most states, the committee is in close touch with the congressional delegation. Such contact is especially welcome to members of Congress since it establishes closer relations with influential members of their constituencies and provides the congressmen with an opportunity for showing the voters that they are looking after their interests.

Georgia's quest for the accelerator has involved the cooperative efforts of the Atlanta Chamber of Commerce, the State Science and Technology Commission, the State Department of Industry and Trade, the University of Georgia, and Georgia Tech. It also brought forth from Senator Richard B. Russell (D–Ga.) an attack on the geographical distribution of federal research funds. "Georgia and the other southern states," he told the Georgia Press Association last month, "are entitled to share equitably in the intellectual, scientific, and economic benefits that flow from our own tax dollars, which go to support government research. I, for one," he states, "refuse to concede that all the brains and intelligence are concentrated in a few enlightened pockets of the country such as New England, Chicago, southern California, or even Texas."

In Portsmouth, Ohio, the accelerator was the subject of a talk given by the president of the local Chamber of Commerce to the Rotary Club at a luncheon meeting held at the Elks Club. Following the meeting, the Portsmouth *Times* urged its readers to write to President Johnson "so that the administration may know that thousands of persons here are vitally interested in landing the plant."

In the state of Washington, a consultant to the Tri-City Nuclear Industrial Council was quoted as telling the Pasco Kiwanis Club that the accelerator would bring "literally thousands of small industries to the Tri-Cities." In a paraphase of the speech, the Tri-City *Herald* said the speaker "emphasized that what Tri-Citians say to their friends and acquaintances may be picked up by the Atomic Energy Commission." And it went on to quote him directly as saying, "We have to firmly believe that we can do everything necessary to make Hanford the best spot for the accelerator."

In Colorado, the Proton Accelerator Committee of the University of Colorado has been working closely with the Governor's Science Advisory Committee and various state development groups. Early last month, in an address to the Denver Chamber of Commerce, the staff director of Forward Metro Denver was quoted as saying: "Scientifically and geographically, we feel we have a strong case. What's more, our entire congressional delegation in Washington, regardless of politics, is united behind our proposal. It doesn't hurt us to have Rep. Wayne Aspinall [D–Colo.] on the Joint Committee on Atomic Energy—the body that must give final approval to the AEC selection."

In Houston, Texas, following a meeting with Representative Albert Thomas (D–Texas), the executive vice president of the Houston Chamber of Commerce said, "We have some fine support from four universities and the Manned Spacecraft Center." And the Houston *Post* commented editorially, "the presence of the space center enhances Houston's attractiveness. It has contributed greatly to the development of Houston as one of the nation's major centers of scientific research and has helped tremendously to create the sort of community which the laboratory's staff would find congenial and conducive to its work"—which shows how quickly the former have-nots can find new rationales once they have been admitted to the circle of affluence.

As things now stand, because of the large number of proposals, AEC is running a bit behind schedule in its initial screening. It expects, however, within a few days to select what it considers to be the most promising proposals for further screening by the evaluation committee that was established by the National Academy of Sciences (*Science*, 18 June). However, all proposals will be sent to the NAS Committee so that it may look over the entire field. The NAS Committee, chaired by Emanuel I. Piore, vice president and chief scientist at IBM, is expected to report by December at the latest. It may select "three or four or as many as eight or ten" sites as meeting the criteria, according to a commission official. The AEC will then make a choice, probably no later than mid-December, so as to include funds in the budget that will be submitted to Congress in January. What happens then is not certain. The White House will no doubt have a say in this business, and it is not likely that the Joint Committee on Atomic Energy will stay out of it altogether, although its membership is so widely distributed that it would be difficult to use the committee as a vehicle for favoring any one region. Finally, once the final decision is in, it will be interesting to observe the reaction of the 45 states that don't get the accelerator. If the leadership of the scientific community worked like some other segments of our society, the inevitable disappointment of these states might be regarded as a tempting source of potential support for other ventures in federal support of research and development. But there is no indication that anyone is thinking along those lines.

—D. S. GREENBERG

FDA: Scientific, Medical Groups Support Agency in Dispute with Fountain over Access to Drug Data

A congressional investigation of the Food and Drug Administration (FDA) that began over a year ago in low-keyed fashion has recently become the focus of an argument over the rightful limits of legislative inquiry into scientific and medical affairs. The argument finds Representative L. H. Fountain (D–N.C.) in a familiar but not altogether comfortable spot—at odds with a substantial portion of the medical and scientific communities.

