New Drugs: Is Government Supervision Adequate?

MORTON MINTZ

"THE MORE we have examined the handling of the new drugs by the Food and Drug Administration," Hubert H. Humphrey told the Senate last October, "the more we have been surprised, shocked and disappointed . . . Often, testing has been going on in a manner which should have sent shivers down the spine of the medical profession . . . drugs intended for use by victims of chronic disease—day after day, year after year—were released by FDA even before—I repeat—before—chronic toxicity tests had been completed on animals . . . shocking reports of injuries and deaths to test patients, as received by drug companies, have often gone unreported to FDA, or have been downgraded by skillfully contrived half-truths, or have been reported accurately to FDA, but virtually ignored. . . Drugs have been approved which FDA now admits should never have been approved. Drugs have been kept on the market long after FDA admits they should have been eliminated . . ."

Senator Humphrey made these disclosures on October 3, 1962, just as the Kefauver-Harris drug-reform bill was being enacted into law. Many of its provisions, such as the requirement that experimental drugs be properly tested on animals before being tested on human beings, go a long way toward correcting the drug abuses that have been making headlines since Senator Kefauver began his investigation of the drug industry three years ago. Under the new law, the Secretary of Health, Education and Welfare (HEW) can order a drug off the market instantly if there is evidence that it is an imminent hazard to the public health; drug companies must list the side effects of their products in their advertising; and a new drug must be proved "effective" as well as safe before it can be marketed. Furthermore, physicians must obtain the consent of patients before giving them experimental drugs, unless this is deemed not feasible or not in the patient's interest.

The FDA, moreover, has been given greater powers for factory inspection and quality control. In addition, tighter regulations for human testing proposed last summer by Anthony J. Celebrezze, the new Secretary of HEW, went into effect this February. These require that the FDA must be notified of *all* clinical (human) trials of new drugs, and that the FDA must be kept fully informed of what happens during testing. The clinical testing must be properly planned and executed by qualified investigators, and again must be based on adequate animal studies.

BUT THE EFFECTIVENESS of the new law and of the regulations depends greatly on the organization that exists to administer them. Senator Humphrey, the only licensed pharmacist in Congress, is beginning hearings on the FDA this month, but the Senate Majority Whip has already gathered enough evidence in the preliminary investigation by his Government Reorganization subcommittee to cast grave doubts on the agency's use of the power it already had, let alone its ability to exercise more. And Senator Everett M. Dirksen, far from being encouraged, found in the belated issuance of the new HEW regulations "an unparalleled example of bureaucratic inertia." The fact is that the FDA could have issued them at any time since 1938.

That year marked the passage of the first significant drug-safety legislation since the FDA was established fifty-six years ago. It resulted from the disastrous carelessness of a manufacturer who the year before had marketed sulfanilamide in liquid form, using an automobile antifreeze as the solvent. More than a hundred people died. The 1938 law prohibited the sale of any new drug unless the FDA allowed an application for it to become effective. The FDA's decision was to be based on its evaluation of the animal and clinical testing reported by the manufacturer in his application. It was ruled that human testing was to be under the direction of an expert "qualified by scientific training and experience to investigate the safety of drugs." The FDA, however, has never set standards for an "expert," on the debatable ground that to do so would interfere in the practice of medicine. Even if this premise could not be challenged, the fact is that clinical testing is sometimes performed by research scientists who are not physicians. The new HEW regulations, moreover, set higher standards for the initial clinical tests than for those which follow, and their adoption by the FDA would seem to imply that the FDA agrees that it had some rights to set standards without interfering in the practice of medicine. Though FDA Commissioner George P. Larrick has complained that he could not find a consensus on the definition of an "expert," he has never asked professional or industry groups to help him obtain agreement and arrive at workable definitions. Nor did the FDA regulate or require reports on drug testing on humans.

