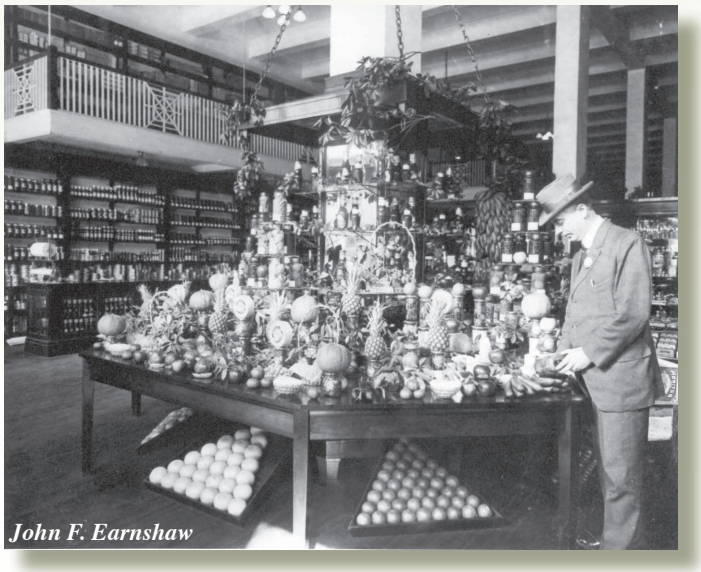
FDA's Yearly Project Plan: "Its Principal Virtue Being an Obviation of Vagueness"

by Suzanne White Junod, Ph.D.

The Food and Drug Administration's (FDA's) Centennial also is the centennial of the "invention" of the federal food and drug inspector. The Bureau of Chemistry employed scientists from its inception, but the 1906 Pure Food and Drugs Act created a new civil service position—that of the federal food and drug inspector. Harvey Wiley, first head of the bureau that eventually would become FDA, originally had thought that state inspectors could be called upon to enforce the new federal statute, thus making federal inspectors unnecessary. After all, Wiley believed that the laboratory scientists with their scientific analyses would "really" enforce the new law; inspectors were mere "sample grabbers" in the scientific process. Southern congressmen, however, accused the new statute of containing, in its inspection provisions, "a Trojan horse with a bellyful of inspectors."[1]



John F. Earnshaw

As issued on October 17, 1906, the first rules and regulations for the enforcement of the new statute were a compromise: "Samples of unbroken packages shall be collected only by authorized agents of the Department of Agriculture, or by the health, food, or drug officer of any State, Territory, or the District of Columbia, when commissioned by the Secretary of Agriculture for this purpose."[2] It was not until roughly 1913 that formal relations between federal and state food and drug officials were established to enhance the ability to coordinate and supplement regulatory actions taken by federal, state, and local authorities. During that seven-year interval, the position of federal food and drug inspector was invented.

Walter G. Campbell, a Kentucky lawyer, took the first Civil Service examination for inspectors to enforce the federal 1906 statute. Wiley, perhaps sensing his leadership potential, personally selected Campbell as the first Chief Inspector. After Wiley's departure in 1912, Campbell refused the Bureau Chief appointment, believing that a chemist should hold the post and that science and enforcement should be in separate organizations. Later, when this experimental separation failed, Campbell served two terms as Commissioner (1921-1924 and 1927-1944) and directed the overall strategy that eventually led to passage of the Federal Food, Drug, and Cosmetic Act of 1938.

Campbell's appointment marked the inauguration of a new era for the newly-appointed inspectors. Wiley had been overheard remarking that he was "damned if he knew what to do with them [the inspectors],"[3] but Campbell and his colleagues quickly chucked the net grocery bags they were issued on their first day of work under the closest park bench and went on to reinvent their roles and relationships within the bureau. Campbell wrote the first *Inspector's Manual*, frowned on inspectors who dressed too casually while making their rounds, and insisted that inspectors on the

Dr. Junod is a Historian with the Food and Drug Administration, Rockville, MD.

road stay in "respectable" hotels. These were just outward signs that federal food and drug inspectors were maturing and assuming a more visible and more valuable role in FDA's scientific regulatory work. It became apparent that their on-the-ground work was extending far beyond mere sampling. Moreover, inspectors and chemists began working together, achieving results that neither alone could have secured.

