscal year when the reactivated program went into effect. (8) The losses from insect and rodent depredations were enormous. Ground up bugs and rodent feces and urine in cereal foods were intolerable. The key to success of the program was protection by good storage facilities. Sam Fine, director of FDA's Kansas City District, tells a vivid story on how it happened (names have been omitted):

We had the heaviest concentration of grain elevators, terminal elevators, and country elevators that you'd find any place in America because the territory at that time included Oklahoma, Kansas, Nebraska, and northwestern Missouri. I invited myself to make speeches to the grain and feed dealers associations of the various states. They all had annual meetings, and in no uncertain terms I told them that the Food and Drug Administration was going to clean up the wheat industry. I was about as popular as the plague as the result of this. I can remember a meeting in Omaha where there were 800 farmers and elevator operators there and I underwent the most hostile questioning I'd ever undergone before or since in my career from those people. But, I implemented the program.

I can remember making a seizure of one car of wheat in Kansas City, and I can't think of the man's name right now. He had worked closely with George Larrick during the investigational phases of the program. This man got me out of bed one night at about one o'clock in the morning and I found he got Larrick out of bed at two o'clock in the morning in Washington to talk about that seizure. He didn't want it to take place. The seizure took place. Neither Larrick nor I would back down. I got the first injunction against a country elevator in the country. This was against a small elevator in eastern Kansas. I got the first massive seizures and the first prosecution against a small country elevator in south eastern Nebraska. All of this created a great deal of interest in the grain industry. They decided that the Food and Drug Administration did mean business on this.

About a year after that one of our inspectors inspected one of _____ 's grain elevators in southwestern Nebraska, and it was really an atrocious old elevator of the old wood frame metal clad variety — just impossible to maintain sanitation in. I read the report, and the inspector had taken some beautiful photographs and I phoned _____ . I said, "_____ , how would it look if I enjoined you for operating a filthy elevator," and I named the town in Nebraska. He said, "I'll come see you." He came over to see me and I showed him the photographs. He looked at me and said, "I will bulldoze it into the ground if you will not enjoin me." So we made a deal. He bulldozed it into the ground. (9)

The reaction of this grain industry leader was not unusual. I recall hearing that more than half of the total grain storage capacity of the United States was replaced during the few years of the FDA sanitation program. Today's concrete and metal construction is virtually rodent-proof. Heat sensors in the bins tell elevator operators when the grain needs to be turned or fumigated. Perfection has not been achieved; vigilance is still needed, but conditions now are infinitely better than in the '40s and '50s.

ADDENDUM

After publication of the first two installments of the articles on Crawford by Wallace Janssen in *The AFDO Journal,* the following letter was received from Eugene Spivak. Mr. Spivak joined FDA in 1948 in Denver District and was the Director of Investigations for Detroit District from 1970 until his retirement in 1987. — *Editor*

November 5, 1990

Dear Sir:

I thoroughly enjoyed Wallace Janssen's article, "Crawford" (Part II) in the July 1990 issue of *The AFDO Journal.* This paper preserved and gave recognition to a colorful, innovative era identified as *The National Grain Sanitation Program* and the one-year *Investigational Program* that preceded it. It was a thrill to read this recounting of those times, and the Sam Fine anecdote at the end reflects his honesty and dedication. He was one of FDA's most principled and fighting regulatory officials.

I worked full time in the Investigational Program and spent considerable time in the implementation of the National Grain Sanitation Program. From my perspective, J. Frank Nicholson, Division of Microbiology, was the force and the science behind the program. It was he who examined the data from the Investigational Program and established the wheat/flour ratios. For example, for every weevil exit hole in a kernel of wheat, there was an additional 5 kernels in which the weevil had not yet emerged. Thus, in a 100 gm wheat sample with 3 exit holes, there are 15 kernels with weevils at some stage of their development. This level of wheat contamination yields 50 weevil fragments per 100 gm of straight flour — the level of fragments considered adulterated and subject to seizure. This initial proposal was met with howls from the trade. They were undoubtedly correct when they proclaimed that seizures of 3-exit hole wheat would be disruptive to grain trading.

Nicholson's evaluation disclosed that mouse pellets in wheat were significantly more insidious than rat pellets. Mouse pellets are of the same approximate dimension and specific gravity as wheat kernels, and, therefore, there is no effective means for separation. There are embedded hairs in the pellets because mice continually lick their fur. Ground up pellets release hairs to the flour. Since there is no such thing as cleaned wheat (just as there is no such thing as cleaned milk for cheese production), mice must be excluded from wheat storage areas — "Wheat is food, keep it clean."

Nicholson died a few years after the program got under way and I'm not sure that the chroniclers of the history of those times will credit him for his basic contributions to the program.

Further to your second paragraph on [page 9] summarizing the situation leading up to The National Grain Sanitation Program, it could be noted that

the FDA's emphasis on bakery inspections resulted in many prosecutions with concurrent media exposure, particularly in the St. Louis area. Surprisingly, FDA sampling found rodent and insect filth in products from *clean* bakeries. Samples of the flour they used revealed the insect and rodent filth. FDA then moved its emphasis to flour mills, and a major clean-up followed punitive actions. Again, we were startled to find significant insect and rodent filth in flour from clean mills. At this point, FDA had no real knowledge of the relationship of wheat to adulterated flour, and thus the Investigational Program was born.

Your paper was certainly stimulating; it awakened many memories. Thanks!

Sincerely,

Eugene Spivak
Sonoma, California

CRAWFORD
III

War in Korea brings a nuclear threat and a need for civil defense preparations against possible radioactive contamination . . . A natural disaster, the Kansas City flood of July 1951, was real. Jurisdictional lines disappear as local, state, federal, and industrial organizations work together on the clean-up . . . A stunning challenge to Commissioner Crawford's leadership came Dec. 8, 1952, when the Supreme Court struck down FDA's factory inspection powers as unconstitutional.

