

FDA: New Pressures, Old Habits Bring a Change at the Top

According to a recent anecdote, Robert H. Finch, Secretary of Health, Education, and Welfare, complained to predecessors shortly after taking office that he was besieged by civil rights controversies. "What kept you busy when you were here?" he is supposed to have asked them. "Well, there was always the Food and Drug Administration," was the alleged reply.

It was not long before Finch, too, found himself embroiled in disputes centered in FDA. Among these were the Panalba incident in May (*Science*, 29 August); the cyclamates problem in October, when the Secretary grumbled that Commissioner Herbert L. Ley, Jr., was "waffling" in the face of evidence that the artificial sweetener should be removed from the so-called "GRAS list" of food additives "generally recognized as safe"; and a series of congressional hearings, embarrassing to Finch, on FDA's internal problems.

By October it was clear that Finch had lost confidence in Ley. For his part, Ley said in a recent interview he never felt he could count on the Secretary's support: "It was a very lonely year in that regard."

Finch Downs Ley's Burden

While Ley and his supporters ascribe the FDA's dysfunctions in the past year to inadequate resources and lack of firm political backing, Finch not surprisingly looked upon them as the product of poor management. Following the cyclamates contretemps, the Secretary ordered a study of FDA by the Deputy Undersecretary of HEW, Frederic V. Malek. This report's conclusions were that the agency should be reorganized internally and raised in bureaucratic standing. In conjunction with these changes, Finch announced on 10 December that he was replacing Ley and two top associates. Ley was offered another post within HEW but declined it.

The new Commissioner is Charles C. Edwards, a surgeon turned management specialist. Described by HEW officials as a "hard-nosed" decision-maker, Edwards previously was head of the health and medical division of Booz, Allen, &

Hamilton, a Chicago management consulting firm. Before that he was director of socio-economic affairs for the American Medical Association.

Edwards and the new FDA organization will surely be put to a test before long. Rising concern about the safety of many commonly accepted food additives and the developing controversy over the birth control pill are typical of the issues, involving scientific judgments, very large economic interests, and the health and welfare of consumers, with which the FDA must wrestle. If past history is a guide, however, it will take more than clarifying the lines of responsibility and the setting of more effective deadlines to solve FDA's chronic malaise. If a clear sense of purpose and identity is not soon asserted, the agency will, in all likelihood, slump back into its old "waffling" ways, which long predated Ley.

FDA was established in the late 1920's to take over administration of the Food and Drug Act of 1906 from the Bureau of Chemistry of the Agriculture Department (FDA was subsequently transferred to the forerunner of HEW). It was originally administered by scientists who relied on the courts to enforce their findings. But the agency gradually acquired rule-making and enforcement powers of its own. Enforcement officials came to dominate FDA, and its scientific capabilities declined. Then the "chemical revolution" and advances in scientific measurement introduced a new complexity to the agency's job. By the late 1950's there was widespread concern that the FDA was not equipped with the legal authority, the personnel, or the attitude necessary to cope with its new challenges. A series of reforming laws, reorganizations, and personnel shakeups followed, stimulated by constant congressional pressure. Among the important new duties were (i) the determination of safe levels of pesticide residue in foods under a 1954 law; (ii) administration of the 1958 food additives law which contains the Delaney amendment, invoked in the cyclamates case (it bans food additives which in any amount cause cancer in test animals);

(iii) regulation of all color additives to foods, drugs, and cosmetics in 1960; and (iv) the Kefauver-Harris drug amendments of 1962 (requiring judgments on the efficacy as well as safety of new drugs). Prodded by Senators Estes Kefauver (D-Tenn.) and Hubert H. Humphrey (D-Minn.), FDA sought to upgrade its scientific and medical staffs. The last three commissioners, including Edwards, have been doctors. (It is perhaps indicative of the new pressures on the FDA that Edwards is also the third commissioner in 4 years.)

Consumer Chores Pile Up

In recent years the agency also came to administer a grab bag of other consumer protection programs: regulation, under laws passed between 1960 and 1969, of a wide variety of hazardous household chemicals, flammable products, including fabrics, and mechanical and electrical products, including toys; supervision of manufacture and distribution of nonnarcotic "dangerous drugs" such as amphetamines and barbiturates; the Fair Packaging and Labeling Act of 1965; and shellfish, milk, and food sanitation programs transferred to the agency in 1968 in the reorganization of the Public Health Service. Between fiscal 1955 and fiscal 1970 the FDA's budget grew from \$5.1 million to \$72 million, the number of employees from 829 to about 4250.