Fountain's dispute with the FDA began when the House Government Operations subcommittee on Intergovernmental Relations, of which he is chairman, moved from the general considerations which had occupied it for nearly a year to concrete studies of FDA's handling of particular drugs. FDA's policy on giving information to Congress has only one formal limit: FDA may not disclose pharmaceutical industry secrets, such as formulas. For the rest, however, the policy is more or less dependent on political winds. When congressional-executive relations are poor (as, for example, when the Eisenhower administration faced a Democratic Congress), the rule book for executive agencies calls for a certain amount of closeness with agency information. When they are good, as they are at the moment, the word goes out that executive agencies are expected to be open and helpful. Few civil servants enjoy having their official actions prominently displayed before the public, and this openness may go against the bureaucratic grain. (A few years ago, for example, the Food and Drug Administration attempted to have the law changed to enable it to cover a wider

range of documents with a blanket of confidentiality—and one of the opponents of this move, which was unsuccessful, was L. H. Fountain, who was beginning to develop an interest in the agency's operations.)

In general, however, agencies have very little choice about supplying information. But in the present case, what seemed to the agency to be "cooperation" seemed to the Fountain committee and staff to be bureaucratic foot-dragging or, worse, deliberate obfuscation. Committee investigators did have access to the files they requested, but often the files would have inexplicable gaps, and the investigators had to make five or six trips before they felt their grasp of the situation was adequate. In addition, the staff was troubled by an agency ruling (later relaxed) that required a representative from the commissioner's office to be present whenever the staff interviewed a lower-ranking official of FDA.

At several points in the hearing, it was made clear that Fountain felt "cooperation" to be more mythical than real. But the simmering antagonisms did not burst open until the agency attempted publicly to discourage Fountain from obtaining certain documentation he felt he needed. There were two items at issue. One was a tape recording of a meeting of scientific consultants called to advise the agency on a particular group of antihistaminic drugs. The second was a list of names of patients for whom adverse reactions to an anti-depressant drug (Parnate) had recently been reported, together with the name of the reporting physician.

On the first point, officials of the agency, including Commissioner George Larrick and medical director Joseph Sadusk, claimed that handing over the tape "would interfere with cooperative relations between FDA and scientists, would prevent frank and open discussions at such meetings, and would destroy our attempt to set up good procedures." If scientists knew the tapes would be made public, Sadusk said, the result would be "stilted discussions, and our efforts to handle advisory committees would be interfered with."

On the second point, it was argued that submitting the names of doctors and patients violated the confidentiality of that relationship, and that it would hamper the efforts of the agency to elicit cooperation from doctors in reporting adverse drug reactions. Resistance in the agency was so strong that the FDA officials are known to have taken the case to Secretary Celebrezze for final decision, where they were overruled, reportedly on the basis of "conversations with the White House." The material has now been sent over to Fountain.

On the face of it, it seems likely that almost every trained scientist would support the position taken by Larrick and Sadusk. A good many already have. Fountain's efforts to obtain this material have elicited critical mail from the National Academy of Sciences, the Greater Philadelphia Committee for Medical-Pharmaceutical Sciences, and the Mid-West Committee on Drug Investigation; the communication from the Mid-West Committee was reportedly signed by 30 well-known scientists. There has also been correspondence from one unit of the American Medical Association, though no formal word from the AMA's top leaders. While none of this correspondence has yet been made public, an apparently steady theme is that this kind of activity would end by interfering with clinical investigation of drugs in general. A hostile editorial making that point has appeared in *Medical World News*, an influential medical weekly edited by Morris Fishbein, a former editor of the *Journal of the American Medical Association*. "If patients are to be faced with the threat that their illnesses and their names may be revealed in Congressional testimony," Fishbein said, "it will intensify the difficulty of securing competent clinical investigators to assess new remedies." Finally, the newly functioning medical advisory board* of the Food and Drug Administration met in July and supported the agency's position in several resolutions, including one on confidentiality of records and another on advisory boards. These two resolutions read as follows:

> One of the foundations of the practice of medicine is the confidentiality of the doctor-patient-hospital relationship. Furthermore, the reporting by doctors and hospitals of information concerning the effects of drugs to the Bureau of Medicine is extraordinarily dependent upon the preservation of this confidential relationship.
>
> We are deeply concerned, therefore, at the recent insistence of a Congressional committee that confidential records containing specific names of doctors, patients, and hospitals, be released.
>
> It is our belief that the purpose of the Congressional committee could have been properly met by obtaining records in

Surgeon General Resigns To Take University Post

President Johnson this week announced the resignation of Surgeon General Luther L. Terry and said he was seeking "the most adventurous, imaginative doctor in the country" to fill the vacancy.