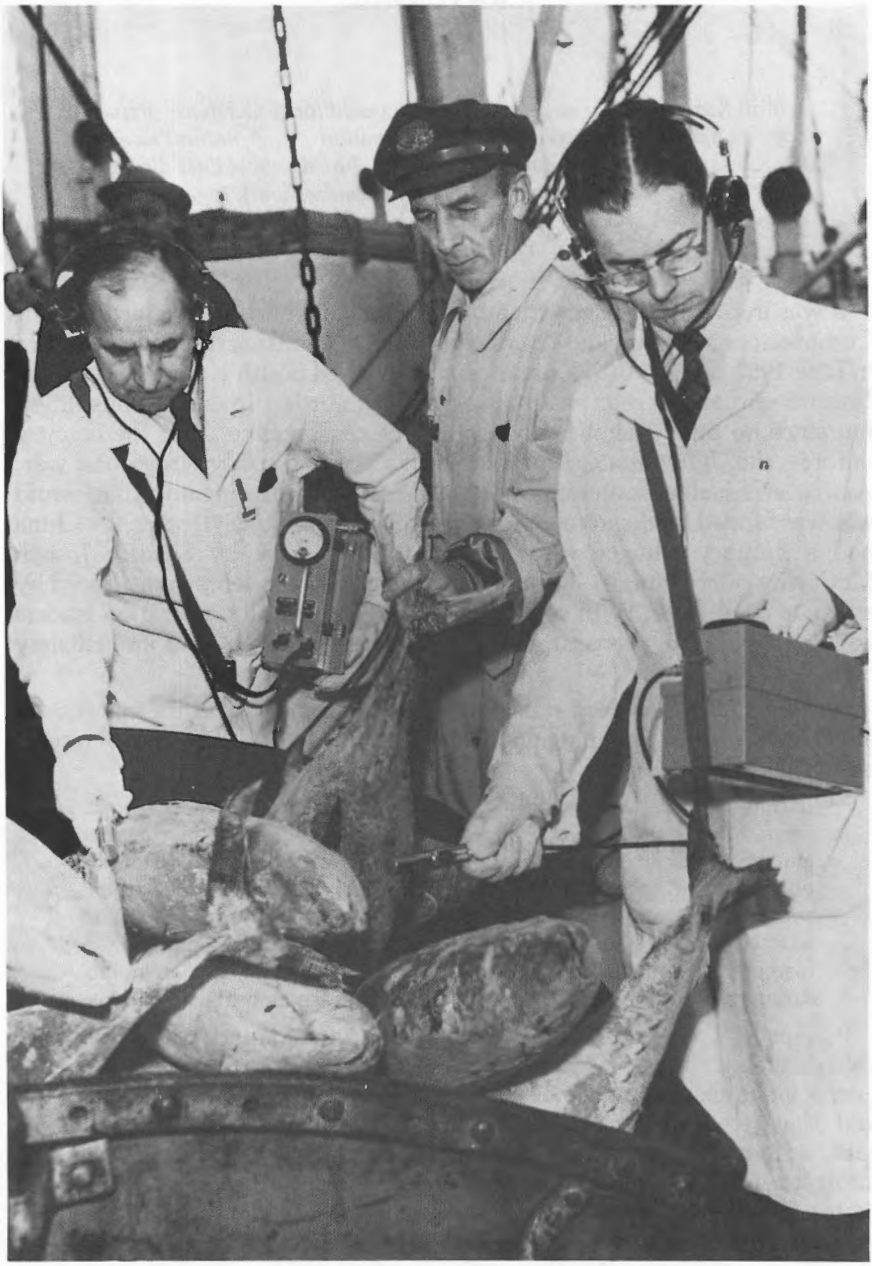
It was in "a world beset with anxiety" (1) that Charles Crawford became Commissioner of Food and Drugs. Profound pessimism gripped the country in June 1950 when North Korean troops invaded South Korea. The United Nations sent an international police force with orders to end the hostilities, but since no other member nation had the resources to enter the country in force, the United States found itself involved in a costly, unpopular war. American casualties soon topped 100,000. Fear of escalation into a third world war was fanned by the involvement of Chinese communist troops, for China had a military alliance with the U.S.S.R. Charges by Senator Joseph McCarthy of communist infiltration in the U.S. were being investigated by a Senate committee. With such a crisis before them, administration leaders adopted a policy of preparation for nuclear war, and FDA was immediately involved.

Commissioner Crawford was particularly concerned about the inadequacy of FDA's resources. Summing up the situation in the fiscal 1951 annual report, he wrote:

> In times of national stress normal regulatory activities must be expanded; preparation must be made for operations that will meet any disaster emergency. In event of enemy attack on this country it would be the obligation of federal, state, and local food and drug enforcement personnel to impound all dangerously contaminated foods, drugs, and cosmetics, and to supervise storage or destruction of such material. A further task would be prompt supervision of the resumption of manufacturing operations to assure adequate controls under abnormal conditions.

By April 24, 1951, the FDA had completed its presentation of a one week civil defense training program in each of its 16 field districts. Four teams of instructors each visited four districts. About 400 federal, state and local food and drug personnel received the training. The general goal was to acquaint each administrative officer, chemist and inspector with the technical information needed in case of warfare directed against the continental United States. Instruction was given in atomic, biological, and chemical warfare, as well as the elementary nuclear physics for understanding the phenomena of atomic explosions. (2)

In 1952 equipment purchases were started to provide each FDA district with Geiger counters and other instruments and to equip a small research lab in the Division of Pharmacology in Washington. In 1953, at the Nevada



Checking frozen Japanese tuna for radioactivity in 1954. Left to right: Albert A. Wausat, FDA's resident inspector in Long Beach, California; a U.S. Customs officer assisting in the inspection; and Dale C. Miller from FDA's Hazardous Substances Regulation Branch.

proving ground, FDA scientists experimented to determine the effect of an atomic explosion on drugs. It was found that where packages survived intact there was little adverse effect on their contents, except for initial radioactivity that might affect immediate use, and a reduction in the potency of insulin and vitamin B12. In 1955, elaborate tests of the effects of radioactive fallout on packaged foods exposed under market conditions were conducted in cooperation with the Federal Civil Defense Administration, the Department of Agriculture, and national food trade associations. About 60 varieties of food staples in representative types of packaging were exposed at varying distances from the atomic blast. From this came recommendations on decontamination or destruction. (3)

The first large scale radiological examinations of food were made in 1954 when FDA inspectors began round-the-clock checking of frozen tuna from Pacific waters exposed to fallout from atom bomb tests. More than 35 million pounds of the fish were checked with Geiger counters. None was found with more than normal background radioactivity. (4)

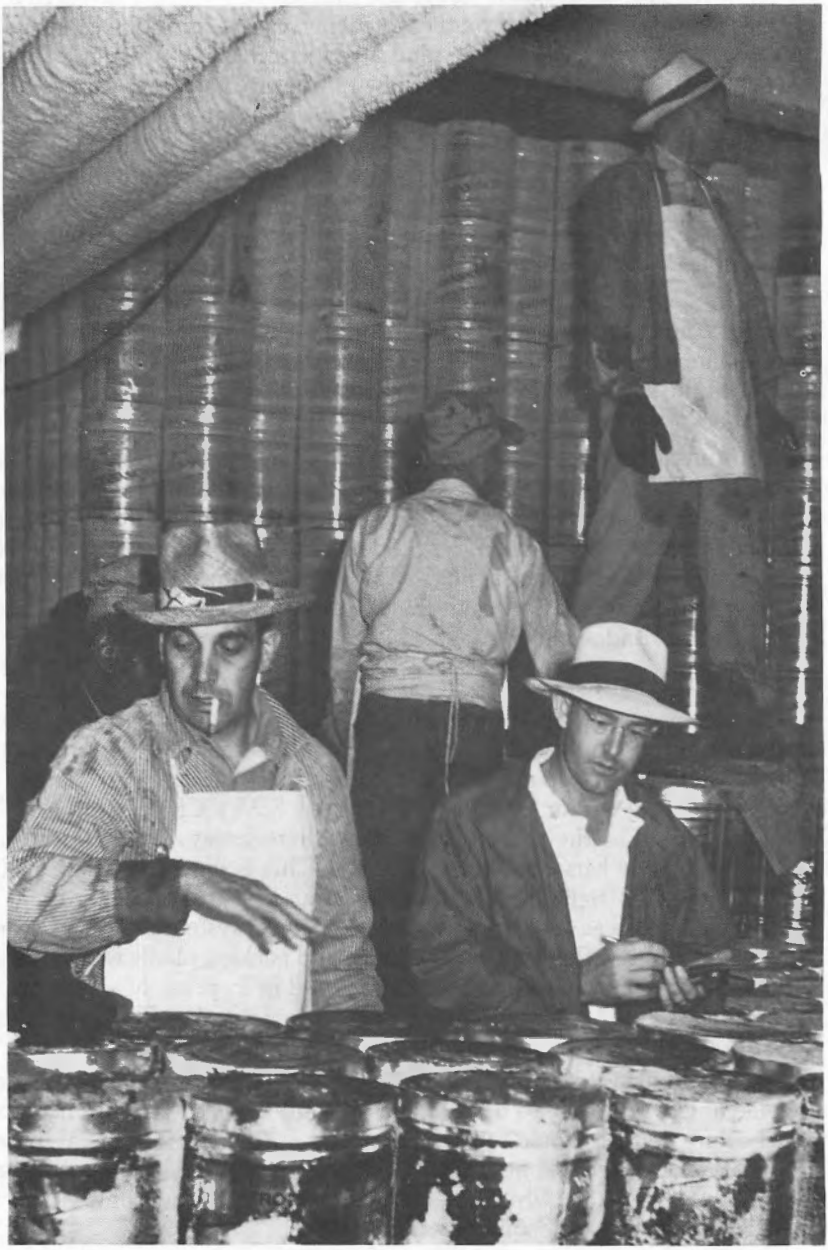
Determining the extent of radioactive contamination of foods, drugs, and cosmetics, and workable procedures for decontamination, were major concerns of FDA scientists through the 1950s and 1960s. Monitoring of fallout was stepped up in 1961 when the Soviets resumed open testing of nuclear weapons. From this came the FDA's "total diet studies," which now detect and measure many substances in the U.S. food supply, including vitamins and pesticide residues. (5)

