There is no evidence that the addressees were in any way moved by this desperate-sounding resolution. In large part this is because it is a good question who is "responsible for federal policy concerning support of fundamental research." There are lots of proposals, reports, and notions floating around, but if there is any sort of comprehensive and governing policy, it is well concealed among the plethora of agencies, congressional committees, institutions, statesmen, and would-be statesmen who crowd the arena of science and public affairs. Easily won success and traditional aloofness from politics have accounted for the scientists' traditional reluctance to join the scrap for a share of public largess. But now that the scientific community is beginning to hurt, perhaps it will conclude that eloquence and resolutions addressed to the wind are not sufficient.

—D. S. GREENBERG

Goddard at FDA: New Rules for the Game

In the 5 months in which he has been commissioner of the Food and Drug Administration, James L. Goddard has instituted regulatory action against many major drug companies, overturned the philosophy on which his predecessors based drug regulation, and given a substantial push to efforts to sharpen the agency's scientific capabilities. He has also brought the agency into the public eye, and elevated its status within the executive branch of government, which has tended in the past to ignore its existence and downgrade its importance. "We're *there*," commented a Goddard aide, "and now they know it." It is far too early to know whether Goddard has merely pulled off a reversible coup d'etat or institutionalized a permanent revolution. Dissidents are already whispering—and the drug industry is plainly hoping—that Goddard is more concerned with changing the "image" than with changing the reality. Jealousies within the world of Washington health politics and possible political curbs on Goddard's attacks on industry raise further questions about how far the new commissioner will go. But whatever the future holds, Goddard has already accomplished at least one bureaucratic miracle: FDA these days is where the action is.

What Goddard has done, first, is to change the rules of the game by which drug regulation is played. Rule number one, in the old regime of George Larrick, FDA commissioner for 11 years, was public obeisance to a kind of credo: "Most of the drug industry is honest and incorruptible; excesses are committed only by an undisciplined few who are not really in the family." It is a notion that the new commissioner frankly scorns. He loses few chances to stress that what he terms "the disease of irresponsibility" runs straight through the industry and involves its most prominent leaders. His regulatory actions—including moves against Warner-Chilcott, Parke-Davis, Pfizer, Burroughs Wellcome, Hoffman-LaRoche, Lederle, and others—carry the same message.

Industry's public reaction to this aspect of Goddard's activities has so far been a somewhat dazed repetition of the old saws. In a recent speech to the Pharmaceutical Manufacturers Association, for example, Goddard went out of his way to point out that he had complaints against the advertisements of one-third of PMA's member firms (*Science*, 15 April). PMA president Joseph Stetler reached for the old formula. Goddard's remarks "might unfortunately be interpreted as an indictment of the entire drug industry because of its overemphasis on isolated instances without acknowledging the integrity and responsibility which our industry has consistently demonstrated," Stetler said. Industry's private reaction does not carry quite the same conviction. There is abundant speculation about the nature and motives of the man, somewhat reminiscent of the way college students, among themselves, discuss professors, and a kind of uneasy feeling among the discussants that they do not yet have his full measure. In at least some sections of the industry there is an unwillingness to believe that Goddard really means what he's been saying, and a tendency to expect that he will slow down his attacks. This expectation, together with industry optimism that Goddard will make good his promises to speed up the agency's processes for reviewing new-drug applications and modernize its information system, probably accounts for the fact that criticism of the new commissioner has been relatively restrained. They like his science; his politics has them worried.

Another rule of the old game, more important than the first, was that the Food and Drug Administration should interfere as little as possible in the relations between drug manufacturers and physicians. The rule has deep roots in the traditions of American medicine—belief in the autonomy of doctors and in the competence of solo practitioners to make their own decisions about therapy, belief that government restrictions constitute tampering with "the doctor-patient relationship." But it also has roots in the economic self-interest of the companies, who can sometimes persuade practitioners of the value of remedies which independent research has discredited. A case in point is that of the cold-preparations containing antibiotics, which Goddard recently ordered off the market in an action that may decrease pharmaceutical sales by as much as $25 million annually. Competent researchers familiar with the action of antibiotics have long said they were useless against colds; practitioners—and the public—have gone on depending on them (*Science*, 30 August 1963). There are also more subtle examples—case after case where industry advertising seeks to establish broader use for a product than clinical evidence justifies, and frequently succeeds.