The President made the announcement at the clinical center of the National Institutes of Health, in Bethesda, Maryland, where he signed an act authorizing a $280-million, 3-year extension of the NIH program of grants for construction of health research facilities. During his visit to NIH, which was the first by a Chief Executive since Harry S. Truman visited the center, he warmly praised NIH's achievements, predicted that Congress would approve additional health legislation, and toured a children's leukemia ward and a heart surgery unit. The President's press secretary said that Johnson, who suffered a heart attack in 1955, "personally feels some obligation" to the research programs at NIH.

Terry, who was appointed by President Truman in 1961, will become vice president for medical affairs at the University of Pennsylvania, succeeding Isidor S. Ravdin, who is retiring. By law, the surgeon general must be a commissioned officer of the Public Health Service, but there is nothing to prevent Johnson from commissioning an outsider and appointing him to the position.—D.G.S.

* Members of the board are as follows: Mark W. Allam, dean, University of Pennsylvania School of Veterinary Medicine; Harry F. Dowling, professor of medicine and head of the Department of Medicine, University of Illinois; Sidney Farber, professor of pathology, Harvard Medical School, and director of research, Children's Cancer Research Foundation, Boston; William M. M. Kirby, professor of medicine, University of Washington School of Medicine, Seattle; Norman Kretchmer, professor and executive head of the Department of Pediatrics, Stanford Medical Center, Stanford University; William R. Mann, professor of operative dentistry, dean of the School of Dentistry, and director of the W. R. Kellogg Foundation Institution, University of Michigan; John G. Morrison, practicing physician, Oakland, California; Arthur T. Richardson, dean of the Emory University School of Medicine and professor of pharmacology, Emory University; and Wesley W. Spink, professor of medicine, University of Minnesota, Minneapolis.

which actual names of patients, doctors and hospitals had been deleted.

We therefore recommend that steps be taken through appropriate channels so that in the future the confidentiality of these records will be preserved.

* * *

Whereas the kinds of decisions that scientists are called upon to make in advisory committee meetings are not open-and-shut and therefore require free, unrestricted and often contentious discussion in order to reach a final decision which will represent the concensus of informed opinion, and

Whereas since such free discussion requires further review by the individual members of the committee after the meeting, in order that a proper permanent record may be made, it is often necessary that the proceedings be recorded or verbatim transcripts made which will later be edited by members of the committee in establishing the final report, and

Whereas scientists would, in general, be unwilling to indulge in such free discussion if the detailed discussions were to be made available to a third party,

Therefore, be it resolved that such recordings and transcripts be held confidential and that they be used only for the purpose of arriving at minutes and recommendations which would then be approved by members of the committee, after which the recording and transcripts would be destroyed, and that under no circumstances would they be transmitted to a third party, and

Be it also resolved that a copy of this resolution be transmitted to the office of the President of the United States through appropriate channels.

Principles and Cases

There is little doubt that, as the writers of letters and resolutions evidently believe, the principles that have been associated with this dispute are of some importance to the scientific community. Unfortunately, it is not altogether clear that the principles and the immediate case are related as purely as some of the critics believe. First, some relatively minor points. In fairness to Representative Fountain, it must be said that there is absolutely no reason to believe that the confidentiality of the material would be violated through display in public hearings. It was intended for the background information of Fountain and his staff. Indeed, there is one circumstance which makes a joke of the whole issue of privacy: representatives of the drug companies marketing the antihistaminic preparations were permitted to sit in on the very meeting recorded on the tape to which FDA wanted to refuse Fountain access. (The company representatives left the room in the final hour of a 6-hour session in which the recommendations were being drawn up.) The fabled "confidentiality" of the doctor-patient relationship also has its limits: names of patients suffering adverse reactions are routinely solicited by drug companies as well as by the FDA, and in fact have been frequently seen by congressional staff investigators studying the agency, including Fountain's investigators. The agency doesn't like this, but it has been going on for several years. Why FDA tried to draw the line on Parnate remains unclear.