A disaster that was real

Civil defense activities were a rehearsal for manmade disaster; a natural disaster, the Kansas City flood of July 1951, was real. "If the powers that be had listened to Walter Tyson, the Kansas City lab helper, it might not have happened," wrote Gordon Wood, then FDA's Chief Inspector. "He (Tyson) pointed to the place on the map where Jersey Creek flows under the levee into the Missouri River and said 'This is where the dike will go out.' Walter was right and 30 minutes after the break the Kansas City industrial district was deep under water." (6) A vast system of railroad yards, storage warehouses, flour mills, stockyards and packing plants was inundated with water and mud. Similar damage occurred in Topeka, Manhattan, and other cities along the Kansas River and its tributaries. For FDA, the Kansas City flood still ranks at the top of its many disaster experiences.

"All of our inspectors are working long hours under blistering heat among unbelievable wreckage and destruction, without lights or water. Unbearable stenches are getting worse by the hour. The mire underfoot is caking and drying to dust, which will be worse. Wherever they are, their white coveralls, as long as they stay white, stand out in conspicuous contrast to the background of mud and oil coated debris . . . ."

Inspector Scanlon was handling calls for information and advice on the Kansas City, Kansas side. The phone rang and a tearful and pleading feminine voice said, "We have just gotten into our flooded home. Will you *please* have this dead hog removed from my bedroom!" (7)



A footnote on the flood: an inspector checks frozen eggs which had been submerged in a cold storage plant. Operators of this plant had brought in dry ice by boat, and, by scattering it over the top layers, managed to save some of the eggs that had remained above water.

The clean-up was probably the most extensive cooperative effort ever handled by combined local, state, federal, and industry personnel working together. As the *Food and Drug Review* reported: "The arrangements were not planned ahead of time, or in Washington, but were made on the spot by the enforcement officials closest to the problem. City, county, and state lines were largely disregarded, as well as questions of jurisdiction. Whichever agency had the authority used it and whichever inspectors were available were utilized by the officials designated to run the show in any given area."

Evan Wright, director of the Kansas Food and Drug Division, coordinated the state and local forces. Because the local agencies had the necessary embargo authority, which federal law does not provide, the FDA inspectors were assigned to assist them and were given authority to issue embargoes and releases signed by the local officials. Meetings with trade organizations and representatives of the grain trade, livestock shippers, the building industry, the railroads, and others, resulted in understandings that facilitated the disposal of unfit material, the clean up of premises, and prevention of improper disposal of contaminated products. (8)

Inspection authority lost—and regained

A stunning challenge to Commissioner Crawford's leadership came on December 8, 1952, when the Supreme Court struck down the FDA's factory inspection powers. The 8-1 opinion by Justice Douglas held that language authorizing inspection "after first making request" and providing criminal penalties for refusing permission to inspect, was too contradictory and uncertain to stand as criminal law. The court said it "was not fair warning to the manager that if he fails to give permission he is a criminal." (9)

It fell to me to write the press release announcing Crawford's great decision that factory inspections would continue as usual, notwithstanding there was "no legal compulsion on a plant owner to admit inspectors if he does not want to." (10)

Confident that the majority of companies would want FDA inspectors to continue monitoring their industries, Mr. Crawford explained in detail the kinds of violations that require plant inspection for effective enforcement. Insanitary conditions in food establishments and lack of controls to ensure drug potency and correct labeling were cited as particular hazards to public health not detectable without plant inspection.

In the same release Crawford announced the FDA's intention to seek legislation for "a simple change in wording" to restore its inspection authority. Instead of "after first making request and obtaining permission" he proposed "after giving written notice . . ." He said the inspection section had proved workable and highly useful up to its invalidation and that he was anxious to avoid any change except to restore its validity. He also reported assurances from leading trade associations that they would support the proposed legislation. These included the American Drug Manufacturers Association, the American Pharmaceutical Manufacturers Association, the Toilet Goods Association and several food groups including the Grocery Manufacturers

of America. He said they should be "commended for their action in the interest of public health and welfare." (11)

The court's ruling came just prior to the inauguration of President Eisenhower in 1953. Recognizing a public health emergency, the President, in his first message to Congress, called for legislation restoring the FDA's inspection powers. A bill was promptly introduced.

If Crawford was disappointed in not getting just the "simple change in wording" that he suggested, he certainly was not surprised. Yet the bill finally worked out by the legislators, government officials, and industry lobbyists was an improvement. It spelled out such important details as the contents of the "written notice," the report by inspectors of any unsanitary conditions observed that was to be left with management, receipts for samples collected, and reports to management of the results of laboratory analysis of samples. But no one in FDA was prepared for what happened on the floor of the House when the final text was being debated. (12)

The language of the bill was strong, but the scope of inspection was drastically reduced by interpretation. Congressmen with drug trade constituents said it was "not intended" that inspections should include access to any records other than shipping records, or that inspectors be allowed to check formula cards (to learn what was in the products), or complaint files (to follow up on defective products), or personnel records (to see if technical employees were qualified) or prescription files (to detect illegal drug diversions).

This interpretation, or referral to the "Intent of Congress," was being construed as equivalent to actual law, and FDA was left with inspection authority that, in many situations, was far less than what it had prior to the Supreme Court's decision. It was a deflating and depressing experience for FDA, one that seemed to permeate the agency. What could be done? At this point it occurred to me that if Congressmen could interpret the law, so should FDA. I then wrote a press release announcing the steps taken to put the new inspection law into effect. It was immediately approved.

Inspectors were already giving written notices when presenting their credentials; they were leaving written reports on any insanitary conditions observed, and written receipts for samples taken in connection with an inspection. District offices were reporting to the management of food plants the results of analyses of samples for determining the presence of filth or decomposition. As to "records", the release then quoted Crawford as follows:

> Modern production and distribution are carried on to a large extent through the medium of written instructions and records. The legislative history indicates Congress did not intend to include prescription files, formula files, complaint files, and personnel files within the scope of required inspections. FDA interprets this to mean that inspection of these records will be on a voluntary basis.
>
> Accordingly, inspectors have been instructed to ask permission to see such records or files whenever there is any need or reason to examine them or to obtain information contained in them.

> The inspector may state reasons for asking to examine a particular record or file but will not otherwise press the owner, operator, or agent for permission to see it.
>
> The Food and Drug Administration will not attempt to predetermine what action may be appropriate in future situations which seem to necessitate inspection of records, but will endeavor to resolve these problems as they arise, keeping in mind the health, safety, and interest of consumers and the Congressional intent in the statute as a whole to protect public health.
>
> In 47 years since passage of the original pure food and drug law the great majority of the regulated industries have always cooperated fully in observing its provisions and by assisting in our work of enforcement. We have every reason to believe the regulated industries will continue this cooperation." (13)

Nine years later, in the 1962 Drug Amendments, Congress changed its mind about restricting FDA's access to prescription drug establishment records, but left in place its "intent" as to food, cosmetic and over-the-counter drug records.

The Chloramphenicol experience

Late in June 1952 the entire FDA field staff was put to work on a nationwide investigation. Reports had come in about serious blood disorders and fatalities associated with the antibiotic drug chloramphenicol. Nearly 400 inspectors, chemists, and physicians put in a hot week-end calling on doctors, hospitals, and clinics to gather information about these reactions.

