bility for, the activities in space of nongovernmental entities.

When the radiocommunications conference at Geneva began, the United States was asking for allocations of 2725 megacycles for communications satellites and the Soviets were proposing some 1600 Mcy/sec. The meeting produced an agreement to allocate 2800 Mcy/sec for communications satellites; American delegates at the conference said this should be sufficient to accommodate anticipated traffic growth until the 1975–1980 period.

The new agreement makes about 15 percent of the radio spectrum available for all space services, as compared with about 1 percent allocated in a 1959 agreement which the new Geneva pact supersedes.

Increased activity in space obviously exerted pressure on the delegates to reach agreement on a revision of the Table of Frequency Allocations, which is the key to the regulations which govern radio operations throughout the world. Without such an agreement, interference from earth-based transmission would have caused chaos in satellite communications.

Ban on Bombs

No such utilitarian rationale seems to underlie the American-Russian meeting of minds which led in October to the adoption in the General Assembly of a resolution calling on all states to "refrain from placing around the earth any objects carrying nuclear weapons of mass destruction, installing such weapons on celestial bodies, or stationing such weapons in any other manner."

While this agreement not to orbit H-bombs is viewed as a corollary of the test ban treaty, there is a question as to whether the agreement marks any significant change, since the declared policy of the United States for some time has been to refrain from arming space unless someone else does, and the Soviet Union tacitly has taken the same line. This and other recent joint gestures by the two countries may fairly be taken as signs of good intentions but so far have made no appreciable difference in their actions.

One old lesson which still applies in relations between the U.S. and the U.S.S.R. is that progress in such matters as exchanges, technical cooperation, and agreement on legal principles in space cannot be taken as necessarily reflecting stable progress in basic political relations.—JOHN WALSH

FDA: Drug Agency Answers Critics by Attempting To Step Up Science, but Many Critical Problems Remain

The trouble with science in the Food and Drug Administration, a subject currently agitating the agency, the drug industry, and several committees of Congress, is that it is somewhat in the position of a penguin in the tropics: it is difficult to get it there in the first place; it requires heavy insulation from an essentially unsuitable environment; competition from more native forms of life is apt to be rough; and when all is said and done, it is not likely to feel altogether comfortable.

The FDA, which was established in 1906, is a component agency of the Department of Health, Education, and Welfare charged with supervising a variety of laws regulating the standards of foods, drugs, cosmetics, and related products shipped in interstate commerce. From the beginning its principal job has been to enforce the law, but as the products within its purview have grown more complex, the agency has come to depend heavily on scientific information to guide and support its decisions. And over the years, between its function as a "cop" and its function as a "scientist," the FDA has developed an acute schizophrenia which makes it the despair of the many critics who feel that the "cop" has gotten the upper hand.

A rundown of some of FDA's actual activities will perhaps illuminate the point. Last March, in its monthly bulletin on enforcement and compliance, the FDA reported seizure of a lobster Newburg heat-and-serve dinner in which scallops were found to have been substituted for lobster. Last December it seized half a million bags of cocoa beans on charges of insect infestation, and last February it cleared for sale canned bacon sterilized by irradiation. The current (November) bulletin reports seizure of canned tomatoes containing excess peel, a novelty toy lacking the precautionary labeling required by law, the seizure of 957 tons of contaminated food, and the initiation of 36 federal court actions on mislabeled or substandard drugs, therapeutic devices, antibiotics, and medicated feeds.

These are worthy tasks, everyone is agreed that someone should be doing them, and the record of FDA for doing them well far outdistances the record of its European counterparts. But the task of distinguishing lobsters from scallops is not in the same class with the sophisticated scientific analysis demanded for clearance of a new drug, and there is considerable feeling that the enforcement officers who dominate the agency have been a bit cavalier in their treatment of science.

