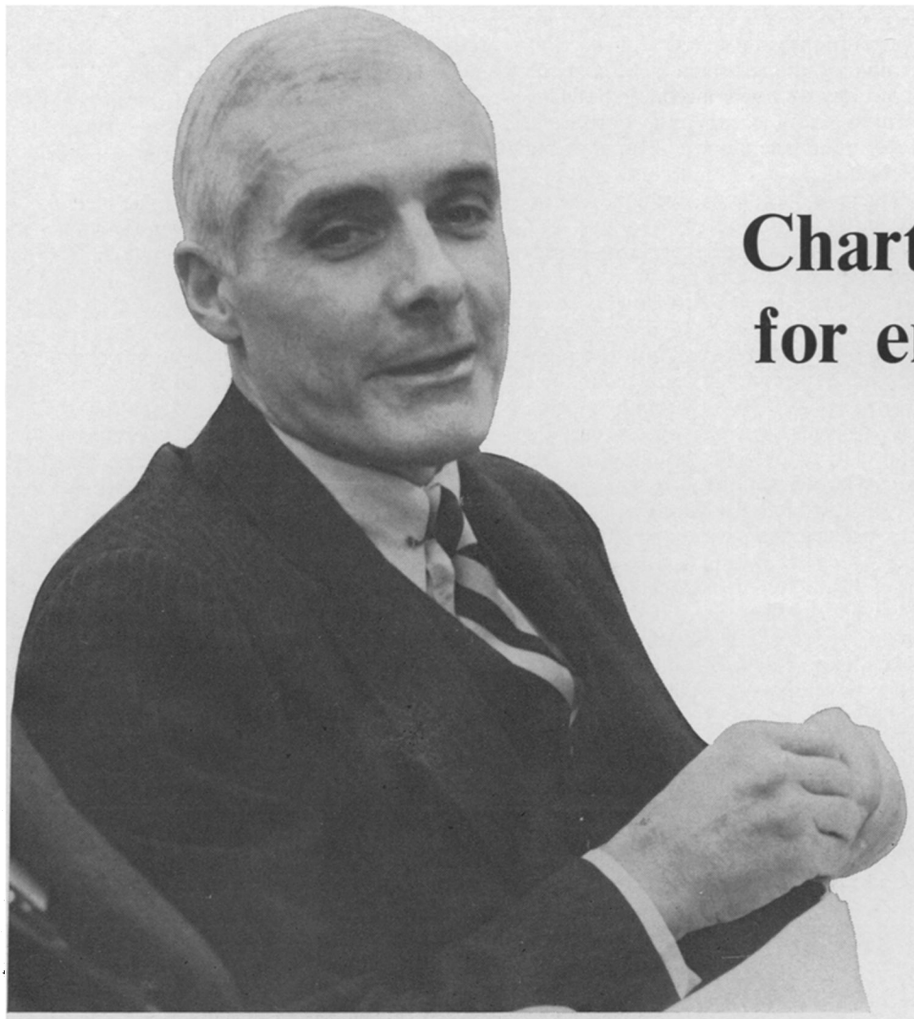


Charting a new role for embattled FDA

Dr. Charles Edwards, the Finch-Nixon appointee as FDA commissioner, is seeking a place at the center of policy making in HEW

by Barbara J. Culliton

" 'Most men,' " quoted Dr. Walter Modell, " 'live lives of quiet desperation.' Since the Food and Drug Administration never really lived, one can say it has spent more than half a century in a state of suspended desperation. . . . The FDA is a noble conceptus that never lived; a grand plan that never had a chance."

In an editorial entitled "Requiem for the FDA," published in the January-February issue of CLINICAL PHARMACOLOGY and THERAPEUTICS, Modell, a long-time FDA critic, goes on to memorialize the agency, proposing that Congress bury it and create in its place an undefined entity called the Federal Drug Commission.

"That kind of stuff bugs me," says Dr. Charles C. Edwards, commissioner of the Food and Drug Administration since last December. The agency has been castigated in the press, criticized on Capitol Hill, assaulted and suborned by turns by the drug industry it regulates and denigrated from within its own ranks. Often the criticism leveled against it has been well founded. But it does not necessarily contribute to a more effective FDA.

"Our society cannot tolerate endless conflict," Commissioner Edwards declared at his first meeting with 100 top FDA staffers in January, "and neither can this agency."

The former Mayo Clinic surgeon, who has been more administrator than physician since he gave up practice in 1961, approaches FDA with the healing attitude of a physician. "FDA's internal and external conflicts have been traumatic and there is a definite limit to the amount of trauma any living thing can endure. When that limit is reached, either death occurs or the trauma ceases. It then becomes necessary for healing and the restoration of strength and vigor."