Today FDA is probably the most important consumer protection agency in the federal government. The public is aware of it mainly as a drug agency, with some reason: FDA spends over 40 percent of its resources on the regulation of the \$5-billion-a-year drug industry, and drug matters have absorbed much of the commissioner's time. The agency spends somewhat less time and money regulating the \$100-billion-a-year food industry, and this fact is beginning to draw fire. Last fall, for example, Chairman Paul G. Rogers (D-Fla.) of the House Interstate and Foreign Commerce subcommittee on public health and welfare was informed by agency officials that the staff working on implementation of the Fair Packaging and Labeling Act, never larger than 11 persons, had been reduced in the last year to two men working part time, due to a tight budget.

A staff study of the FDA's consumer protection activities and responsibilities, dated 14 July 1969, concluded lugubriously that "the American public's principal consumer protection is provided by the Food and Drug Administration,

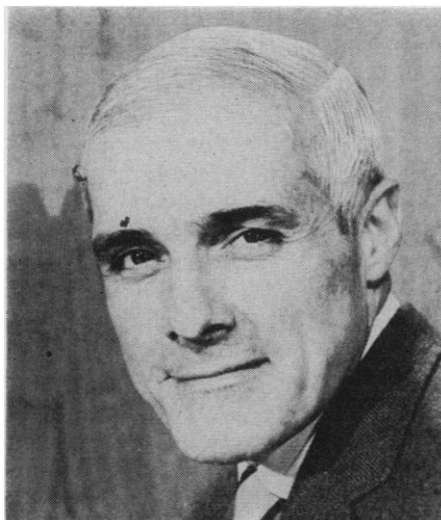
and we are currently not equipped to cope with the challenge." The study group, headed by Maurice D. Kinslow, an FDA official presently acting as special assistant to Edwards, expressed concern about almost every area of FDA activity: its scientific capability; inspection activities; and regulation of food standards and labeling, medical devices, cosmetics, hazardous substances, and flammable products.

The Kinslow report clearly implied that the cure for the agency's shortcomings lay outside FDA, with HEW, the White House, and Congress. It was leaked to the press and is said to have increased the strain between Ley and Finch, who asked Deputy Undersecretary Malek for a different assessment of the agency's problems, focused on management. Malek and Finch consulted a wide range of FDA's critics, including James S. Turner, an associate of Ralph Nader at the Center for the Study of Responsive Law (*Science*, 21 November) and author of a forthcoming critique of FDA. The Malek report recommended a reorganization of FDA along "product" lines in an effort to consolidate regulatory authority.

Uptight Habits Dominate Agency

But the more vigorous critics of the FDA, including Turner and some prominent congressional investigators, dismiss the Kinslow report and the Malek reorganization as superficial, because both ignore what they consider to be the agency's lack of zeal in employing the resources it already has.

According to these critics, a characteristic inability to act forcefully is noticeable even in the regulation of drugs, the area in which the FDA has the strongest legal mandate and the most resources. These charges of foot-dragging from pro-consumer critics ironically reinforce complaints from the drug manufacturers, who have long grumbled about the time it takes FDA to clear new drug applications and other paperwork. The agency requires 19 to 26 months to approve an average new drug application, according to the Pharmaceutical Manufacturer's Association (PMA). The Kinslow report blamed "inadequate data (from the manufacturer) or improperly designed clinical studies" for a large part of the delay. The industry, on the other hand, blames FDA's shortage of skilled clinical personnel, red-tape procedures and supercautious judgments on evidence presented by the drug companies. The admitted caution is in part, of course,



Charles C. Edwards

a legacy of the thalidomide case, in which Dr. Frances O. Kelsey became a national heroine for her stubborn refusal to approve marketing of the drug.