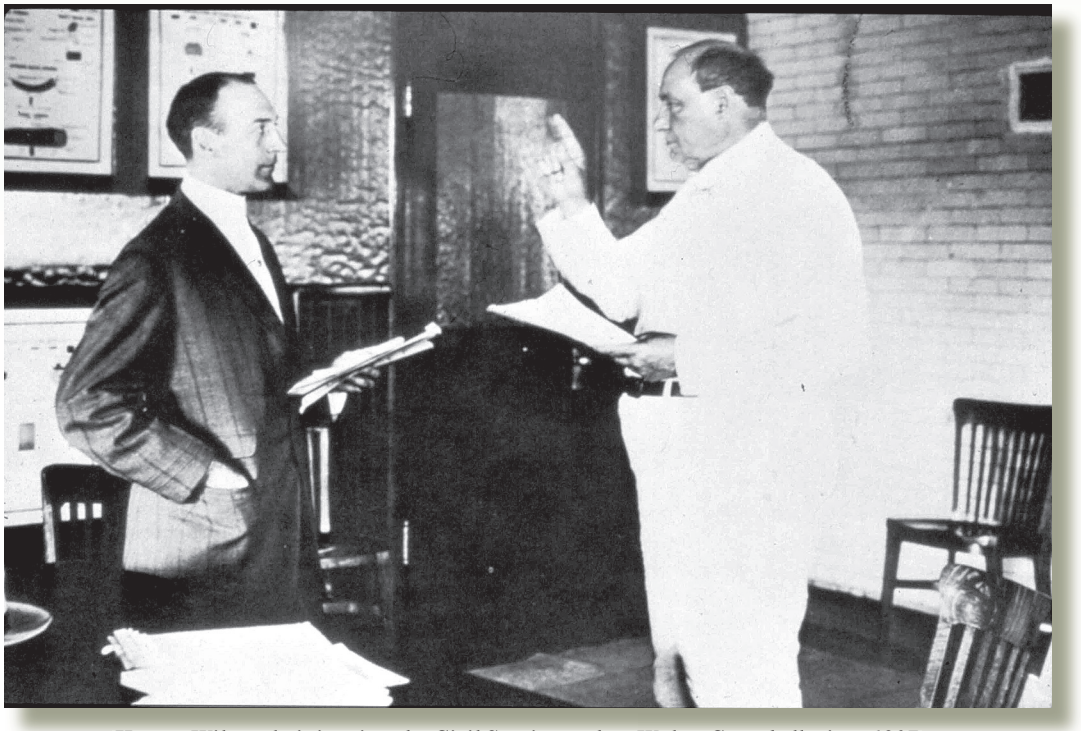
A noteworthy pepper case, for example, originated at a spice manufacturing plant in Baltimore, when an enterprising inspector tried to figure out why a company that made spices would want to import rather than export spent pepper shells. Adulteration seemed the most likely explanation, leading him to team up with a New York chemist to inject a quinine solution into bags of empty pepper shells sitting on the dock and destined for the plant. When samples of the company's packaged pepper were analyzed in New York's laboratory, there was indisputable evidence of quinine contamination. The foreman in charge of pepper-grinding at the plant swore it was impossible until the government witness revealed the trick.

In court, the company was represented by Charles Wesley Dunn, esteemed founder in his later years of the Food and Drug Law Institute. According to witnesses, Mr. Dunn, "was the very picture of outraged dignity," but he lost the case. The judge ordered the pepper to be sold as "ground black pepper containing from 10 per cent to 28 per cent of added pepper shells," all costs to be borne by the manufacturer.[4]

Such *ad hoc* sampling, however, created some problems. As stated in the 1921 *Annual Report*, "[A]s a result, many regulatory problems were taken up prematurely before they had been studied sufficiently to formulate a final policy or to adequately present the situation to the Courts."[5] Campbell devised a project system for handling regulatory work that enabled the Chemistry Bureau to prioritize the many demands on its meager resources. Campbell called it the "Project Plan," and it was a notable improvement over mere *ad hoc* "sample grabbing," helping to establish the groundwork for systematic legal action in entire industries. Over time, the plan minimized inefficient, scattered actions against individual products; instead, early regulators learned to act systematically, targeting abuses in entire industries, and reforming them through carefully-chosen legal actions.