Clearly, Edwards has no intention of presiding over the demise of what he considers a keystone in the whole structure of national and public health. He calls it "one of the most important agencies in the Government," and the vigor with which he hopes to infuse it represents less a restoration of earlier glory than the establishment of an entirely new kind of stance, more revelant to the demands of today's medical and pharmacological problems.

Dr. Edwards comes to the FDA with a background in medicine and in scientific management, a combination that drew Health, Education and Welfare Secretary Robert H. Finch to him as head of an agency that has toyed with, then chewed up administrators like cats do beetles. Finch expects the new FDA chief to guide a reorganization of what should be in fact, as well as in name, the nation's foremost consumer protector and has encouraged him in changing top management.

It is a job Edwards has been growing toward for almost a decade. From 1962 to 1967, he worked for the American Medical Association, first as assistant director for medical education and hospitals, then as director of the division of socioeconomic activities.

The attitudes that spelled trouble for him at the medical association may be just what suit him for his present job. "Edwards's liberal views," says a

former AMA colleague, "spelled a limited future for him at the AMA. This is not to say he is a wild liberal—only that he was too liberal for the AMA. By the world's standards, he's a moderate." From the AMA, Edwards moved to Booz, Allen and Hamilton, a big-time management consulting firm that frequently handles studies for the Government. He headed the Chicago-based firm's health and medical division and headed studies ranging from revisions of Medicare and Medicaid programs to feasibility assessments for the development of new medical schools.

Edwards's experience in scientific management, his associates contend, certainly suits him to the challenge of introducing efficiency to an agency that can take upwards of two years to clear a new drug and which can get tangled in its own wires as it did recently over the safety of flavor-enhancing monosodium glutamate (SN: 10/4, p. 295).

But FDA has dimmed shining lights before, and in the hot political waters engulfing the agency, Edwards is untested.

The fine line, for instance, between amity and hostility to the drug industry is one he still has to walk. Says C. Joseph Stetler, president of the Pharmaceutical Manufacturers Association, which represents most of the major drug houses in the United States, "Edwards's relations with the drug industry are good."

The industry has often been a thorn in the FDA's side. But within the industry, there are heads wise enough to see the merit of a stable and even effective drug-regulating agency.

"For purely proprietary reasons," says Stetler, "we would like to see him straighten out the agency." Both Edwards and the PMA have indicated that they would like to sit down together, perhaps in the presence of a third, neutral party, to discuss the terms of their living arrangements. The new commissioner is also on speaking terms with organized medicine. Like the drug industry, it has a stake in FDA's decisions and has not been loath to exert its influence.

Present cordiality aside, Edwards is not unaware of the conflicts looming in his future. "Every day," he says, "I learn more about what a rock-em, sock-em environment this is. You have to be thick skinned." And he has been on the job only two months.

In political controversy, Edwards's relations with the brass at HEW, with his immediate superior, Assistant Secretary Roger O. Egeberg, and with Finch will weigh heavily. The ties appear to be close. Edwards has been on the list of men the Administration wanted almost from the beginning. And whether he happened to be around when the FDA job came open or it was opened for him is moot.

Edwards's predecessor, Dr. Herbert L. Ley Jr., was anything but close to Secretary Finch, who at one time intervened and then withdrew in a squabble over Ley's move to bar Panalba, an $18-million-a-year combination antibiotic, from the market. Though in the Panalba situation it was Finch who stumbled, the controversy is symptomatic of the inability of the two men to work together. Finch finally ousted Ley after other embarrassing encounters involving FDA's handling of MSG and cyclamates (SN: 12/13, p. 552).

But as Edwards himself is quick to point out, he is a Finch appointee and has that in his favor. He believes his views of FDA's future parallel, at least, those of the Secretary. "I see FDA as part of the total health care system in this country," says Edwards. "The whole system is in trouble, not just the FDA. I intend to work with HEW on this issue, not sit on the sidelines. In this regard, I would like to contribute to the Nixon-Finch Administration."

Sophisticated and personable, Edwards appears not to hide his meaning behind rhetoric. He has the look and low-keyed manner of a man who wants to get things done by working from a power base within the establishment, not by bombarding it from without.

In his intentions for FDA, he builds on the base established by James L. Goddard, who was top cop at FDA from 1966 until mid-1968. Edwards wants to be more than cop.

Goddard came to FDA like a missionary to a pagan land, preaching reform with a gusto of an old-time Bible thumper and putting the drug industry on instant notice to shape up or face drastic action. Edwards speaks with a lowered voice.