The FDA was concerned only with the testing done on drugs for which marketing applications were filed. Currently, the agency receives an average of 375 new-drug applications a year, but manufacturers have been testing four to five times as many without reporting them. In 1959 alone, manufacturers tested 1,900 new drugs on humans. Since the Second World War the drug industry has expanded tremendously, and ninety per cent of today's prescriptions are for drugs that were unavailable twenty years ago. Meanwhile, qualified investigators are in increasingly short supply, and some manufacturers have decided that the mere possession of an M.D. or Ph.D. degree in basic medical science is sufficient for clinical testing. "Nobody knows," Humphrey told the Senate, "how many thousands of drugs have been tested, have caused harm, have been shelved, and never reported, never discussed . . . the most dangerous part of the iceberg has lain below the surface."

Of Mice and Men

Though the new regulations finally require that the FDA be informed hereafter on all clinical testing while it is in progress, its past performance in evaluating the relatively few medical-research reports it did get has not been reassuring. Even less reassuring has been its anaesthetized response to various cries of alarm.

"We firmly deny," Commissioner Larrick told Senator Kefauver's subcommittee in June, 1960, "that new-drug applications have been allowed to become effective on the basis of inadequate laboratory and clinical investigation work." The sixty-one-year-old commissioner has been with the FDA for forty years. In 1955, a year after he became head of the agency, a Citizens Advisory Committee had found cause to urge the FDA to develop better methods for evaluating new drugs. In June, 1960, Dr. Barbara Moulton, a former FDA medical officer, testified before the Kefauver subcommittee that the situation was "extremely dangerous"; in October of the same year she presented extensive evidence to document her charge, and in September a special committee of the National Academy of Sciences National Research Council called for remedial action "with the least possible delay."

In July, 1961, Dr. Louis Lasagna of Johns Hopkins University gave the Kefauver subcommittee some insight into the quality of animal testing that sometimes preceded the clinical testing: "I have been approached to start human testing of a drug," he said, "with the only information available being the amount of drug necessary to kill fifty per cent of mice receiving the drug in one intravenous dose."

There were warnings from the agency itself. In October, 1961, an FDA statistician, drawing on thirteen years' experience, said in a paper presented at a conference of FDA's top officials: ". . . the low quality of research data in NDA's [new-drug applications] is general and not isolated . . . Unfortunately for the medical officers, they must within short periods of time make decisions one way or another . . . they are forced to gamble; the information which they need to reduce almost to zero the risks of an incorrect decision too often is unavailable to them, because of weaknesses in research methods . . ."

BUT SUCH CRITICISM had little real impact on the FDA hierarchy or their superiors in HEW—until the scandal about the thalidomide sleeping pill. A number of details in that story, as brought out by Senator Humphrey's subcommittee, amply illustrate the shortcomings of FDA's head-in-the-sand posture about drug testing.

Smith, Kline & French Laboratories of Philadelphia tested thalidomide in 1956-1957, without any reported deformities resulting among 875 patients. Not having required that it be informed, the FDA knew nothing of this until March, 1962. In September, 1960, the William S. Merrell Co. of Cincinnati filed an application to market the sedative. It came out later that Merrell and three other subsidiaries of Richardson-Merrell, Inc., ultimately distributed 2.5 million thalidomide tablets to 1,267 physicians for "experimental" use.

About a month after Merrell had first applied to the FDA, it issued to its sales force a manual on how to present physicians with its clinical-testing program for Kevadon, its brand name for thalidomide. "You can assure your doctors that they need not report results if they don't want to," the manual stated, "but that we, naturally, would like to know of their results. Be sure to tell them that we may send them report forms or reminder letters, but these are strictly reminders and they need not reply . . . Let them know the basic clinical research on Kevadon has been done.

"Don't get involved by selling a basic clinical research program instead of Kevadon," the manual continued. *"Appeal to the doctor's ego —we think he is important enough to be selected as one of the first to use Kevadon in that section of the country* . . . Don't forget that you are a salesman, a professional salesman."

Perhaps such an approach to testing helps explain why the former chief medical director of the Veterans Administration, Dr. William S. Middleton, has found that "the desultory returns from over 1,200 physicians . . . could have no scientific significance or validity. Yet," he added, "this formula for deriving new drug introduction and acceptance has obtained for many years." When the FDA finally investigated last summer, it discovered that only 276 of the 1,267 physicians had reported to Merrell in writing on their clinical trials, and further, that at least one-fifth had not signed the statement of investigative qualifications that FDA regulations required the manufacturers to obtain.