In the past few weeks, prodded by congressional criticism that has focused particularly on the agency's handling of new drugs, the FDA has been indulging in one of Washington's increasingly popular pastimes—an activity known as "upgrading science" or "upgrading research." FDA's reorganization plan will inject a fairly small dose of science into its enforcement-centered structure and temper, but it is not likely to silence the critics who have been calling for a complete scientific transfusion, and it leaves the Bureau of Medicine, the division reponsible for new drugs, wholly untouched. The plan's new features are the appointment of a scientist (as yet unnamed) to serve as an associate commissioner and the establishment of a National Advisory Council. The Advisory Council, to which no appointments have been made, will be composed of university, industry, and consumer representatives. It is to be patterned after the advisory committees of the Public Health Service and the National Science Foundation which help distribute research funds, but since FDA sponsors no outside research, its advisors will be in a less strategic spot to exercise real responsibility. What, exactly, it will do has not yet been figured out.

The rest of the reorganization plan, according to the official announcement, simply "adjusts existing functions and deploys the staff so that they will be able to operate more efficiently." The former Bureau of Biological and Physical Sciences will be divided into two bureaus, a Bureau of Scientific Research and a Bureau of Scientific Standards and Evaluation. The former will deal with long-range studies in food and nutrition, the latter with setting standards and tolerances of substances in pesticides, cosmetics, antibiotics, and certain drugs.

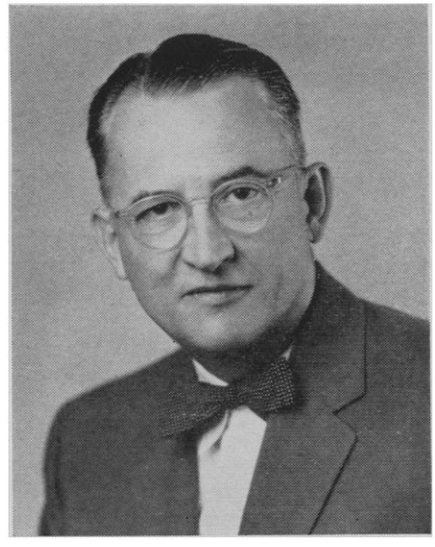
Science at Home

"Our research has to be oriented to the basic mission of FDA," Commissioner George P. Larrick commented last April, "and it would be impossible . . . to get scientific results directly and immediately useful to an enforcement agency by relying solely upon

research conducted in some other organization." Science in the FDA has always been, and will continue to be, based on the idea that it can best be done at home. Top FDA officials, usually nonscientists, have traditionally expressed satisfaction with this arrangement. But both outside and inside critics have long recognized that low salaries, crowded laboratory conditions, the enforcement orientation of the work, and the comparatively lower status of scientific, relative to administrative, personnel have produced difficult recruiting problems, and that FDA's scientific staff work, even granted its special nature, is not generally considered to be first-rate.

Senator Hubert Humphrey (D–Minn.), one of the agency's severest critics, has been studying the FDA as chairman of a subcommittee of the Government Operations Committee. He has already made public his dissatisfaction with the agency's plan. "Comparatively little is accomplished by mere establishment of a new post . . . or by retitling and shuffling other science units," Humphrey said. "FDA must become more than a regulatory agency with a few scientific activities. It must become a regulatory-scientific agency with a stature as high as that of the National Institutes of Health. It is not going to gain NIH's reputation by a game of 'musical chairs' or by merely inventing new titles on its stationery or on office doors."

FDA plans to keep a close eye on its advisory panels (in the new setup, all roads lead to the Commissioner's office), for it has had little experience with such committees, and the experiences it has had recently have given it a lot of headaches. A special panel that recommended that antibiotics be withdrawn from cold remedies in both prescription and nonprescription use (on the ground that they were useless against colds) raised such a violent storm in the medical profession and the drug industry that the agency is considering reconvening the panel. A pronouncement by another panel that the oral contraceptive Enovid was not implicated in incidences of thrombophlebitis, and that it was generally safe for use, is gradually becoming the focus of an intense debate. On the other hand, a six-man permanent advisory committee on investigational drugs, headed by Walter Modell of Cornell Medical College, which has been helping FDA iron out some serious problems con-



George P. Larrick

nected with the administration of the 1962 drug laws and regulations, has, apparently, been very successful in widening contacts between the agency and the scientists whose work it affects, and in smoothing out specific irritations between them. Modell's committee—the agency's first permanent advisory group—meets monthly, and is responsible to Commissioner Larrick. It was set up as a dry run for similar panels, and it is now expected that advisory panels on other problems will follow its model. The advisory committees are to be coordinated by a new appointee, Clem O. Miller, who comes to the job from posts at NIH and the National Academy of Sciences, preceded by 19 years with the drug industry. A danger will be, as Senator Humphrey pointed out, that "some people . . . would apparently like to set up some 'senior panel' over FDA and stack the panel. Their hope is apparently to have the panel, then exercise a veto over any of FDA's drug decisions which self-interest groups don't like."