Hundreds of medical case histories were collected. The extensive and complex information required evaluation by medical experts. To get such advice the FDA called on the Medical Sciences Division of the National Research Council (NRC), which appointed a committee of outstanding authorities on hematology and infectious diseases headed by Dr. John Holmes Dingle, Professor of Preventive Medicine at Western Reserve University, Cleveland, Ohio.

On August 14, 1952, the FDA issued a press release announcing its decision, based on the NRC committee's findings, to continue certifying the antibiotic for distribution under "revised labeling that will caution physicians explicitly against its indiscriminate use." Aimed specifically at the practice of many doctors in prescribing this potent drug for minor respiratory conditions, the release quoted Commissioner Crawford as follows: "The Administration has weighed the value of the drug against its capabilities for causing harm and has decided that it should continue to be available for careful use by the medical profession in those serious and sometimes fatal diseases in which its use is necessary." He said the decision was "similar in principle to one made every day by thousands of doctors throughout the country who weigh the need for a potent drug against the possibility of harm to the patient." (14)

Chloramphenicol, marketed in 1949 as Chloromycetin, is still regarded as life-saving in certain severe infections, such as typhoid and some drug-resistant staphylococcic infections. But the 1952 investigation showed it could

also cause aplastic anemia and related conditions in which the bone marrow loses its ability to manufacture both red and white cells of the blood. The new labeling recommended by the NRC committee said: "It is essential that adequate blood studies be made when prolonged or intermittent administration of this drug is required. Chloromyectin should not be used indiscriminately or for minor infections."

Though widely publicized by the drug manufacturer (Parke-Davis) and the American Medical Association, the FDA warnings against promiscuous use and the need for blood studies failed to have the desired effect. Eight years later, in 1960 - 1961, FDA was repeating the experience of 1952, and again calling on the NRC to advise what should be done to ensure the proper use of chloramphenicol. On January 26, 1961, Commissioner George P. Larrick announced the recommendation of another NRC panel that chloramphenicol "is a valuable drug that should remain on the market for use in treating serious infections both in hospitals and in the home." (15) It also called for changes in labeling to add emphasis to the warnings against use in minor infections and the need for adequate blood studies. Said the panel experts:

> Beyond this, there is need for the continuing education of the physician through the media of medical meetings and the medical literature. This, of course, is a responsibility of the leaders of medicine and not the Food and Drug Administration.
>
> More effective education of physicians in the proper use of drugs must be a continuing consideration. The role of the pharmaceutical companies in post-graduate medical education cannot be overestimated. Leaders in medicine must face this situation boldly and realistically if standards of practice are to be improved. The medical educators who constitute the editorial boards of a number of medical journals could exert some influence if they would improve the advertising that appears in their journals." (16)

The chloramphenicol experience did not go unnoticed by the writers of the 1962 Drug Amendments. It could have been the principal reason why Congress amended the Federal Food, Drug, and Cosmetic Act to require FDA regulation of medical journal advertising so that it would provide doctors with the kinds of information needed for drugs like chloramphenicol.

Food standards and consumer consultants

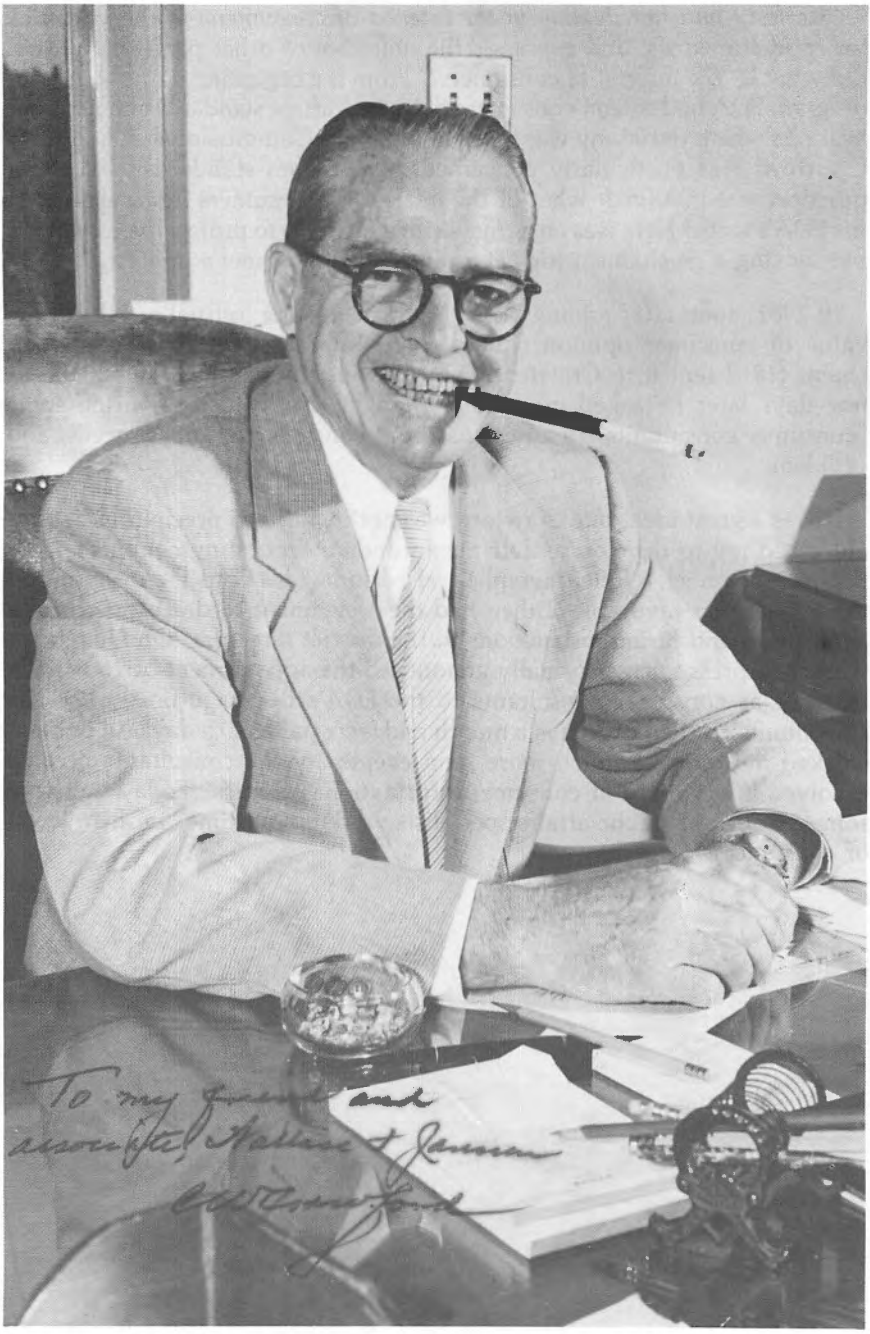
Statutory authorization to establish and enforce food standards was a major objective in the 1938 law. Support for this provision came from both consumer and industry advocates. The resulting language could well have been written by Crawford:

> Whenever in the judgment of the Secretary such action will promote honesty and fair dealing in the interest of consumers, he shall promulgate regulations fixing and establishing for any food, under its common or usual name so far as practicable, a reasonable definition and standard of identity, a reasonable standard of quality, and/or reasonable standards of fill of container . . . (17)

"Honesty and fair dealing in the interest of consumers" is the yardstick for food standards, and expresses the objective of other parts of the law. But what is "the interest of consumers?" From the beginning of the standards program FDA had sought consumer advice in drafting standards and at public hearings where testimony was taken. As Deputy Commissioner, Charles W. Crawford was particularly concerned. Aside from standards, a broader question was involved: what of the interest of consumers in all aspects of the FDA's work? Here was an agency with a mandate to protect the consumer, but lacking a mechanism for determining the consumer's interest.