ON NOVEMBER 29, 1961, a year after the company had filled its application with the FDA, Merrell learned from West Germany that thalidomide had been associated with birth deformities. The next morning it notified Dr. Frances O. Kelsey of the FDA, who had been withholding approval of the drug. At that point, Commissioner Larrick could have issued a public warning—the very course recommended by Dr. Herman I. Chinn, our deputy scientific attaché in Bonn, in a dispatch relayed to the FDA and HEW in January, 1962. Larrick, however, chose to let the company handle the matter.

Why the FDA didn't undertake an immediate effort then to retrieve the drug puzzled Senator Jacob K. Javits (R., New York), among others. He

asked Commissioner Larrick, during the preliminary investigation by Humphrey's subcommittee, what happened when Dr. Kelsey got the information.

JAVITS: "Then did you just talk to the company in general?"

LARRICK: "It was not conclusively proved at that stage."

JAVITS: "When was it?"

LARRICK: "There was strong circumstantial—there would be people who would give you an argument about it now . . . who would say that the problem here has been exaggerated."

Larrick admitted that the FDA could accomplish the retrieval of drugs more effectively than any company, but added that he was "not quarreling" with what Merrell did.

What Merrell did, according to its own report cited by Humphrey's subcommittee, was send a warning letter in early December, 1961, to its "active" thalidomide investigators, although the FDA was unaware that they represented only one-tenth of the physicians who had received the experimental tablets. Three months later, Merrell and its affiliates finally wrote all of them asking them to destroy or return the remaining supplies. "At the time," Commissioner Larrick said later, "I thought that was sufficient."

That it was not sufficient has become by now a familiar story. After reports published in mid-July of Dr. Kelsey's achievement in blocking the application of thalidomide, the FDA embarked on a crash program to ferret out the unsuspected numbers of tablets that had got into the hands of the public. A month later, the FDA, finding that substantial quantities were still at large, had to plead with the public to clean out medicine chests and flush all unidentified pills down the toilet. Nearly twenty-one thousand persons in this country had obtained thalidomide from both foreign and domestic sources, and at least nine women who took it during pregnancy bore babies without arms and legs.

Drugs on the Market

Recently the FDA has decided that it does have a quarrel with Merrell, and it has asked the company to show cause why its method of distributing the thalidomide tablets should not be referred to the Justice Department for possible legal action. Thalidomide, at least, was never allowed to go on the market. Other drugs that had to be recalled were. One was Marsilid, and in its case the FDA displayed what can be called remarkable patience in dealing with its manufacturer, Hoffmann-La Roche of Nutley, New Jersey. Marsilid was first approved in 1955 for use, with limitations, in treating critical cases of tuberculosis. Later it was found to have effect as a psychic energizer, or "happiness pill," and the company applied for a supplemental new-drug application for its use in treating mental depression. But Marsilid also was associated with 246 known cases of hepatitis (liver damage), fifty-three of which resulted in death. At least 400,000 patients used it. Hoffmann-La Roche, it would seem from the account given Humphrey's subcommittee by the FDA, was rather casual in reporting some of the hazards of Marsilid. Although it received the first reports of deaths and injuries in connection with the drug in September, 1957, it did not mention liver damage to the FDA until half a year later, in February, 1958, when it asked permission to change the label. By the end of 1958, the adverse reports on a variety of side effects were mounting and the drug company asked for another supplementary new-drug application under which a brochure listing new restrictions on its use would accompany the drug. The FDA, in turn, suggested a strong warning to be printed in bold type on the label.

The strong warning was not put on, however, and during the next year the company continued to market the drug. Nonetheless, the FDA approved the supplemental new-drug application in January, 1960. Seven months later, it renewed its request for the stricter warning label. Finally, in September, 1960, its request was complied with, but the sale of Marsilid under a proper warning label was short-lived. It was withdrawn from the market the next January, because, as the FDA put it, "drugs with similar therapeutic usefulness but with greater safety were available."

But these drugs had been available and marketed since 1959. Moreover, the five Veterans Administration hospitals that had tested Marsilid had discarded it much earlier, between December, 1958, and June, 1960, because of reports of "severe liver damage," "excessive toxicity" and—in a hospital system with more psychiatric patients than any other in the world—"limited usefulness."