The proper role of the FDA in controlling pharmaceutical products that

reach physicians is at the heart of the difference between Goddard and Joseph Sadusk, former director of FDA's Bureau of Medicine, who resigned shortly after Goddard took over. Goddard believes, to put it simply, that physicians are gullible and the industry will try to gull them. He believes that there are times when the government knows better than the doctors, and he does not balk at issuing orders that limit physicians' discretionary authority. His recent order against the use of long-acting sulfonamides is a case in point. Sadusk, on the other hand, believed that if doctors knew all the facts they could make decisions themselves. The few regulatory actions that were initiated during Sadusk's reign were essentially confined to changing the labeling of various products. "The government has an obligation . . . to fully inform the practicing physician on the efficacy and safety of drugs but to not go beyond this point," Sadusk said in a recent speech partly explaining his departure. "To tie the hands of the doctor by dogmatic directives . . . is unjustifiable."

Sadusk's view is shared by the American Medical Association, which seems on the verge of a campaign against Goddard's policies. AMA president James Appel recently attacked the FDA in a speech in which he claimed that the agency's actions were infringing on doctors' freedom: "The apparent tendency to spread the regulatory umbrella over as broad an area as possible . . . and the apparent basic regulatory concept that the effective and safe use of drugs by physicians can be assured only by regulatory fiat concerns the AMA, since the decisions not only denigrate the physician but destroy his freedom to practice the best medicine of which he is capable on each individual patient."

Puppets and Puppeteers

Industry rhetoric is strikingly similar. One of Goddard's earliest actions, for example, was to order the removal of an anticonvulsant drug called Elipten from the market. FDA claimed that Elipten caused sexual precocity and masculinization in children; that the manufacturer (CIBA) had withheld evidence of these effects from the agency; and that, in any case, the drug's effectiveness in treating convulsions was in doubt. CIBA's response, in addition to stressing the firm's belief in Elipten's efficacy and denying that it had intentionally withheld information, included the following statement: "CIBA feels strongly that the ultimate decision as to the use of Elipten should be left with the prescribing physician who is in the best position to weigh the benefits versus the possible risks in the treatment of a particular patient." It was this rhetorical coincidence, in the old days, that made critics wonder who, in the relations between FDA, the doctors, and the industry, were the puppets and who the puppeteers.

Such a sudden change in the theory governing regulation has obvious implications for agency stability and morale. Theories have theorists behind them—or, if not theorists, at least large numbers of individuals who acquiesced in and supported the old order. And it is a fact that Goddard's appearance has precipitated a number of resignations not only in the upper echelons of the agency but down below as well.

Partly because of the resignations, but chiefly because of an authorized expansion, the agency now has 700 openings. These are viewed by Goddard supporters as an administrator's dream—a chance to staff the agency with people specifically attracted by Goddard's ideas and vigorous approach. Evidently such people exist, for Goddard's staff reports a striking number of unsolicited applications arriving every day. He has apparently created a spirit not unlike that of the early days of the Peace Corps or the poverty program, drawing in people who recognize the hardships but want to be in on the fight.

As far as the existing staff is concerned, Goddard is exploring, seeing who likes him and who he likes, who he can work with. No one will be fired—a near-impossibility under civil service rules—but some may be, in genteel ways, supplanted. In the meantime, the number of people making decisions is small. Goddard brought in only one assistant—an able, energetic young man named Ted Cron who formerly worked with Francis Keppel in the Office of Education—and has made no significant permanent appointments. The important posts of director of the Bureau of Medicine and deputy commissioner are being held by longtime FDA employees to whom Goddard has given "acting" status.