Nevertheless, in the days ahead, Dr. Edwards, who does not want to dwell on FDA's past failures, will confront a host of issues inherited from earlier inactivity.

Goddard, who conceded that FDA could not give the public even reasonable guarantees that all drugs on the market are either safe or effective (SN: 1/28/67, p. 91), enlisted the National Academy of Sciences to evaluate the efficacy of all drugs marketed between 1938 and 1962, the year the Kefauver-Harris amendments, demanding efficacy as well as safety of drugs, passed the Congress. Getting the Academy to undertake the job, Goddard reasoned, had two advantages: it could marshal a scientific staff large enough to study the 2,800 compounds involved, and it could speak with the voice of scientific authority FDA could not muster.

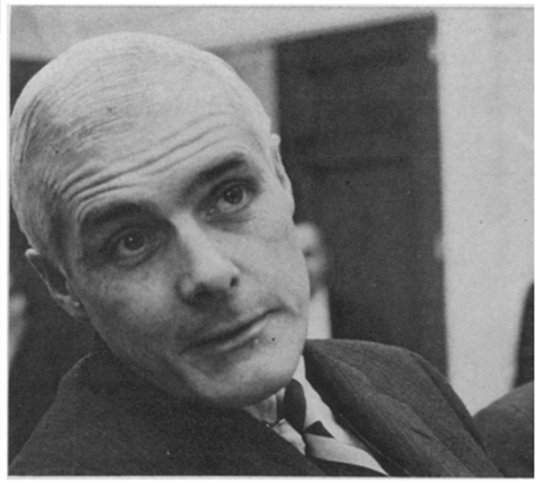
The Academy findings have been in for more than six months. Most of the drugs it questioned remain on the market. Panalba, for example, is still sold, because its manufacturer, the Upjohn Company of Kalamazoo, Mich., has challenged in court FDA's authority to ban the drug without a hearing (SN: 7/26, p. 76). Others have yet to emerge from the FDA papermill. In a move to get things moving, Edwards intends to publish in the FEDERAL REGISTER all of the Academy's findings, even before they have been re-evaluated by FDA scientists. This, he believes, will give affected manufacturers early notice that they will have to be ready with evidence of efficacy if they are to elude loss of license for particular compounds.

The controversy surrounding oral contraceptives also faces Edwards

Photos: Ed Laredo

Edwards and Rogers will discuss new scientific expertise within the FDA.

. . . Edwards at FDA



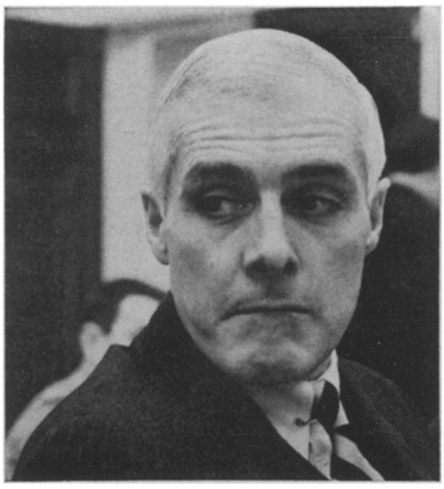
Bugged by glib criticism of FDA.

squarely. Confronted by Senate hearings (SN: 1/24, p. 93) and mutterings from the British that birth control pills increase the rate of heart disease, he last month recalled the disbanded advisory committee on obstetrics and gynecology and now plans to meet with it every four to six weeks. "We are particularly anxious to review the British data once we receive them," he comments, but neither he nor any other responsible medical man can be expected to draw any precipitous conclusions.

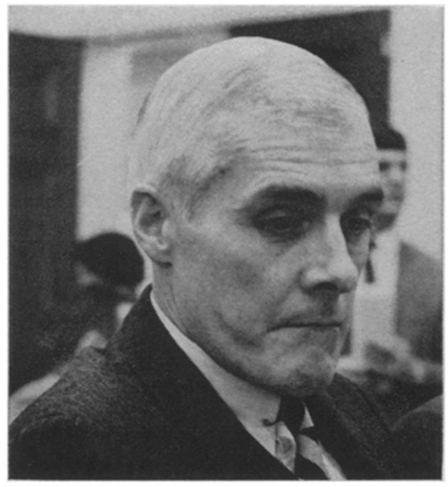
Cognizant of the fact that FDA is not what it might be in all areas of scientific expertise, another heritage from the past, Edwards intends to place more reliance on advisory panels. Already the agency has about 100, but few are used as extensively or as well as the panel reviewing contraceptives. And even there, changes are in the offing. "I plan to introduce a system of rotation. No individual should serve for more than five years," Edwards says, "and I intend to expand its membership by about three and appoint a new chairman." The committee now has 14 members.