Why did the FDA permit Marsilid to remain on sale until 1961? Larrick's explanation is that it was regarded as valuable in "near deathbed cases," but this was true only initially when it was used to treat tuberculosis, not mental depression.

Larrick has said that he is "proud" of the FDA's handling of Marsilid. Dr. Moulton, on the other hand, seemed prouder of the press when she testified about an earlier request to change the label. Marsilid's hazards, she said, "were well known in the Bureau of Medicine long before the newspapers began to carry reports on the subject. When this occurred there was prompt if not entirely effective action by FDA to revise the labeling. Prior to the newspaper publicity, however, we raised our voices in vain."

ANOTHER DRUG that had to be withdrawn from the market was MER/29, a Merrell product intended to reduce the amount of cholesterol in the blood, although the role of cholesterol in heart disease is controversial. Senator Humphrey has called the FDA's handling of the application for this drug "shocking . . . a sharp indictment of the FDA itself—its laxity, its tardiness in seeking to remove the drug from the market, its failure to protect the public interest."

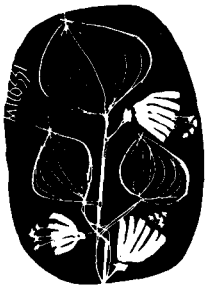
The new-drug application for MER/29 was filed in July, 1959, and was assigned to a thirty-two-year-old FDA physician who had only recently completed his residency in internal medicine. He was promptly contacted by Merrell's F. Joseph Murray. "The company was extremely anxious to get the drug on the market," the young man recalled. However, the report of the FDA pharmacologists on MER/29 was unfavorable. And, the physician said, he was aware that scientists at the National Institutes of Health were concerned about MER/29's effects. (Later, their research showed that in blocking the formation of cholesterol,

MER/29 largely defeated its purpose by causing an abnormal accumulation in the blood vessels of a related fatty substance, desmosterol.) The FDA physician felt that MER/29 might be helpful in dealing with arteriosclerosis. Nonetheless, he repeatedly held back approval by judging the application incomplete because it failed "to report clinical studies in full details." But twenty-two days after he again made such a judgment, on April 19, 1960, FDA's young medical officer let MER/29 be marketed—before, according to Senator Humphrey, the "full details" were in, and even though he regarded its value as "theoretical." The new drug went on sale, not because its effectiveness against heart disease and arteriosclerosis had been established but "solely on the evidence of safety."

By September, 1960, the FDA had so many disturbing reports about the effects of the drug—cataracts, baldness, changes in hair and skin color—that it asked Merrell to submit a supplemental NDA and to revise the label to warn against use of MER/29 in women of child-bearing age. Meanwhile the adverse reports continued to pour in. On November 16, 1961, FDA scientists recommended that the drug be withdrawn, but the FDA administrators did not suspend the application. For a total of two years the Merrell product, heavily advertised in medical journals, was profitably sold as a prescription drug and taken by more than 300,000 persons. Then in March, 1962, by sheer accident, the FDA learned, as it reported to Humphrey's subcommittee, that reassuring data in the NDA from tests on monkeys "had been falsified." (The FDA investigation of this has been followed up by a Federal grand jury.) In April, Merrell recalled the drug. In May, Larrick cited clinical evidence showing "that the drug was unsafe," and suspended the application. In August, the FDA admitted that the decision to allow marketing had been a mistake.

That decision was made two months before Larrick had told the Kefauver subcommittee that it "is extremely improbable" that falsified data would not arouse the FDA's suspicion, and "categorically" denied that the review of new-drug applications "may in some instances have been superficial." The criterion for release of a drug, he said, is whether "the good in saving lives and alleviating suffering clearly outweighs the hazards."