In 1951, soon after joining FDA, I noticed a trade journal article on the value of consumer opinion studies to the management of a retail food chain. (18) I sent it to Crawford, who had just become Commissioner. A few days later he asked me what I thought of the idea of hiring some "consumer consultants" to advise us about consumer attitudes, needs, and problems.

It was a great idea, but Crawford was not inclined to precipitous action. He asked me to develop a staff memorandum requesting comment from topside personnel. While the replies raised some questions the reaction, on the whole, was favorable. I then had the assignment to draft the position description and hiring instructions to the district directors. On November 9, 1952, a press release formally announced the appointment of 16 women to serve as consumer consultants to the FDA's district offices. (19) The consultants worked two days a month and were paid $20 a day! All of them worked more, some much more, and eventually the consultants became involved in a variety of consumer information activities. Today there are some 33 of these public affairs specialists working full-time "in the interest of consumers."



A portrait of Commissioner Crawford taken on his last day in office.

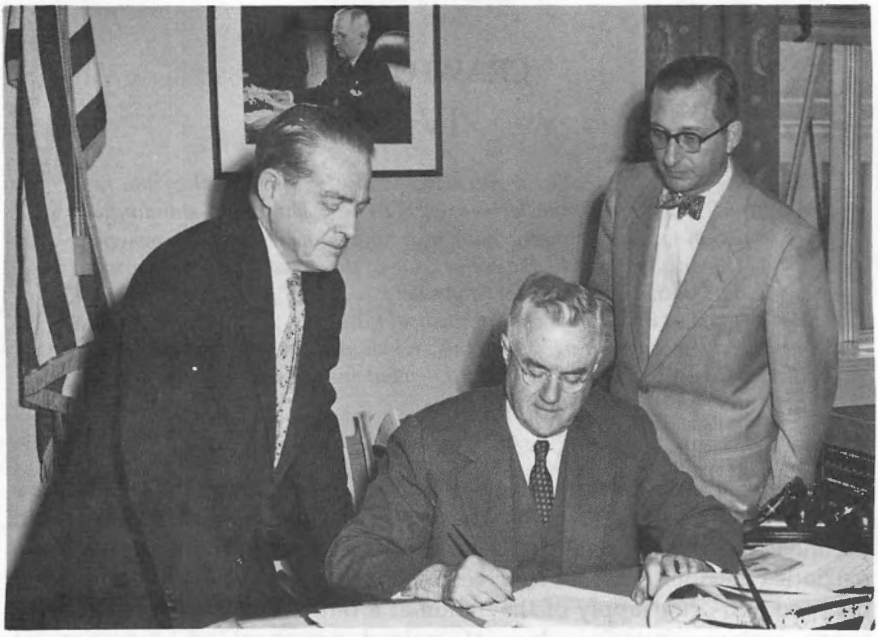
CRAWFORD
IV

Breaking loose from a fiscal rut: Crawford's 1953 proposal of the first Citizens Advisory Committee on the FDA . . . The bread standards—mass action to insure honesty and fair dealing in the interest of consumers . . . "Chemicals in food," the major issue of the bread standard hearings, brings innovative legislation for food safety . . . The "Rx Legend" becomes Federal law, a milestone event of medical history . . . Stretching the law with a new label warning: "Keep this and all medications out of the reach of children" . . . Charles Crawford—what his contemporaries thought of him.

World War II had major effects on FDA. Testing drugs for the military services took the time of many chemists, yet Commissioner Dunbar had declined to ask additional funds for FDA's war work, considering this a patriotic contribution owed to the country. Thus the agency had to protect the food and drug supply of the nation at a time when the industries were facing serious obstacles—loss of trained personnel, deterioration of irreplaceable equipment, shortages of material, and calls for increased production of essential items. Wartime economics were preventing adequate civilian consumer protection. FDA was lagging farther and farther behind compared with its constantly growing responsibilities.

Conscientious officials adopted attitudes and policies designed to produce maximum results from minimum funds, and the FDA was often praised as the taxpayers' biggest bargain in government. But this did not help in getting more money. In fact, the attitude of firm adherence to principle, necessary in effective law enforcement, on more than one occasion led to appropriation cuts. In 1953 the FDA's $5,648,000 budget was cut to $5,000,000 by the House Appropriations Committee. Its chairman, New York Congressman John Taber, was offended because of an FDA advisory opinion given to a constituent that canned "baby beets" could not legally be simulated by cutting large beets into little balls. FDA thought this would violate the standard for canned beets and result in consumer deception; the Congressman thought otherwise. As a result of this cut the FDA had to discharge some 100 of its employees—the first reduction in force in the history of the agency. (1)

Such actions by members of the legislative branch attracted little attention, for the FDA was inadequately covered by the general press and lacked public support. This absence of popular interest and concern was reflected in the personnel figures. With slight changes, the appropriations and manpower of the FDA were practically the same in 1953 as in 1938 when the new Federal Food, Drug, and Cosmetic Act, with its greatly enlarged responsibilities, became fully effective. In the meantime, expanding population and technology, a rising volume of products to be inspected, and increasing costs of administration kept consumer protection at a standstill.



Federal Security Administrator Oscar P. Ewing signing the 1952 bread standards, with FDA Commissioner Charles W. Crawford (left) and Bernard D. Levinson, the examiner who presided at the lengthy hearings, looking on.

On September 1, 1953, Commissioner Crawford attempted a new approach. To the Under Secretary of the Department of Health, Education, and Welfare, Nelson A. Rockefeller, he delivered a personally drafted memo outlining the inadequacy of FDA's resources. Mr. Crawford pointed out that FDA inspections of 96,000 manufacturing, processing, and warehousing establishments were being made only once in every twelve years. Yet 20 percent of the samples collected warranted court action. "Unquestionably, the work could be multiplied several fold without approaching the point of diminishing returns." The memo concluded:

> The present trend toward reduced manpower for this service is fraught with such danger to the welfare and health and even the lives of consumers that a thorough-going inquiry should be made into the obligations of the Food and Drug Administration and the sufficiency of the budgetary allowance for its work. Perhaps you and the Secretary may wish to consider the appointment of a committee of distinguished citizens to conduct such an inquiry and report its conclusions and recommendations to the Department. The committee could give an authoritative answer to the question whether present enforcement of the pure food and drug law is adequate to protect the public. (2)

The appointment of committees to investigate problems was a popular practice during the Eisenhower administration. It had not gone unnoticed by Commissioner Crawford. His suggestion was quickly adopted. A small appropriation was easily obtained for the proposed investigation, and the Citizens Advisory Committee on the Food and Drug Administration officially

came into being on February 3, 1955. In five months the Committee had made its recommendations — more than 100 — of which none was as important as the following:

> The Food and Drug Administration now has insufficient funds, staff, and facilities to meet its essential responsibility of protecting the public health . . . The required expansion in personnel and facilities is between a three- and four-fold one, within five to ten years; such expansion should be progressively authorized by increased appropriations, as fast as it can be absorbed from an efficient organizational standpoint. (3)

The Committee's report documented the needs, and its important recommendation set up a long-range fiscal goal which was sought with consistency and success in the ensuing years. Budget officials calculated that an average annual fifteen percent increase in manpower could produce a fourfold expansion of the FDA staff in ten years. Such leaders as Representative John H. Fogarty of Rhode Island, an expert on the government's health and welfare activities, sold the FDA expansion program to Congress. Commissioner Crawford retired before the Citizen's Advisory Committee was appointed, and he lived only to know the first results of his important suggestion. Under Commissioner George P. Larrick, the Food and Drug Administration began to catch up with its great responsibilities after years of public and congressional apathy. (4)