FDA's scientific problems are most acute in its Bureau of Medicine. The bureau, which has the agency's highest turnover rate and is the target of perhaps the most intense pressure from industry, recently was reorganized to help it cope with the increased work load that followed passage of the new drug laws in 1962. The laws now require proof, from the manufacturer, of the efficacy as well as the safety of proposed new drugs, more detailed information on drugs under investigation than was formerly asked, and closer liaison between FDA and drug researchers on the progress of such investigations.

The new laws greatly strengthen the government's control over the marketing of drugs; they grew out of the Kefauver investigation and got the final push, in a reluctant Congress, from thalidomide. The last time the drug laws were strengthened, incidentally, in 1938, it was in response to a tragedy in many ways parallel to thalidomide: the proposal had been stalled in Congress for 5 years when over 100 people suddenly died from taking a drug, "Elixir Sulfanilimide," which had been inadequately tested by the manufacturer. The new law was then speedily enacted.

Since August 1962, roughly the period of its reorganization, the Bureau of Medicine has been without a director. A description of what took place when the last director was appointed, in May 1959, will give some idea of what is going on now. At that time the drug industry was fighting to make sure the post went to an FDA career civil service official and not to a political appointee. Here, in the words of the "Pink Sheet," an authoritative, inside drug-trade newsletter available only to industry (obtained here as part of an exhibit prepared by Senator Humphrey), is why: "Even if Flemming [then Secretary of Health, Education, and Welfare Arthur Flemming, who was to make the appointment] wants to keep the FDA 'politically pure,' he may need a strong expression of views from the regulated industries to help withstand pressures from party job seekers. . . . While industry may have little to fear from any topside FDA political appointment made by the Eisenhower administration," the "Pink Sheet" continued, "a break in the career and merit tradition . . . could pave the way for potential difficulty after some future national election." After the industry mobilized to present its views to the Secretary, an FDA career officer was appointed medical director.

Drug Decisions Under Pressure

This is the generalized framework. In specific situations, representatives of a drug company frequently make FDA offices an extension of their own. The record shows how Frances Kelsey, the physician responsible for evaluating the new-drug application for thalidomide, was plagued with telephone calls and visitors urging her to say when the drug would be released and telling her

of the financial impact of delay on the company. In dozens of cases the record is similar; the agency's position, according to Larrick, is that "it is up to the particular physician whether he minds having drug representatives around." In practice, however, physicians who have been unwilling have found company representatives hard to dismiss.

The same issue of the "Pink Sheet" tells the following story about the "nonpolitical" appointment, in 1953, of the present Commissioner of Food and Drugs, George P. Larrick, who began his career with the agency as an inspector in 1923. According to the newsletter, "because Crawford [the former Commissioner] had delayed public news of his impending retirement, it took heroic efforts on the part of industry to maintain the FDA career tradition for the top spot. Brad Mintener," the newsletter continues, "a long time personal friend of President Eisenhower's, went to the White House on the matter, and subsequently agreed to resign his post in private industry to become Assistant HEW Secretary, thus insuring Larrick's appointment as FDA Commissioner."

The post from which Mintener resigned, incidentally, was that of vice-president and general counsel for Pillsbury Flour Mills, an outfit within the regulatory purview of Food and Drug. Mintener has maintained his interest in affairs of the agency: he was a member of a special citizens' advisory committee whose report, in addition to suggesting a scientific overhaul, also encouraged FDA to replace its stress on law enforcement with a plea for self-regulation by industry. Mintener is now serving as a lawyer for Richardson-Merrell, a firm currently under study by a grand jury for possible law violation in submitting questionable data to the government on one of its products (Mer/29), which was later removed from the market at the request of FDA.