The "Project Plan," as envisioned by Campbell, was designed "to provide for systematic investigations, uniform procedure and sympathetic administration in every unit."[6] According to Campbell, the principal good to be gained from such a plan was "the obviation of vagueness."[7] In a 1921 *Food and Drug Review* article, Campbell stated:

> The end to be served is the chief factor in determining the character of an organization. Sweeping changes have taken place in the Bureau of Chemistry in the last decade. The task of enforcing the Food and Drug Act immediately after its enactment was of a kind quite



Harvey Wiley administering the Civil Service oath to Walter Campbell, circa 1907.

William Chaffee

different from that involved in its enforcement today. An innovation such as the passage of a law to control commercial practices is followed by a period of adjustment, chiefly voluntary, by the industries in an effort to make their operations legitimate. Through the period of this transitional stage infractions were frequent. Since the Act, though criminal in cast, is corrective rather than penal, there was required of the Bureau in the beginning an effort to make the nature of the violation as exact as known. Normal development gradually reduced the scope of violations until eventually the ordinary case was one which came within a debatable zone.

This necessitated a new consideration based upon more extensive information and concerning manufacturing practices and greater knowledge of the law as interpreted by appellate courts. This change in condition required a corresponding change in organization, the outstanding modification being the plan of decentralization. Effective administration of an organization in which authority has been extensively delegated is practicable only when there exists some plan by which unity in viewpoint is established and coordination in all phases of work in all branches guaranteed. Otherwise action will be dictated by opportunism with different subdivisions proceeding on varying subjects in individual and varying ways to conclusions inevitably unsatisfactory and perhaps contradictory.[8]

John Breckenridge

Richard E. Williams

Campbell's original "Project Plan" has evolved into the Office of Regulatory Affairs' present-day Workplan. This Workplan directs the program activities of investigators, laboratory analysts, and regulatory specialists in FDA's 5 regions, 20 district offices, 13 laboratories, and 130 resident posts. It is created, revised, and finalized yearly by staff aided by sophisticated computers, and it includes more than 30 types of regulatory activities and over 1,200 possible program codes. Regulatory actions—tracked and documented through the plan—are scrutinized routinely throughout the agency and by Congress.

The yearly Workplan represents an intensive collaboration between staff in FDA's Centers for foods and cosmetics, human drugs, biologics, veterinary medicine and feeds, and devices and radiological health. According to Susan Baer, whose division spearheads the effort each year, "The process begins in the Spring using resource estimates based on the congressional budget [that] is under consideration by the Congress for the following fiscal year, and the Workplan issues prior to the beginning of the fiscal year in August or September."[9] Because it is coordinated closely with budget and performance plan initiatives, Baer says that it "is frequently revised if the congressional appropriation differs substantially from the Administration's proposed budget."[10]

---

1 James Harvey Young, *From Oysters to After Dinner Mints: The Role of the Early Food and Drug Inspector*, 42 J. OF THE HISTORY OF MED. 31.

2 40 Rules and Regulations for the Enforcement of the Food and Drugs Act, June 30, 1906, Oct. 17, 1906, Sec. 4, Regulation 3, Collection of Samples, FDA History Office.

3 Willard D. Bigelow, *The Detail of the Enforcement of the Food and Drugs Act*, 23 DA YEARBOOK 321-24 (GPO 1907).

4 RUTH DE FOREST LAMB, AMERICAN CHAMBER OF HORRORS 151 (1936).

5 ADMINISTRATIVE REPORTS 1907-1949, at 455 (CCH 1950).

6 W.G. Campbell, *The Project Plan Fundamental in Regulating Commerce in Food and Drugs*, 5 FOOD AND DRUG REVIEW 1-2 (N 1921).

7 *Id.*

8 *Id.*

9 Personal correspondence from Susan Baer, Director, Division of Planning, Evaluation, and Management, Office of Regulatory Affairs, FDA to Suzanne Junod, FDA Historian (July 2004) (on file with FDA History Office).

10 *Id.*

PICTURES PROVIDED COURTESY OF FDA HISTORY OFFICE