Standardizing the staff of life

Charles Crawford was a great believer in food standards. At the time I became his information chief (1951) standards of identity had been formulated for more than 200 different foods in 16 different categories. They defined and distinguished some 12 cocoa and chocolate products, ten milk and cream products, 60 kinds of cheese, three salad dressings, nine canned fruits, 15 different packs of shellfish, eggs and six egg products, butter, oleomargarine, 40 canned vegetables, six tomato products, and preserves, jams, jellies and fruit butters. (5)

Rapid progress had been made in standardization during the 1940s. Much of this was due to the persuasive leadership of Crawford and his industry collaborators. In his 1948 paper reviewing "Ten Years of Food Standardization" he had described the process as "a joint undertaking by government and industry" and "fundamentally a delegated legislative function." (6) The early hearings generally went smoothly because there was little to fight over. It made sense to limit the amounts of water in different varieties of cheese, or in mayonnaise, catsup, bread, canned vegetables, etc. It made sense to set maximum limits on cheap ingredients and minimum limits for desirable and costly ingredients, below which they must not fall. It made sense to designate the ingredients which must be used so that the product would meet consumer expectations, and rule out any that would so change the product that it would not be what the consumer expects. It made sense for all concerned: producers, wholesalers, retailers, and consumers.

It was no accident that Congress used the word "shall" when requiring in 1938 that standards be issued whenever needed to "promote honesty and fair dealing in the interest of consumers." The cut-throat price competition of substandard products in those depression days was driving quality products off the market. Buyers willing to pay for a good product could not be sure of getting it. They had lost their freedom of choice in the market because they could not depend on the labeling or appearance of products to guarantee their content. (7) And because the advisory standards relied on to enforce the 1906 law had not been specifically enacted or authorized by Congress, enforcement in the courts had been become very difficult and uncertain.

If variation from a standard did not change the basic identity of a food, and was indicated by a "distinctive name" on the label, there was no ground for legal action. To establish a violation the government had to introduce testimony that an undeclared variation was one not expected by consumers in an article bearing the name of the food, and was one not sanctioned by good trade practice. Upon essentially the same facts some courts and juries would convict while others would not. Manufacturers could not be certain of their legal obligations or stabilize their operations. Consumers' interests could not be effectively protected. Congress changed that in 1938, with strong support from the regulated industries.

Flour and bread headed the list of foods to be standardized, and in 1939 the FDA held its first hearings to establish national standards for the "staff of life." They went more smoothly than expected, notwithstanding a new and complex development, the enrichment of staple foods with vitamins that had been found to be specific in the prevention of serious deficiency diseases. (8) It had taken many years of nutrition research and major discoveries to achieve this important public health breakthrough: an enrichment formula scientifically devised to replace essential nutrients lost in the milling process and adding others needed for health protection. Amended several times, this familiar list still appears on labels of enriched flour, bread, and other cereal products. (9) A famous Supreme Court decision helped to restrain the proliferation of non-standard variations. Henceforth "enriched" would mean that the complete official formula had been used, and no other. (10)

Having achieved flour standards, the next major item on the FDA standards agenda was bread. Hearings begun in 1941 went on 26 days and produced a record of 4,162 mimeographed pages. The government was represented by William W. Goodrich, a University of Texas Law School graduate hired to help with the administration of the new 1938 Federal Act. One of Charles Crawford's most valued colleagues, he later became FDA's Chief Counsel. But before the bread regulations could be completed World War II intervened and in 1943 the proceedings were stopped at the request of the War Food Administrator because of possible interference with war measures to cope with material shortages. In 1948, over five years of economic and technological change required additional testimony, and the hearings were reopened. It was a Pandora's box—when concluded, the record made by 170 witnesses in 116 days totaled over 17,000 pages. (11)

How could one explain or justify these lengthy, expensive proceedings? To some extent they could not be justified. There was too much legal nit-picking, too much infighting between suppliers of competing ingredients. But there were important health and scientific issues that had become controversial. At the time I joined FDA (March 1951) we were still receiving letters from misinformed, often angry people who had been listening to radio lectures attacking the pending bread standards. The lectures, broadcast over one of the nation's major stations, were by a self-styled "international expert" who was found to have a criminal record (practicing medicine without a license) and no qualifications as a nutrition scientist. Posing as an expert diet consultant the radio commentator was carrying on a sustaining program that plugged various food products as answers to the listener's every health problem. Potential business resulting from the listener queries was being steered to a mail-order vitamin company with which he had a financial arrangement. (12)

The FDA, engaged in a major effort to protect consumers, was being attacked for doing the opposite. Particularly, it was charged with refusing to improve the nation's bread by not including soy flour as a required ingredient in the standard for "white bread." Never objecting to soy flour as a bread ingredient, the agency simply could not legally compel its inclusion in the standard for a product known to consumers and labeled as "white bread." But the radio spieler was able to make this the nutritional "cause celebre" of the bread standards battle.

Final approval of the standards on May 14, 1952 was a milestone event of Commissioner Crawford's administration. Particular care was taken in the public announcement to report on how the various controversial issues had been resolved. Most important was the status of so-called "chemical" ingredients, especially the widely used "bread softeners." The polyoxyethlene types of emulsifiers or softeners were ruled out because evidence of their safety was not considered adequate, and because the softening effect on bread was likely to deceive consumers as to its freshness. But mono- and diglycerides in shortening, which could produce similar softening, were allowed in limited amounts for their emulsifying action. Altogether over 30 materials proposed as optional ingredients were excluded by the standards. (13)

FDA's internal house organ, the *Food and Drug Review*, described the bread hearings as the longest in FDA history and the most controversial:

> The controversy over softeners took more than two-thirds of the time and most of the attention at the hearings, which lasted 142 days. When the proposed order was announced, however, the McCay [soy] formula bread fans were the most vociferous and emotional. In the following 21 months the Administrator, FDA and members of Congress received about 2,000 letters in protest against establishing a "ceiling on nutrition." Carleton Fredericks, self-elected nutritionist, took up the battle in numerous radio broadcasts, and each outburse brought in a wave of consumer protests — many militant, a few amusing, and some pathetic.

> One correspondent went so far as to state that she thought white bread should be made entirely of whole wheat flour, but also should contain soy flour, wheat germ, and everything else that is good for people, and the public should not be permitted to eat any other kind. A pathetic letter came from a woman who said she was old before her time—no teeth, failing eyesight, arthritis, etc.—because the Government has let the bakers take all of the good out of bread. One wave of letters contained only one question, reminiscent of "have you stopped beating your wife?"—they asked, "What would be a baker's punishment for making bread too nutritious?"
>
> The protesters lost sight of the fact that the agitators were using plain white bread as their "battle cry," while most of the bread on the grocers' shelves today is enriched. They closed their minds to the importance to the consumer of keeping enriched bread a distinctive product of adequate nutritional value, in contrast to plain bread with wheat germ today, and tomorrow some other currently promoted and publicized added substance, without regard to its actual nutritional contribution. They also forgot that McCay's "Golden Triple Rich" bread had never been sold as ordinary white bread. (14)

The most urgent reason for reopening the bread hearings had been the increased use of chemical ingredients and additives. Food technology had produced a host of new food ingredients whose safety was neither questioned or proved. It was simply not known. Unlike new drugs they did not have to be proved safe before marketing. True, responsible firms were subjecting their new products to scientific scrutiny and discussing the results with FDA, but it was becoming obvious that voluntary action could not be relied on. Every now and then acutely toxic chemicals were turning up in foods and beverages—a revival of the days of Harvey Wiley's "poison squad." Procedures to set safe pesticide residue tolerances under the 1938 law were not working. Topping all this, the regulatory and research effort needed to assure safety of so many new additives under existing law was clearly beyond the FDA's resources.