Since former chairman Dr. Louis Hellman of New York's Downstate Medical Center took a position with HEW, Dr. Roy Hertz of the Rockefeller University was named temporary chairman by the panel members. Dr. Hertz is an outspoken critic of the pill, warning that it may be linked to cancer. Edwards has no illusion that there will routinely be new evidence every couple of months, but he intends to rely on outside opinion to help shoulder the responsibility for FDA decisions.

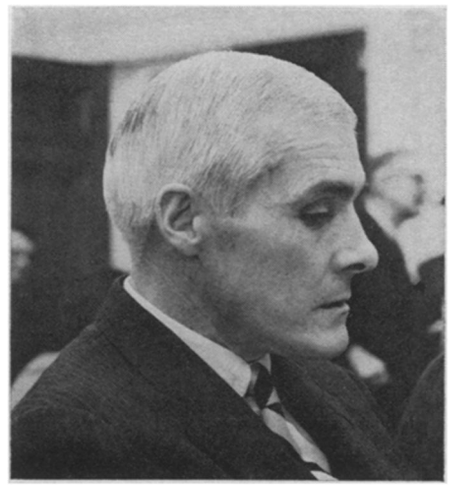
Another inheritance is the safety of food additives. Once dismissed as harmless, they are another priority issue at the new FDA. Since MSG and cyclamates were opened to question, the entire



The trauma must come to an end.



But conflict clearly lies ahead.



Decisions will be made without bias.

GRAS (Generally Regarded As Safe) list has come under suspicion. Already Edwards has contracted with the Academy to devise a methodology for their evaluation. And he has established an in-house committee to advise him on priorities governing which of them should be examined first.

Another whole question is the general level of scientific talent at FDA. Rep. Paul Rogers (D-Fla.), second-ranking Democrat on the House Subcommittee on Public Health and Welfare, has proposed the possible transfer of FDA's scientific responsibilities to the prestigious National Institutes of Health.

The idea does not sit well with the new commissioner.

"That," says Edwards, who plans to discuss the proposal with Rogers as soon as possible, "would destroy the FDA. It must not be turned into nothing more than a policeman. While we have some weak scientific talent in this agency, we also have some that is very strong, and we plan to bring in more." What he seeks is a middle ground. "While I would like to create an atmosphere for creativity and research here," he declares, "I do not think FDA can, or should, be imbued with an academic atmosphere like that at NIH."

Among the new talent Edwards is expected to bring in are Drs. James Grant and Henry Simmons. Dr. Grant, who is reported to be the man in line for the job of deputy commissioner, served on the staff of the recent White House Conference on Nutrition (SN: 1/10, p. 37) and may be symbolic of a new FDA direction.

In the past, the FDA has paid little attention to the food industry. Edwards intends to take that industry on now in a move to guarantee safety and nutritional quality of such processed foods as imitation milk, as he now is empowered to do with drugs. The way was cleared when Deputy Commissioner Winton B. Rankin, whose tenure went back more than 25 years to an earlier FDA, was eased out with Ley. Dr. Simmons, who trained at the Tufts-New England Medical Center in Boston and is currently with Edwards's old firm, Booz, Allen and Hamilton, is expected to be named to the Bureau of Drugs which plans research on new analytical techniques for determining bioavailability of drugs.

Traditionally and legislatively, the FDA's role has been that of the policeman of the snake oil days. Edwards's bent is to see the agency take a more positive attitude, encouraging the development of new drugs rather than simply blocking the sale of unproven or potentially hazardous ones, and taking its place in HEW as an equal to other health-related agencies in the formation of broad policy. Edwards, in short, sees no reason why the new FDA need resemble the old at all. He envisions an agency that can flexibly meet society's demands. "We must be able to shift and change the organization to adjust to our needs," he says.

The health care system in America is in trouble. Malnutrition among the poor often predisposes them to disease, yet they are the last to receive medical attention. Concern with the nutritional quality of food could serve as a first step in alleviating some of their medical problems. Affirms Edwards, "In my judgment, it is time for everyone to recognize that FDA is not an isolated agency but a part of the total health care system."

Edwards does not believe that involving FDA in broader issues would, of itself, solve its existing problems in handling its regulatory functions. But it might well increase the agency's stature, its authority and its ability to attract the kind of qualified scientist it needs if it is either to meet its present commitments or take on new ones. And that, after two months on the job, seems to be what he has in mind. □

Edwards confers with FDA counsel William Goodrich before House testimony.