But two congressional investigators suggested this year that FDA's cautious behavior is not wholly in the Kelsey tradition of zeal to prevent the sale of harmful or inefficacious drugs. Representative L. H. Fountain (D-N.C.) of the House Government Operations Committee and Senator Gaylord Nelson (D-Wis.) of the Senate Small Business Committee both claimed that FDA displays similar resistance in reaching a decision to take off the market drugs shown to be ineffective or dangerous.

Both men were particularly critical of FDA's slow pace in publicizing and implementing the recommendations of the Drug Efficacy Study of the National Academy of Sciences-National Research Council. Although the NAS-NRC reports began arriving at FDA in October 1967 the agency had published less than 14 percent of the recommendations by December 1969.

The Drug Efficacy Study was a massive undertaking by NAS-NRC to review all "new" drugs issued between 1938 and 1962 and still on the market. The 1962 Kefauver-Harris amendments required such drugs to meet the new efficacy standards by 1964. But, probably for reasons of workload and potential trouble with industry, the FDA devoted little attention to this problem for another 2 years. The 1938-62 vintage drugs still on the market number some 3,700 preparations, with perhaps 10,000 separate usage indications. An evaluation of each one was required. The drugs include 150 of the 200 most prescribed drugs on the market.

In 1966 the newly appointed commissioner, James L. Goddard, decided to bring in outside assistance to accomplish the review. He had dual motives in turning to the Academy. First, outside help would relieve FDA of the very large work burden. Second, as Goddard explained in a recent interview, "when the time came to implement the recommendations, it would be difficult for the industry to challenge the prestige of the Academy." NAS-NRC set up 30 panels of physicians to review evidence submitted by the manufacturers or available in the literature. In all, the panels issued over 2800 reports. Under the terms of the FDA contract, these are supposed to remain confidential until reviewed by the agency and published in the *Federal Register*.

Paul Bryan, a physician who heads the FDA Bureau of Medicine task force on drug efficacy, recently said the delay in publication was "terribly disheartening." Part of the problem is a cumbersome internal administrative "sign-off" procedure by which each recommendation is passed through several layers of the Bureau of Medicine and the Bureau of Compliance, frequently twice or more, before receiving the commissioner's permission to publish. The opportunities for delay are numerous and practically uncontrolled. In the speediest cases the review may take 2 months, but in many it has consumed a full year or more.

The FDA review is, however, only the beginning of a protracted administrative process to withdraw an ineffective drug or make labeling changes. The NAS-NRC study, at FDA's direction, rates the drugs as "effective," "probably effective," "possibly effective," or "ineffective" for each usage. On publication, the FDA gives a manufacturer 30 days in which to present new evidence and seek a hearing if the drug is judged "ineffective," 180 days if the drug is judged "possibly effective" and 1 year if the drug is judged "probably effective." The hearing process consumes additional time, and the manufacturer may then challenge the whole proceeding in the courts. The drugs remain on the market during this period.

Last May, Fountain called Ley before his subcommittee and protested that the whole procedure violated the 1962 law, which in his opinion allowed only two judgments to be made: either there is substantial evidence that a drug is effective, or it must be taken off the market.

W. Donald Grey, an investigator on Fountain's subcommittee staff, later commented that the FDA seemed deliberately to avoid its responsibilities. "The one pattern I could see emerge as I went over their (FDA's) actions (on drug efficacy) was that they would twist and turn to find a way to leave the drug on the market. . . . (they) displayed a lack of will to regulate when it comes to hitting the pocketbook."

To Mediate or to Advocate?

Turner, at the Center for the Study of Responsive Law, is another student of FDA who believes that its problems lie as much in a lack of regulatory vigor as in a shortage of resources. Turner is working on a report on the agency's record in regulating the food industry, where he detects a confused sense of mission as well. Turner argues that the agency has developed a tendency to cast itself as arbiter between the consumer and industry, rather than as the consumer's advocate. As a result, he asserts, the consumer interest, not being strongly represented in agency proceedings, is often subordinated to the requirements of industry in the drafting of regulations and standards.

For example, Turner says, FDA allows food manufacturers to omit important information from product labels in some cases. He cites a much-assailed 1966 decision by Goddard that permits marketing of cola beverages without a label noting that they may contain added caffeine. The decision, strongly sought by industry (and, Turner believes, possibly influenced by the White House), defined caffeine as a normal ingredient of cola beverages. Another example cited by Turner concerns the controversial food additive monosodium glutamate (*Science*, 17 October). FDA allows MSG as a "permissive" ingredient in some foods, including mayonnaise and salad dressings. As such, it need not be listed.