Testimony at the bread hearings was confirming a disturbing situation. It was natural that FDA's Commissioner Paul Dunbar should discuss it with an FDA friend in Congress, Representative Frank B. Keefe of Wisconsin, ranking member of the appropriations subcommittee which handled FDA's finances. On May 9, 1949 Mr. Keefe was "recognized for 60 minutes" to explain the need for a "House Select Committee to Investigate the Use of Chemicals in Food Products." (15) Keefe's presentation, probably prepared by Charles Crawford, was largely composed of cases from the record of the bread hearings. Passage of Keefe's resolution was assured by its reintroduction by Representative Adolph J. Sabath of Illinois, who had served 25 terms in Congress and was Chairman of the Rules Committee. Debated and passed on June 20, 1950, the investigation under House Resolution 323 began September 14, 1950 under the chairmanship of James J. Delaney of New York.

Early in those hearings Charles Crawford, then FDA's Deputy Commissioner, was called to testify on the kind of legislation the agency thought was needed. He presented the first draft of a proposed bill "for the regula-

tion of chemical additives in food". (16) Patterned after the new drug section of the 1938 law, it finally evolved into three specialized amendments: the Miller Pesticide Amendment of 1954, the Food Additive Amendment of 1958, and the Color Additive Amendment of 1960. With these laws on the books it could be said, for the first time, that no substance may be legally introduced into the U.S. food supply unless there has been a determination that it is safe. Crawford's expertise contributed to all of them.

The Rx legend becomes a law

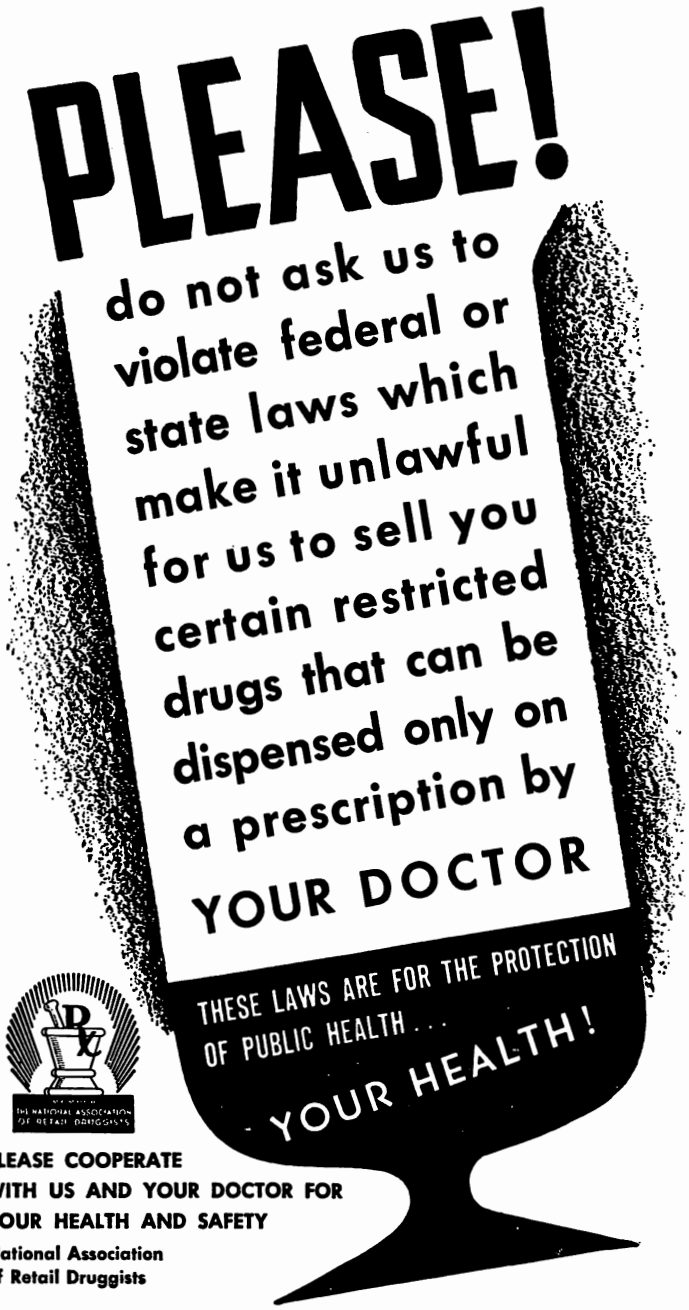
"Refilling of prescriptions for dangerous drugs without specific authorization of the prescribing physician will be a violation of Federal law under the Durham-Humphrey Bill (H.R. 3298) which the President signed today, according to Food and Drug Administration officials." This was the lead sentence of the press release I wrote for Commissioner Crawford explaining provisions of one of the most important public health laws ever enacted by the U.S. Congress. The major "news" of the legislation was its resolution of the legal status of prescription refills. The sale of restricted drugs without prescriptions was already a Federal violation through interpretive regulations and court decisions under the 1938 Food, Drug and Cosmetic Act. (17)

Actually, no pharmacist was prosecuted until December 1943, when a Maine grand jury indicted a druggist for selling sulfathiazole over the counter. U.S. Navy medical officers had informed FDA that their venereal disease program was not effective against sulfa-resistant gonorrhea. Enlisted men had been attempting self-medication with sulfathiazole bought from the drug store at 10 cents per tablet. The offense was misbranding, caused by repackaging the tablets without "adequate directions for use." The court imposed a maximum $1,000 fine, suspended it, and put the druggist on probation. (18)

The problem of illegal sales of prescription restricted drugs grew rapidly. It also changed. By 1951, in 90 percent of the cases, the drugs sold or refilled without prescription were barbiturates or amphetamines, which in many sections of the country were causing as much addiction as narcotics. The other 10 percent of the cases involved mainly sulfa drugs, penicillin, thyroid, and various hormone preparations dangerous for self administration. But frequently the violators were found to be selling both the habit forming and other dangerous drugs. (19)

"Leads" for investigations came from hospitalized victims, police officers and social workers in "skid row" areas, coroners, physicians, venereal clinics and others involved with drug abuse problems. In each case, inspectors would make "buys" to establish the facts about the operation. And the facts, reflected in case records of the Crawford years, showed that while illegal drug sales continued to be responsible for more human tragedies than all other violations combined, the number of drug stores involved was declining. The majority of pharmacists were refusing to sell the restricted drugs without bona-fide prescriptions.

With the shutting off of supplies of barbiturates and amphetamines from ethical stores, and enforcement pressure against the fringe operators, the illegal traffic in these drugs was being driven underground. As a result, the



"A national association of druggists has furnished its members placards explaining the druggist's responsibility and asking his customers not to request him to violate the law. This same association is seeking a better federal law to meet the problem of unauthorized refilling of prescriptions." FDA *Annual Report*, 1950, p. 9.

FDA's job was changing. Quoting the 1952 Annual Report: "Physical danger faced by FDA investigators may be expected to increase as it becomes necessary for inspectors to trace distribution of harmful drugs through underworld channels." One inspector that year had been held at gun point for 2 hours and another had his skull fractured with a blackjack. In those days it was not a federal offense to attack an FDA inspector.

Law abiding, professional pharmacists on the other hand, continued to have serious problems complying with regulations and a law that had been designed more to exempt than to regulate their activities. There were, particularly, no consistent rules concerning prescription refills, a major source of pharmacy income. The issue was joined when FDA's Commissioner Dunbar compared a prescription to a check, which could be cashed only once. (20) Common practice at the time was that unless the doctor indicated otherwise, any prescription could be refilled indefinitely. The public health consequences of such laxity in drug dispensing were serious and alarming. Pharmacists were on the spot; consumers were demanding refills; physicians often were non-cooperative and annoyed at being called to authorize refills. In 1950, while the Durham-Humphrey law was being debated, the National Association of Retail Druggists furnished thousands of member stores with placards explaining the pharmacist's responsibility and requesting customers not to ask them to violate the law.