By a curious aspect of the FDA's decision-making machinery, approval of a new-drug application can be given by a medical officer "on his own initiative, without review by any of his colleagues," according to Dr. Moulton. And as Commissioner Larrick has testified, the medical officer's decision "represents an institutional decision that the drug is safe for use under the conditions and in the dosages prescribed in the labeling." But when a medical officer believed a drug to be unsafe and wanted to deny its approval, the situation was different. According to Dr. Moulton, he had to have "the unanimous support of the Chief of the New Drug Division, the Director of the Bureau of Medicine, the Commissioner, and usually also the Director of the Bureau of Enforcement and the General Counsel's office."



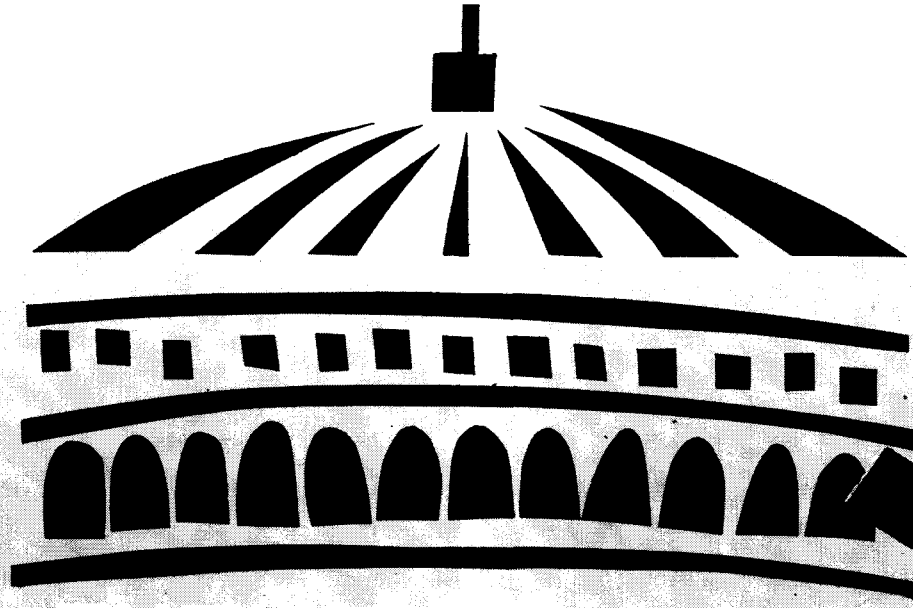
The agency statistician described an FDA physician's plight quite well in the internal report already cited. "The medical officer," he said, "is in an untenable position because if he were to adopt the view that an application were incomplete unless the research supporting it were properly conducted, he would pass few applications. But this would result in a major shift in FDA policy, and have a far-reaching effect on a major industry. Clearly, a shift of this magnitude is not to be made by the medical officers."

In view of the medical officer's responsibilities, however, it seems strange, as Senator Humphrey points out, that the physician handling the NDA for MER/29 "never consulted with the National Institutes of Health *before* the drug went on the market. Nor did NIH initiate such consultation," although it "has been supporting considerable research on cholestrol-lowering substances."

This lack of communication between two branches within HEW particularly irritated Senator Humphrey, who for years has been trying to bring about a systematic exchange of drug data between the FDA, the hospital systems of the Public Health Service and the Defense Department, and the NIH, which "has the greatest pool of drug research information in the world." He has found "little systematic communication," even among the institutes of the NIH. The thalidomide scandal has brought Senator Humphrey some measure of success, however. The NIH, for example, is now methodically feeding the FDA the result of an electronic data-processing survey of fifty thousand pregnancy case histories, yet NIH's director acknowledges that he is "not at all certain we would have done" precisely that if the thalidomide story had not been publicized.

As for the FDA itself, Humphrey claims that its high officials "have apparently been content" to let the agency "stagnate as a scientific backwater," despite the "deep interest of a few extremely talented M.D.'s and pharmacologists." The FDA's isolation has made it dependent, in many cases, on plain luck. The "falsified" MER/29 monkey data came to FDA's attention only because an FDA inspector happened to ride in a car pool with the husband of a woman who had quit her job in Merrell's animal research laboratories. Dr. Kelsey's determination to block the marketing of thalidomide was decisively hardened because she "chanced" to read a letter to the editor of one of the world's four thousand medical journals, a letter that associated the drug with peripheral neuritis.