The result is that the "new look" at FDA is chiefly a reflected image of the new commissioner. He appears to rely principally on himself (and Cron) and secondarily on those who are left among the top-level civil servants who formerly served under Larrick. (He has also made it known that he has studied, in detail, the past criticism of FDA by journalistic and congressional outsiders.)

A Soft Spot?

Goddard's approach is not without its dangers. The commissioner's recent decision involving a long-acting aspirin may be a case in point. The product, known as Measurin, is manufactured by Cheseborough-Pond's. Advertising claims that the drug provides 8-hour relief were based on studies by a Massachusetts firm currently under FDA investigation for submitting falsified data on Measurin and other products. (The falsifications allegedly included reports of the drug's helpfulness to patients who were already dead.) FDA's Bureau of Medicine recommended in March that Measurin be taken off the market, since the data that theoretically demonstrated its effectiveness were discredited. But at a higher level it was decided to let the drug remain available and, furthermore, to permit the company to continue its "8-hour relief" advertising claim during the 2-month period allotted for it to substantiate its efficacy claims by further research. In other words, a drug is being permitted to remain on the market and to be advertised in a case where no valid proof of efficacy exists.

FDA insiders and some congressional critics believe that Goddard's action on Measurin smacks uncomfortably of the Sadusk leniency, and that he was perhaps led into it by reliance on the same advisers who made similar decisions under Larrick. These critics also see a number of other instances in which Goddard has been slightly more mild than they think he should have been. And they are troubled by the fact that the actions which have catapulted Goddard and the agency into the headlines concern matters which were on his desk when he took over—matters, such as Elipten, on which the former commissioner had had the facts and had simply failed to move. "We haven't yet seen what he can do himself," one dissident remarked.

To Goddard supporters, this criticism seems little short of ridiculous. "What you're seeing so far is the action of a man impatient with the holdovers from his predecessors," one commented. Sup-

porters are also sensitive to the irony in the simultaneous criticisms that the commissioner is centralizing power in his own office and that he is relying on remnants of the old guard. Goddard's aides feel that those of the old guard who are helping the commissioner have plainly demonstrated their competence, if not yet their loyalty, and that the commissioner needs them. They also feel that, far from intending to centralize power, Goddard hopes to expand the revolution to the farthest outposts of FDA's domain, to the point where each shop, and not just his own, will be generating its own decisions.

Strengthening Science

Along the way, Goddard is plainly determined to improve the agency's scientific status and to cement its always weak ties with the academic community. A cooperative arrangement for the clinical evaluation of drugs has been initiated with Georgetown University's medical school; Goddard hopes this will be a model for similar ties elsewhere in the country. And the new commissioner, perhaps partly trading on his own past reputation (he is a high-ranking Public Health Service officer who previously headed the PHS's Communicable Disease Center in Atlanta), has managed to persuade the National Academy of Sciences to undertake a massive review of the efficacy of some 4000 drugs marketed before passage of the Kefauver-Harris drug amendments in 1962. Goddard's hopes for this project (required by the 1962 amendments) are enormous: "I think it could be the Flexner report of therapeutics," he told *Science* in a recent interview. A subsidiary benefit, in addition to cleaning out the nation's medicine chest of remedies marketed before federal law required proof of efficacy, could be the involvement of hundreds of top scientists in drug problems and, indirectly, with the FDA. (The Academy has not yet announced the details of its plans, but it is certain to lean heavily on academic experts.)

One interesting sidelight is the marked enthusiasm of the drug industry for the Academy review, an enthusiasm which rests chiefly on relief that FDA, whose present scientific competence the industry doubts, is not going to take on the job itself. There is also a feeling, echoed by some of Goddard's critics, that the Academy—and particularly its Drug Research Board—is by no means immune to industry influence. These critics point particularly to the Academy's support for Sadusk in his battle last year with Representative L. H. Fountain over disclosure of medical and scientific records pertaining to certain drugs (*Science*, 13 August 1965). (Support came in the form of a letter to Fountain from Academy president Frederick Seitz, and in resolutions passed by the Drug Research Board endorsing the Agency's position.) Aides report that Goddard is aware of some people's doubts about the Academy but that he does not take them very seriously. "You have to take America as it is," one commented. "If you can't trust the Academy, who the hell can you trust?"