More important than these circumstantial arguments is the fundamental fact that Fountain did not simply invent his requests to give the agency trouble. They emerged, first, from a general feeling, which Fountain evidently shares with every other senator and congressman who has ever studied the agency, that, like other units with regulatory functions, FDA has a difficult time disentangling the public interest from the private interests of the industries it is supposed to regulate. Many critics have felt that there are times when agency decisions do not fulfill the objective of protecting the public from some of the self-interested actions of the industry. Fountain's requests also grew out of a particular context, and dealt with points on which Fountain's knowledge of the agency's activities had led him to become skeptical.

The Parnate case has an extremely complex history. Full discussion of it should await publication of the Fountain hearings, which will provide much supporting documentation. Briefly, however, the situation was this. Parnate, a monoamine oxidase inhibitor used in treatment of severe depression, was withdrawn from the market (under protest of its manufacturer, Smith Kline & French) in February 1964, after being implicated in many instances of high blood pressure and stroke, and in some fatalities. Subsequently it was permitted back on the market under new ground rules, which called for its use only in hospitalized patients or in patients under close observation. Warnings were added against its use in combination with other drugs, and the recommended dosage was reduced. Fountain wanted to know why the decision to remarket the drug—known to have been a matter of some controversy within FDA as well as outside it—was made, and what adverse reactions had been reported since it returned to the market. FDA offered some data, which the Fountain staff evidently had reason to believe were incomplete—a contention supported by the fact that FDA has found it necessary to make several changes in the statement initially submitted during the hearings. Little that had gone on in the hearings before made for an atmosphere of trust between the two parties, and the Fountain staff apparently felt that, without access to the names of patients and physicians, it had no way to verify FDA's assertions or interpretations.

An Eccentric Case History

In the case of the antihistaminic drugs, Fountain's interest was aroused by what appeared to be the drugs' eccentric recent history. The basic drugs in question are meclizine and cyclizine, which have been available for many years both on prescription and on an over-the-counter basis. They are used for treatment of motion sickness, nausea, and vertigo. A related drug, chlorcyclizine, is available on the same basis, and offered for allergies, colds, hay fever, and insect bites. In the aftermath of the thalidomide episode and the increased interest in the possible teratogenic effects of drugs that it engendered, reports began to come in from various European countries linking meclizine with a number of cases of birth deformities. Several countries, including Sweden, Australia, Denmark, and Germany, placed the drug on a prescription basis, and Italy put a warning on the label. Subsequently, animal studies conducted at the National Institutes of Health showed meclizine to be teratogenic in rats, causing cleft palate and incomplete calcification of the vertebral column, femur, humerus, and skull.

In the light of these discoveries, the Food and Drug Administration began seeking out ways to limit the possible harmful effects of the drug in this country. After having failed in efforts to persuade the manufacturers (Pfizer and Burroughs Wellcome) voluntarily to place the drug on prescription basis, change the labeling, and issue warnings to the medical profession, FDA decided to assemble an ad hoc committee whose decisions, while not binding, would be useful support for the agency's position in any regulatory action that might arise. It appears that, at the time, medical opinion within FDA strongly favored restricting use of the drug.

An advisory committee met in April

1964 and made several strong recommendations:

1) That meclizine and cyclizine be removed from over-the-counter sale and be made prescription items only.

2) That labeling of meclizine and cyclizine be revised to include the following general statement: "Safety in early pregnancy has not been established. Animal studies indicate (*name of drug*) causes congenital malformations. Clinical studies to date are inconclusive."

3) That further studies on these drugs be made, with reference to efficacy and teratogenicity.