Humphrey considers it "a miracle that we learn as much as we do." Though many sources—such as pharmaceutical companies, the FDA, hospitals, the Veterans Administration, and the NIH—compile data on reactions, they do not co-operate "to any real extent" with each other. According to Humphrey, the individual clinician "tends to be so busy that often his reports are a fraction of what they might be. This is a crucial point; it explains in part a tendency



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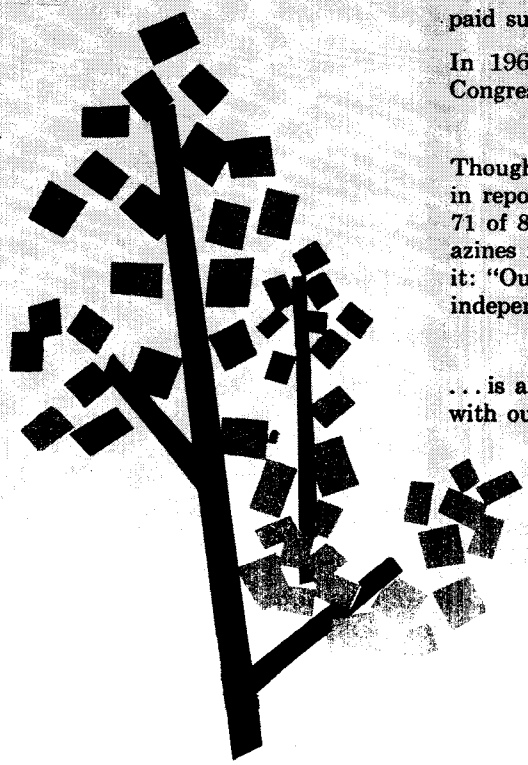

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to overvalue fragmentary favorable reports." Although the FDA itself has had a small reporting program, involving at most 150 out of the nation's six thousand hospitals, Humphrey's subcommittee has "yet to find anyone who has substantially used this program or anyone at the reporting end who had received useful 'feed-back' from it."

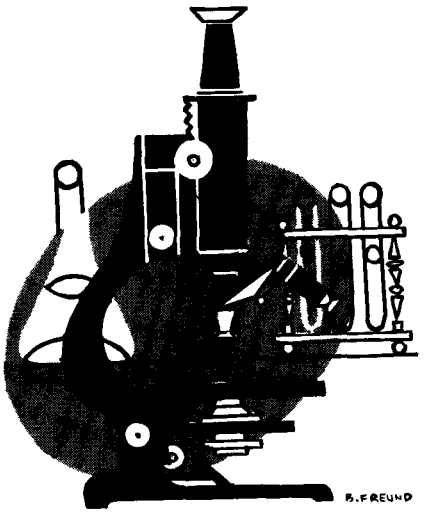
Consequently, Humphrey found it "incredible" that the FDA had not made "systematic use" of outside consultants. Although the agency supplied him with a "nominally" long list of outside consultations, Humphrey found it "completely misleading." "It pretends that an isolated telephone call or letter or short visit for a curbstone—I emphasize—curbstone judgment represented 'consultation.' I am surprised," he continued, ". . . that FDA states consultation has 'routinely' occurred. The men . . . inside the agency who have fought and begged for outside consultation . . . have been discouraged at worst, or ignored at best, from above."

Pressure and Persuasion

The atmosphere inside the agency apparently has been one of considerable discouragement from above, accompanied by constant harassment from some drug manufacturers. Dr. Moulton has told of cases in which orders came "from above" for medical officers to certify drugs about which they had doubts, the justification being that the manufacturers should "be in a much better position to judge their safety." She contended that in many of its activities the FDA had become "merely a service bureau" for the drug industry.

Dr. Moulton has also complained that manufacturers' representatives spend "three or four days a week in the New Drug Branch offices, arguing each point step by step, wanting to know and being told exactly where the application is at all times and which chemists and which pharmacologists are assisting in its review."

One physician who worked on the application for Marsilid, the "happiness pill" associated with hepatitis, left the FDA shortly thereafter to work for Marsilid's manufacturer, Hoffmann-La Roche. The letter he authorized, while in the FDA, to warn



prescribing physicians about Marsilid's side effects did not impress Dr. Moulton, who informed the Kefauver subcommittee that "the important facts were obscured by so much irrelevant material that [it] failed to serve as an effective warning."