Mintener's career is a useful example of the pattern of relationships between the agency and the industries it is charged with regulating. In recent years the Bureau of Medicine in par ticular has been a training camp for high and profitable positions in the drug industry. An extraordinary number of people have slid easily from one to the other, and their example sets a tantalizing image before those physicians who may be called on to make decisions contrary to a company's hopes.

Does FDA have a pro-industry bias, as has so often been charged? Not exactly, although Commissioner Larrick is proud rather than sheepish about the fact that his ex-lieutenants have done so well for themselves, and regards it as a tribute to, rather than an indictment of, his work. The problem is more one of a general temper of agreeableness, a feeling that the other guy has a point, even when a serious public health issue may be at stake. "My philosophy," Larrick said in a recent interview, "is that people in industry are by and large just about as honest as people in government." By and large, in Larrick's experience, this has been the case—the antibiotics division is just recovering from disclosures which caused the resignation of its director—but it is no tribute to either. Larrick's trust in and respect for industry is not reciprocated, principally because the agency must enforce laws the industry does not welcome, but partly because industry would like to see them enforced in some other way. Just how has never been clear, although there is a lot of grumbling that there should be less enforcement and more cooperation. Other critics point out that the degree of "cooperation" seems extraordinary. The Commissioner's desire to be liked by everybody is not about to be fulfilled.

Who Investigates New Drugs?

Richardson-Merrell, the company which must bear the crosses of the attempt to introduce thalidomide in this country and the grand-jury investigation of Mer/29, is implicated also in another problem that has been giving the Bureau of Medicine much trouble—the problem of drug applications containing studies made to order to prove a point, or, in some cases, actually fabricated test results. Drug companies pay generously for outside testing of new products and the anxiety to please the patron at times interferes with the zeal for objectivity. One investigator, a Maryland physician named Bennet A. Robbins, has recently been indicted by a grand jury for submitting falsified data on Mer/29 to the company, which then submitted them to the government. Robbins made drug studies for at least a dozen other companies as well. A related problem is that of the qualifications of the people reporting on new drugs, even when they are honest.

How did the FDA respond to the disclosures on Robbins and Mer/29? In August 1961 a physician then new to the Bureau of Medicine wrote a memo to the bureau chief, William Kessenich, suggesting that a curriculum vitae of each clinical investigator be included in a company's presentation to FDA of a new-drug application that included his work. "In this way," the memo noted, "we can form some idea of the value of his contribution in establishing the safety and efficacy of the drug."

The following month, according to another internal agency memo, the Medical Bureau adopted the policy of keeping such a file, but only on those investigators who were known to have contributed "incredible reports." "For this file to serve its intended purpose," the memo states, "it should not contain the names of investigators who simply are substandard, poor reporters, overly enthusiastic, etc. Instead it should contain the names of those for whom there is good reason to suspect untruthfulness, psychosis or dangerous incompetence and irresponsibility."

When, in April 1962, Commissioner Larrick was able to attract a very prestigious physician, Charles D. May of New York University's School of Medicine, to take on the heavy burdens of director of the Medical Bureau, his candidacy was quashed by someone else in the department (although outside FDA) on the grounds that he was "too controversial" a figure. May had published in a medical journal an article detailing, with illustrations, what he regarded as the excesses of drug advertising—a particularly touchy point with the industry. Since May's experience, the campaign to get a Medical Director has run out of steam, and although agency officials profess to believe that salary limitations are the cause of their troubles (the post pays $20,000 a year), there is plenty of evidence that the nonfinancial restrictions are just as important as the financial ones in discouraging good men from taking the post.

Similar problems are expected to beset appointments to the new scientific posts created by the reorganization plan; FDA traditions, even outside the Medical Bureau, do not hint at an easy future for untrammeled science or a free hand for the responsible science administrators. FDA's reorganization plan falls "far too short," Senator Humphrey pointed out, and the skeletons in the closet will not easily be displaced.—ELINOR LANGER