As finally passed, the new law legalized telephoned prescriptions, including refill authorizations for restricted drugs, if reduced promptly to writing and filed by the pharmacist. It defined the kinds of drugs requiring a prescription, and required them to be labeled with the legend: "Caution: Federal law prohibits dispensing without prescription." Retail pharmacists were enabled to tell immediately from the package whether or not a drug was one that required a prescription.

"Keep out of the reach of children"

"Keep this and all drugs out of the reach of children" is the one warning that today appears on the labels of virtually all O-T-C drugs marketed in the United States, and other countries as well. Similar warnings are seen in the labels of many other consumer products.

As to drugs, the required use of such a warning began in 1954, Commissioner Crawford's last year. A grieving father had written to the Passaic County (NJ) Medical Society relating in detail the poisoning death of his 2-year old son from oil of wintergreen. A warning on the label might have alerted the parents and prevented the accident. Copies of the letter, sent to New Jersey Congressmen Canfield and Frelinghuysen, were referred to Crawford, who personally took charge of the matter. (21)

FDA had been enforcing the Caustic Poison Act since its passage in 1927, but this law applied only to household lye and 11 other corrosive chemicals required to have "Poison" labels. Increasingly, however, FDA was receiving reports of accidental poisonings, particularly of children, from ingestion of other common chemical products and drugs.

In early 1952, when I was offered a free trial subscription to a nationwide newspaper clipping service, I selected "accidental poisonings" as the subject for coverage. The results were disturbing. Deaths were reported from furniture polish, aspirin tablets, disinfectants, sleeping pills, radiator cleaner, ant poison, and paint thinners, to name some of the products involved. Some of them had warnings on their labels, but most did not. (22)

The 1938 Food, Drug, and Cosmetic Act (Sec.502(4)(2)) required label warnings against dangers arising in the use of drugs, but not against their misuse or accidental use. This did not deter Crawford. Always sensitive to the interests of consumers, he told me he was going to "stretch the law" in regard to oil of wintergreen, because he was confident that the courts would sustain his action. On April 10, 1954, the *Federal Register* published the following "Statement of Interpretation":

> *Labeling of drug preparations containing significant proportions of wintergreen oil.* (a) Because methyl salicylate (wintergreen oil) manifests no toxicity in the minute amounts in which it is used as a flavoring, it is mistakenly regarded by the public as harmless even when taken in substantially larger amounts. Actually, it is quite toxic when taken in quantities of a teaspoonful or more. Wintergreen oil and preparations containing it have caused a number of deaths through accidental misuse by both adults and children. Children are particularly attracted by the odor and are likely to swallow these products when left within reach.
>
> (b) To safequard against fatalities from this cause, the Department of Health, Education, and Welfare will regard as misbranded under the provisions of the Federal Food, Drug, and Cosmetic Act any drug containing more than 5 percent methyl salicylate (wintergreen oil), the labeling of which fails to warn that use otherwise than as directed therein may be dangerous and that the article should be kept out of reach of children to prevent accidental poisoning. (23)

What started with Crawford did not stop. In 1955 FDA called a conference of pediatric experts and drug industry representatives to consider a much more serious problem—accidental poisoning by aspirin, commonly thought by consumers to be one of the safest of drugs, but deadly in overdosage. Adopting a recommendation of the conference, FDA published the now familiar legend: "WARNING: Keep this *and all medications* out of the reach of children."

The italicized words were the result of a compromise which I negotiated; the aspirin manufacturers had objected that many other drugs were hazardous to children and should also bear this warning. An advisory ruling was issued, calling on the drug industry to use conspicuous package warnings. Widespread voluntary concurrence anticipated the eventual legislation. (24)

Many subsequent developments over the next 35 years have brought an extraordinary improvement in consumer protection from accidental poisonings. President Bush's 1990 proclamation of National Poison Prevention Week states that, whereas approximately 450 children under five died in 1961 (the first year of the proclamation), only 31 such deaths were reported in 1987, a 93 percent decrease.

Charles Crawford's contributions

The late Dr. Robert P. Fischelis has summed up Charles Crawford's contribution to food and drug law as an instrument for consumer protection: " . . . he had an uncanny way of phrasing language to cover loopholes in any statement that would require living up to by those who were regulated. I think that his great service to the whole food and drug movement was getting statements into shape that could not be distorted or circumvented . . ."(25)

Crawford's habits as a wordsmith were not confined to legislation. He took the same care in letters, articles, and speeches. He also liked to discuss words and phrases with his associates, so as to insure maximum accuracy and effectiveness. He was both dignified and approachable. Taking lunch in the cafeteria of the North Health, Education, and Welfare Building he would commonly join other employees to discuss either personal or "official" business. His great knowledge of FDA made him comfortable in talking about any area of its work, but he was always open to the suggestions of others. He had a standard luncheon menu: apple pie a la mode and coffee. His hobbies were photography (especially western scenes) and building—he constructed both his home in Arlington and one after his retirement in Mill Valley, California.

Quoting again from the 1951 biographical sketch which stimulated the writing of these papers:

> A portrait of Charles W. Crawford would emphasize an impression of quiet strength. Never seeming hurried, he turns out a surprising quantity of work. In appearances before Congressional committees he seems to become cooler as the questioning gets hotter. Stubborn adherence to a position he believes right is another outstanding trait. He writes his own speeches and takes the view that "ghost writing" is akin to misbranding. Efficiency is not allowed to interfere with an old-fashioned sense of duty—on occasion he will take just as much time trying to inform a puzzled consumer as he would spend in answering a similar inquiry from a U. S. Senator or the president of some great corporation. (26)

Crawford chose to retire inconspicuously. He disliked what he called "foofaraw"—a word we have been unable to find in any dictionary, but which to him meant being "fussed over." He told me his intention the day before his departure, and I was able to get his picture taken on this last day of his 37 years of service.

Charles Crawford died of leukemia on September 15, 1957, some three years after retiring. "To the Food and Drug Administration he exemplified FDA work as a way of life. His integrity could not be shaken by the strongest pressure. No problem was too big to attack with vigorous skill. No detail was too small to receive appropriate attention. Admired by the entire staff, he was a personal friend to a large percentage of them throughout the country. To the leaders of industry he was a strict enforcement officer with an open door to air all sides of every problem. When they could not agree, they respected him for staunchly holding out for what he believed was in the best interests of the public." (27)

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Wallace F. Janssen, from St. Paul, Minnesota, was graduated from Macalester College in 1928, with a major in English composition. Beginning in 1929 he held editorial positions with trade journals in the retail grocery and flour milling industries. In 1931 he left Minneapolis to edit *The Glass Packer*, a new York packaging trade journal circulating in the food, drug, cosmetic, beverage, and chemical product industries.

Activities of the Food and Drug Administration soon became a major editorial interest, and in 1933 he reported the Senate hearings on the ill-fated "Tugwell bill," beginning the 5-year struggle which finally produced the Federal Food, Drug, and Cosmetic Act. Recognized as a specialist on the work of the FDA, he was invited in 1943 to become the war-time editor of the drug industry newsletter, *FDC Reports*, and remained as its managing editor until 1951. In that year Commissioner Paul B. Dunbar recruited him to develop an expanded program of trade and public information and education for the FDA. Serving under Commissioners Dunbar, Crawford, and Larrick, he continued as FDA's information chief for the next 15 years.

During this time he carried on the usual functions of agency historian along with those of information director. In 1966 Commissioner James Goddard made these historical functions his principal assignment, while bringing in a new information director from outside.

Reaching mandatory retirement at age 70 in 1975, Wallace Janssen was rehired to continue as FDA's historian and "corporate memory." In 1985 an FDA History Office was officially established, staffed by professionally trained historians. Now, after 60 years as an FDA watcher, writer, official, and historian, Wallace Janssen is contemplating retirement.