The FDA's involvement with the industry was brought home forcibly by the disclosures that the head of its Division of Antibiotics, Henry Welch, was writing articles for professional journals that brought him a profit, as Senator Douglas told Congress last summer, of "approximately $288,000 . . . from the firms he was supposed to be regulating." Dr. Welch was "allowed to resign" in 1960, when the Kefauver subcommittee fully explored the matter, but even then, as Kefauver found, his superiors "were derelict in the performance of their duty . . . they whitewashed it. . . . He was not even asked by [FDA's top officials] how much his 'honorariums,' as he called them, amounted to. That was an outrageous conflict of interest." (The matter is now before a grand jury.)

WHEN the new-drug bill was passed in Congress, both Senator Kefauver and Senator Douglas voiced their concern about the ability of the FDA to administer it, and both called for "an infusion of new blood." Senator Humphrey has made it clear that he has "little reason for confidence in the policy echelons of FDA," but does not attack Commissioner Larrick personally; indeed he calls him "a faithful and dedicated public servant." Last October, however, a second Citizens Advisory Committee, reporting on a year-long study of the FDA, recommended that its top posts should "no longer . . . be held primarily by persons whose backgrounds have been as inspectors, but should include scientists with broad experience as well." The commissioner's post was specifically included. Larrick, who is not a college graduate, joined the FDA as an inspector in 1923 and rose through the ranks, becoming commissioner in 1954. His deputy commissioner started as an inspector in 1925.

But the chairman of the Citizens Committee, George Y. Harvey, who has since become a consultant to HEW on FDA *matters,* blunted what appeared to be a committee attack on Larrick. He told a press conference that the report was directed "to the future," and that Larrick could carry out its recommendations if he takes them "to heart and attracts the right kind of people."

Attracting and holding the right kind of people may prove exceedingly difficult. Dr. Moulton had quit in disgust so that she could speak out. A former scientific director, Dr. Paul L. Day, found life at the FDA impossible after he had criticized the agency for its "lack of sufficient vision of its proper role in the protection of the health of the American people" and "courage to present, adequately, a bold program." He resigned.

In a recent reorganization, Dr. Kelsey was promoted to head a new Investigational Drug Branch, and she has received from the President the nation's highest honor for distinguished Federal civilian service. But generally, FDA medical officers have been overworked in thankless, glamorless, paper-pushing jobs. Under the new regulations and the Kefauver-Harris law they will get hundreds of thousands of additional reports a year. More physicians have recently been recruited for the Bureau of Medicine—twenty-two in February—but there will still be too few specialists to evaluate the highly specialized material that will be flooding in, and they still do not have an effective consulting service.

To attract and hold top scientists to the bureau, Larrick could have pushed for FDA's own research program, as Dr. Day recommended. Larrick could have pressed for exemption of more physicians from civil-

service salary restrictions, and he could have tried hard to make working conditions more attractive. He did neither.

Since 1957, while enforcement and other FDA branches have stayed put in the HEW Building, the Bureau of Medicine has been shifted from a former nurses' dormitory near the city incinerator to ramshackle structures that were not air-conditioned, and from those to a World War II temporary building.