Up to this point, FDA's record is clear. It is what happened subsequently that aroused Fountain's interest. For 9 months, nothing happened at all. On 18 January 1965, medical director Sadusk transmitted the recommendations to Commissioner Larrick, stating that they were endorsed by the Bureau of Medicine. Two or three days later, Sadusk changed his mind and asked that the recommendations be withdrawn. The following month, Sadusk set about to reconvene the advisory committee. When it met again one year later, in April 1965, its recommendations were startlingly different. According to the hearing transcript, three motions (and evidently only three) were placed before it. The first, that the status quo regarding the drugs in question be maintained—that is, that they remain freely available, no mention being made of possible hazards in pregnancy—was voted down. The second, that the committee be reconvened to review "other selected drugs that may have teratogenic effects in lower orders," was passed. The third was a motion to the effect that "the over-the-counter preparations of meclizine, cyclizine and chlorcyclizine may continue to be so distributed providing that their labeling include the warning statement, 'this drug shall not be taken during pregnancy without the advice of a physician.' " That one also passed, and it appears that it will become the basis of FDA policy.

Now, the logic of this decision can be criticized in many ways, and will be. Many medical scientists point out that the time a drug is most likely to harm the fetus is in the first few weeks of pregnancy, frequently before a woman knows she is pregnant. This is the time she is most likely to go to a pharmacist and ask what is available for nausea—and be given one of these familiar products. One government physician who has followed the arguments closely feels it is "medically indefensible" to assume that a label on an over-the-counter product offers adequate protection. "The only people this decision can possibly benefit are the drug people," he said. Fountain, however, was interested not so much in the medical arguments as in the way the decision was reached to overturn the first committee's recommendation and supplant it with a far weaker recommendation. He questioned Sadusk closely on why he had changed his mind on an issue of such potential public importance. Sadusk's reply was essentially that he had never agreed with the stringent recommendation in the first place, but had passed it up the line because it represented the conclusions of respected scientists. Fountain wanted the tape largely to discover what had transpired in the meeting to induce this body of scientists to alter its recommendations. A draft of an edited version of the tape had previously been received by the committee in manuscript form, but Fountain and his staff evidently felt it left key mysteries unresolved.

Two Sides

Thus, whatever else can be said about the Fountain-FDA dispute, it must be said in fairness that there are two sides to it. Fountain's request for the information with which FDA was so reluctant to part grew out of his need for data concerning two cases that have very clear and imminent consequences for the public interest. In the light of past and present FDA policies, neither request was unique or extraordinary. Why some segments of the scientific community have responded so emphatically is a somewhat puzzling question. One factor seems to have been that Fountain has been a favorite villain of the scientific community since his investigation of NIH a few years ago, and there was probably a pre-existing readiness to believe that if Fountain was involved in it, it couldn't be a very good thing for scientists. Another factor is a natural response to signals of distress from a fellow scientist—in this case Sadusk, who has done more in a year to put FDA on the scientific map than any other official accomplished in a lifetime. It is likely that many scientists also sympathize with Sadusk's view, as reported in an article in an industry trade publication, that "he and his bureau should be left alone until he can get his staff to the point where it can do a genuinely effective job"—a point he estimated to be around fiscal year 1967 at the earliest. While this notion may fit in with the views of many scientists who believe that Congress should not interfere with the conduct of scientific agencies, it makes little sense from an administrative point of view. By the same logic, one could say that no new government programs should be reviewed at all until they had been operating for several years. In addition, it is an uncomfortable fact that a good many of the decisions with which Fountain was concerned—including the remarketing of Parnate and the reversal on meclizine—took place after Sadusk assumed stewardship. And it is another uncomfortable fact that, in terms of its potential consequences for public health and safety, the subject of government drug policy is of far more importance than the subject of research-grant administration. When a congressional committee has reason to believe that a particular situation may be dangerous, it takes pressures far more powerful than the dismay of civil servants or the complaints of scientists to make it change its course.

Two more points should be noted. The first is the fact that at least some of the scientific and medical groups who have petitioned Fountain did so on the basis of reports of the hearings which appeared in the trade and regular press, and did not study the proceedings themselves. The second is the possibility, reported in the trade press, that, in an effort to blunt the impact of the forthcoming Fountain committee report, FDA Commissioner George Larrick may retire. Larrick, 64, has been head of the FDA since 1954 and, under government policies, is now free to retire. His retirement would make the report something of an anticlimax.—ELINOR LANGER

Announcements

The University of Southern California has announced plans for a **marine science research center** on Catalina Island, about 20 miles off the southern California coast. The center will be built on a 45-acre tract at the eastern part of the island, donated by the Cata-