The roots of Goddard's political posture are difficult to judge. Industry spokesmen believe he is playing a tactical game, that he knows things are better than he says, but that he is depending on shock value to get results. And, insofar as his motives are tactical, industry leaders seem prepared to go along with him, at least to a certain extent. "If a certain amount of public whipping is necessary to create a new 'image' and a new FDA, we can stand it," remarked one executive, "as long as it doesn't go so far that public confidence begins to be affected. But he has to stop somewhere." Some industry leaders, on the other hand, are known to have already taken their alarms to the White House. But, on the whole, the industry appears willing to trade public attacks for behind-the-scenes reforms the industry favors. These include, for instance, a proposal by PMA that companies submitting new-drug applications (which often fill several cartons and may take years to process) also submit a certified summary of the NDA data, for whose accuracy they would bear criminal responsibility. Goddard's acceptance of the certified-summary idea would dramatically speed the time it takes for new drugs to be reviewed and marketed. Another proposal would relieve individual companies of the need to supply FDA with annual reports of the professional literature about their products and substitute an industry-wide, automated, and comprehensive literature search via the National Library of Medicine.

To soothe each other into believing that Goddard is a blusterer, industry officials cite, among other things, a warning about possible industry nationalization implied in Goddard's speech to the PMA (*Science*, 15 April). "He just didn't mean it," commented one official. "We hear the same rumors he does, and if anything were happening, we'd know about it." Nationalization is a possibility Goddard would deplore as much as the industry executives would, and he is as attached as they are to the idea that the productivity of American drug research is the result of competition and variety. But they are probably wrong about his motives for mentioning it. "I did not mean that nationalization is right around the corner," Goddard told *Science* recently, "but I can remember when people didn't think that federal medical insurance was very likely either. If things continue to go badly, public opinion can change dramatically. I did mean it when I said the industry should watch out, get back into shape, before worse things happened to it."

Many critics believe that Goddard's motives are largely personal. Instant psychoanalyses, focusing chiefly on Goddard's allegedly sturdy ego, abound; and it is certainly true that Goddard does not appear to have his predecessor's need to be liked by everyone. He is by no means shy of conflict. It is widely rumored that he is a disappointed candidate for the office of Surgeon General, and that he would like to use his new job to propel himself to that post or higher. But it must be said in fairness that issue-oriented politicians and administrators are relatively rare in Washington these days, and that a lot of observers might miss it if they saw one.

A Matter of Manners

Whatever Goddard's motives, it has to be reported that his style has not found as much favor in Washington as it evidently has with the public at large. The Johnson administration has shown a distinct preference for public servants considerably more innocuous than Goddard, whose ability to command publicity has sometimes seemed to rival that of the President himself. It is not every new appointee who wins himself a color cover on the New York *Times* Sunday magazine. In addition, FDA is part of a larger agency—the Department of Health, Education, and Welfare—and Goddard has made considerably more speeches and attracted far more attention than HEW Secretary John Gardner or some of its other top officials. It is not just a question of holding too many press conferences. Washington officials appear to believe

that on at least some occasions Goddard has acted precipitously: they cite in particular an occasion on which he publicly threatened criminal prosecution of a major drug firm, before he had the evidence to begin such a prosecution.

Dissatisfaction at the moment appears to rest more on Goddard's manners than on his politics. Publicly, Goddard has Gardner's full backing, and, as far as the White House goes, right now the consumer vote that Goddard is attracting probably at least balances the industry campaign contributions he may be repelling. Nonetheless, how far the White House will go in permitting Goddard's assaults on industry is an open question, and it would not be surprising if, in the next few months, he treaded a bit more softly. What he wants from now on he will have to fight for harder, either in public or behind the scenes. About all that can be said with certainty is that Goddard's honeymoon is drawing to a close.