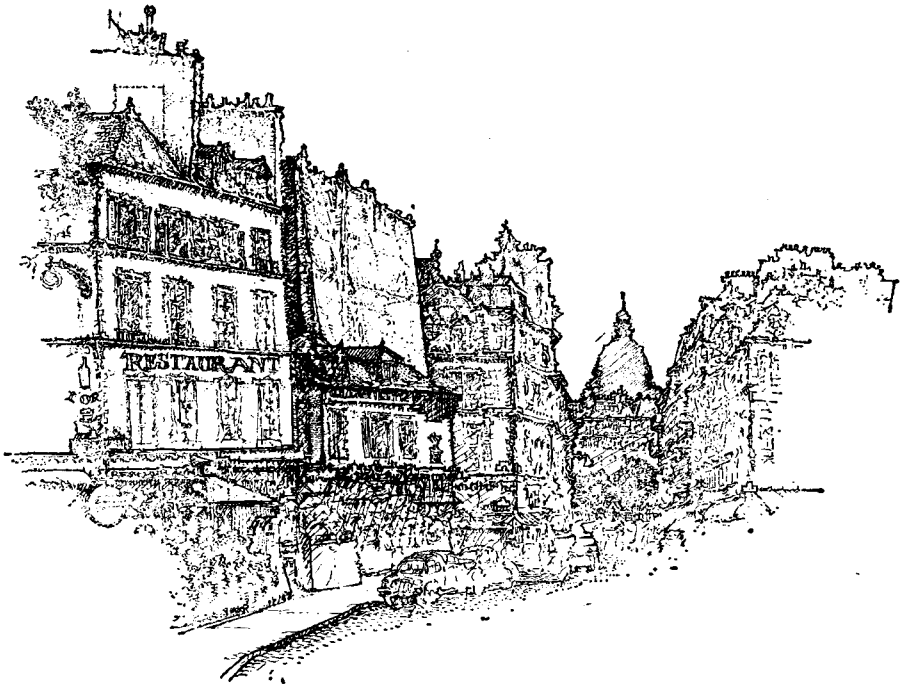
All of these quarters were distant from the Division of Pharmacology, whose work is integral with the Bureau of Medicine because it evaluates the animal testing in new-drug applications. Yet, as of early March, the bureau was destined to be moved once more, this time to a converted automobile-servicing garage in one of the most crime-ridden precincts of Washington and at least a mile from the Division of Pharmacology and other FDA scientists with whom the bureau physicians should consult.

Congress has long treated the FDA shabbily, but Humphrey has said that the price of generous treatment will be a demand for "men with drive, with initiative . . . not just 'going by the book,' by the letter of the law, but by its spirit, its tone, its fundamental purpose."

HEW is assuming that it can put new life into the FDA by teaching the old watchdog new tricks, but in and out of Congress this approach is considered excessively optimistic in view of the past handling of drug problems. Critics believe the FDA can become the great, vital agency Humphrey envisions only if the old watchdogs are replaced by a new breed of scientist-administrators.

THE HEARINGS by Senator Humphrey's Government Reorganization subcommittee this month and next will be followed by more hearings in the House. But it remains to be seen whether the FDA can continue to ignore criticism as it has in the past, or if Dr. Moulton will continue to stand by her testimony of 1960 that "hundreds of people, not merely in this country, suffer daily, and many die because the Food and Drug Administration has failed utterly in its solemn task of enforcing those sections of the law dealing with the safety and misbranding of drugs. . . ."

VIEWS & REVIEWS



The Last 'French' Composer?

ROLAND GELATT

THE VERDICT of posterity is notoriously dangerous to predict, as any critic with an ounce of prudence knows. It is safest not to hazard guesses—let alone make pronouncements—as to the enduring worth of contemporary music. Yet one must live dangerously sometimes, and it is in that reckless spirit that I write of Francis Poulenc, who died—unexpectedly and prematurely—on January 30, three weeks after celebrating his sixty-fourth birthday. For I am foolhardy enough to be confident of Poulenc's foothold on the slopes of Parnassus. He was not, admittedly, a fructifying influence; not a seminal force; not a Great Composer in the capital letters reserved for the likes of Bach and Mozart. But he was an indisputable minor master, and to me there can be no doubt whatever that his music —the best of it—will still be heard a century hence.

Poulenc defies ready classification. He once described himself as "half monk, half guttersnipe" and something of each can certainly be found in his compositions. He could be maliciously irreverent, blithely carefree. Much of the world's merriest music is included in his collected works. He could also compose in a vein of tranquil sobriety and angelic purity. Few twentieth-century musicians have written so successfully for the church. But it is a mistake to push the monk-guttersnipe antithesis too far. In much of Poulenc's most characteristic work, particularly in his songs, he is neither the clown nor the cloistered savant but simply an inspired melodist with a gift for conveying the overtones of verbal imagery in his own unique, immediately recognizable musical tongue.

Poulenc first made his presence felt, toward the end of the First World War, as the precocious scion of a well-to-do Parisian family.