Turner believes FDA regulations and practices have effectively "wiped out" laws dealing with food standards, food additives, and pesticide residue. He and other critics put much of the blame for this on two high-ranking officials of FDA who were transferred from the agency along with Ley. They are former Deputy Commissioner Winton B. Rankin and former Associate Commissioner for Compliance J. Kenneth Kirk. Both had served in FDA for more than 30 years, having started as inspectors. Many FDA critics say

they set the agency's style in administrative and regulatory matters.

FDA is now under closer public scrutiny than at any time since the early 1960's. Then the issue was fairly narrow: how well did FDA carry out its drug regulation duties? Now consumer forces want better performance from FDA in every area. The demand is particularly strong for better regulation of the food industry. That job potentially is several times more difficult than drug regulation, as the food industry is larger and politically more powerful than the drug industry.

The central theme that emerges from recent critiques of FDA (with the exception of the Kinslow report) is the agency's overriding need for assertive leadership. Even his foes concede that when Goddard was commissioner, one always knew where he stood. His admirers think he provided the model for future commissioners to follow. Their assessment is not based as much on what FDA did during his relatively brief 30-month tenure as it is on the man's style, contrasted with his successor Ley. Goddard came to FDA in 1966 after a management career in government, including the Public Health Service. He rapidly made a name for himself as an outspoken advocate of the public interest, a strong critic of the drug industry and, in his handling of the drug efficacy study and new drug paperwork, a resourceful administrator. He had firm support from HEW Secretary John W. Gardner. But Goddard failed to force a permanent change in FDA's attitudes and work habits.

Goddard was eased out of FDA not long after Gardner left in 1968. The Administration found him too controversial. His successor could hardly escape the message not to make waves. In any event, Ley displayed a less assertive temperament. A Harvard professor before he was appointed head of the FDA's Bureau of Medicine in 1966, as Commissioner he seemed to display scientific caution where administrative decisiveness was more appropriate. In comparison to Goddard he appeared to lack resources for coping with heavy, day-to-day pressure.

Ley recently complained with quiet bitterness to the *New York Times* that he found "a total lack of top-side support from the current Administration." But Ley draws back from blaming Finch for adding to FDA's troubles. Goddard, now out of government and characteristically tough-spoken, has no

such qualms. He accuses Finch of "waffling" and political interference in FDA and declares, "It is difficult enough to run an agency and compete for good scientists. It is even more difficult when job tenure becomes subject to politics." (HEW officials say they are only interested in getting FDA to function more efficiently.)

Conclusions Suggested

The experience of the last 4 years suggests some conclusions about FDA's problems of leadership and direction.

First, it is up to the Commissioner to reach an understanding with the Secretary of HEW and the Administration on FDA's regulatory posture. This should be made explicit.

Second, no Commissioner can rely on his superiors to shield him from pressure when it gets down to the daily hassle with industry or other pressure groups. If he needs support for his decisions, it is up to him to find it. Goddard went to the Academy for help because, he says, "The Commissioner needs the support of the scientific community. He doesn't have a good constituency to turn to." Pro-consumer groups represent another potential constituency, provided they organize themselves to apply pressure in FDA proceedings or otherwise work with the Commissioner. Here, again, the Commissioner should take the initiative. The Kinslow report gave prominence to a recommendation that the agency "develop programs that will inform the consumer but which will also provide for more consumer influence or FDA's activities." But an advisory council on food and drugs, on which consumers are represented, has not met to advise the Commissioner in more than a year.

Third, having set a course the Commissioner must keep to it without visible wavering or risk undermining agency morale and public trust. "There's a lesson," Goddard asserts, in the controversy over implementation of the NAS-NRC findings on drug efficacy, "that one can't remain inactive. I hope the new Commissioner takes this to heart."

Edwards comes to the commissionership with a reputation as a skilled manager. But the question now is whether he and Finch will give the FDA the sense of direction it so sorely needs, and whether the new Commissioner can learn to operate resourcefully in the political arena.

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