—ELINOR LANGER

Oceanography: Congress Wants Cabinet Council and Study

The best manner of planning and directing the national effort in oceanography has long been a subject of debate within Congress and between Congress and the Executive Branch. Now, however, Congress, though still uncertain how the oceanography effort should be managed over the long run, is prescribing a provisional answer to this question and calling for a study intended to produce recommendations for a more definitive solution. But the congressional prescription is being critically appraised by some of the President's advisers, and its rejection is not inconceivable.

A cabinet-level oceanography council*, chaired by the Vice President, would be created under a bill on which congressional action was completed last week. The President has until 17 June to sign or veto the bill. The council, a temporary body unless made permanent by some later act of Congress, would advise the President on the planning and coordination of the overall national oceanographic effort—an effort which many people in and outside of Congress believe would be larger if it were given more attention at the highest echelons of government.

The bill creating the council also would require the President to appoint an oceanography commission to review national needs in the field of marine science and engineering, recommend a comprehensive national program, and propose whatever reorganization of the governmental apparatus for oceanography it finds desirable. The commission would consist of 15 regular members drawn from government, academic circles, and industry and four advisory members from Congress. It would have 18 months to prepare its report and submit it to the President, via the new council, and to the Congress. The commission would then disband. Four months after the commission had reported, the council, too, would disband, unless Congress had directed otherwise.

A declaration of policy and objectives is included in the bill establishing the two temporary bodies. It calls for the United States, through direct government action and by support of industry and other private endeavor, to keep its place as a leader in marine science and marine resource development. The declaration emphasizes, among other things, the importance of advancing education and training programs in oceanography and of developing improved methods and equipment for undersea research, exploration, recovery of resources, and transmission of energy.

This new oceanography legislation is the product of a congressional compromise. The final bill, fashioned by House-Senate conferees from the House Merchant Marine and Fisheries Committee and the Senate Commerce Committee, was passed by the House on 26 May and by the Senate on 2 June, in each case by voice vote and without opposition. The original House and Senate bills, passed last year, were quite different. The House measure had directed the President to appoint a study commission but did not provide for a council. The Senate bill provided for a council but left to the President's discretion the setting up of a study commission.

Senator Warren G. Magnuson, the Washington Democrat who chairs the Senate Commerce Committee, noted, in explaining the House-Senate compromise, that the House conferees had questioned the wisdom of including the cabinet-level council. They did so, he said, for two reasons: (i) establishment of the council might prejudge one of the issues to be studied by the commission, by appearing to indicate the kind of governmental structure for oceanography preferred by the Congress; and (ii) inclusion of the council against the advice of administration witnesses who had testified on the bill might lead to a Presidential veto.

Magnuson suggested that the House-Senate compromise had removed the basis for those two objections. Making the council's life largely co-terminous with that of the study commission makes it clear, Magnuson said, that the council's purpose is simply to coordinate current oceanographic activities until a final federal governmental framework is achieved. He said he expected the council to prove itself worthy of becoming a part of that final framework. As for the possibility of a veto, Magnuson observed that President Johnson himself, when he was Senate majority leader and chairman of the Senate's special space committee, laid the groundwork for the national space program by obtaining passage of the National Aeronautics and Space Act, which included a provision for a National Aeronautics and Space Council. "His wisdom then will be matched by similar wisdom as we meet our responsibilities in knowing and using that 70 percent of the earth's surface that is covered by water," Magnuson said.

* In addition to the Vice President, the council would be comprised of the Secretaries of the Departments of State, Treasury, Interior, Commerce, Navy, and Health, Education, and Welfare; the chairman of the Atomic Energy Commission; the director of the National Science Foundation; and such other officials as the President might choose to designate. In case of "unavoidable absence," the council members could be represented at council meetings by alternates, who would have to be officials appointed to their agency posts by the President with the advice and consent of the Senate.