

search and for education programs, but the report recognizes the difficulties of disentangling one from the other and abandons ritual by treating federal support of university research as part of the federal education budget.

The report confirms—and it will come as a surprise to hardly anyone in the university research community—that in the distribution of federal research funds the rich inexorably tend to get richer. Of the \$613 million in federal funds for university research in 1962, 90 percent, according to the report, was concentrated in 100 universities, 59 percent in 25, and 38 percent in 10. In 1952 these top ten were the University of California, M.I.T., Columbia, the University of Michigan, Harvard, the University of Illinois, Stanford, Chicago, the University of Minnesota, and Cornell.

Mrs. Green's letter puts the realities of the assignment of research funds this way:

"In the first place it is difficult to conduct large scale research in an institution that does not have a graduate school of some magnitude, although small projects may be carried on by individual investigators without graduate student assistance. Second, since almost all Government-sponsored research is for a specific purpose, the assignment of it is determined on the basis of its likely contribution to that purpose, and not on the basis of 'spreading the wealth.' Third, research is not in reality, except in the case of agricultural funds and a newly inaugurated program of the National Institutes of Health, assigned to institutions; it is assigned to individual professors. The concentration of research funds indicates the concentration of scientific scholars in a small number of institutions."

But, for Mrs. Green, to understand this is not to forgive. In an interview last week she noted that the survey showed a concentration of federal funds (i) in the sciences, (ii) in a few universities, and (iii) in programs at the graduate level, and went on to say, "it's quite obvious that there are areas of neglect in the educational program."

"It's a strange rationale," she said; "we believe in free education through the 12th grade, and then if someone manages to make it, by pluck or luck, from the 12th through the 16th years, support becomes available again."

Mrs. Green is a strong proponent of federal aid to education, and per-

haps because of her work on a subcommittee dealing with higher education she has been particularly concerned about the unbalancing effect on colleges and universities of the heavy flow of federal funds funneled into the sciences. The haphazard growth of agency programs in education and the dispersion of control over education programs through many congressional committees [*Science* 138 (14 Dec. 1962)] seem to have convinced her that new mechanisms of coordination are required to avoid duplication and competition and to balance the needs of science against other educational needs.

It is worth noting that Mrs. Green feels that there is a "trend toward coordination" of education programs by the Office of Science and Technology, headed by Jerome Wiesner, and that, because of OST's concern with research and with scientific manpower, it is possible that research and education programs in science and technology may be more efficiently coordinated, but at the possible expense of other fields, such as the humanities and the social sciences.

In the past Mrs. Green has raised for discussion the question of whether there should be a Department of Education and Science, with full cabinet stature, to oversee and to enhance the status of the widely scattered programs in the two fields. In her 7-page letter commenting on the new survey she suggested, as one of three major recommendations, that consideration be given to "combining the Office of Education and the National Science Foundation, the only two agencies with a primary concern for education."

While the draft survey was under discussion her views brought her into disagreement with members of her subcommittee, particularly with two minority members, Representative Albert Quie of Minnesota, ranking Republican on the subcommittee, and Representative Charles E. Goodell of New York, who objected to, among other things, recommendations they felt might lead to overcentralization of programs which had profited from diversity of control. Members of the subcommittee at one point also felt that Mrs. Green appeared to be calling for a cut in science programs, action they felt was not called for by the results of the survey.

The disagreement appears to have been largely a matter of emphasis, for Mrs. Green's letter, with its recom-

mendations as published, seems acceptable, for the most part, to the subcommittee members. Because of these differences, and because of such other factors as changes in subcommittee membership in the new Congress, the survey and its accompanying letter are not published as a bipartisan subcommittee report, and whatever impetus this might have given the recommendations is missing.

Mrs. Green's other major recommendations are as follows.

1) "Creation, within the executive branch of the government, of an Inter-agency Council on Education to coordinate the educational activities of all Federal Agencies and Departments."

2) "Creation of a nonlegislative Joint Congressional Committee on Education in order to provide the Congress with an overall picture of Federal educational activities and education needs."

Both proposals have the advantages of being constructive and, at the same time, of proposing no radical departure from convention. The Joint Economic Committee, as Mrs. Green points out, provides a precedent for a Joint Committee on Education, and the idea might well be accepted so long as the committees with major responsibilities for education in both Houses were represented. An awareness of the untidy sprawl of education programs is growing in Congress, and the time may well be ripening for a move toward better coordination.

The problem of correcting imbalances created by federal programs is something else. Congress is willing to vote funds for research and education programs in behalf of defense or against disease and for limited programs for special purposes, but the legislators have so far been unwilling to go much beyond this, because the path is strewn with political pitfalls.—JOHN WALSH

Krebiozen: FDA Deadline Brings New, but Not the Final, Episode in Controversy over Cancer Drug

This is the last of three articles on the Krebiozen controversy.

The latest (though probably not the last) chapter in the Krebiozen chronicle grew out of a clash between the old controversy and the new drug laws. The laws, passed in the aftermath of thalidomide last summer, covered several aspects of drug production and

marketing. Krebiozen was one of about 2500 drugs affected by the sections governing distribution of "investigational" drugs for research purposes.

Krebiozen's sponsors, along with sponsors of the other drugs, were required to file with the Food and Drug Administration, by 7 June 1963, a clinical plan detailing the nature of the drug and its method of manufacture, the results of toxicity studies and of past animal and clinical studies, and the identity and qualifications of doctors participating in the research as investigators. Failure to file this information by 7 June rendered further interstate shipment of a drug illegal and consignments liable to seizure by the FDA. The procedure is weighted in favor of the sponsor, however; after filing, he may continue to distribute the drug unless notified that FDA considers his data inadequate. The sponsor may insist on a final conference before FDA is permitted to halt distribution of a drug.

What the actual effect of the new laws will be is not yet certain, since much depends on how they are enforced. But they are far from popular with the drug industry, one of whose representatives spoke recently of volumes of material "reaching several feet above the height of an average man" being sent off to FDA. If the sponsors of Krebiozen look back wistfully to the pre-thalidomide days when an experimental drug had only to be labeled "experimental," and the FDA notified, for distribution to begin, they will find themselves (for once) in distinguished company.

Although they did not influence the outcome of the FDA-Krebiozen clash, many segments of the drug industry, mentally at least, took Krebiozen out of their files marked "unproved treatments" and put it into a more solemn classification marked "struggle for freedom or research." Many, in short, would not have been sorry to see the FDA back down.

However much FDA officials wished to believe that they were (or, for that matter, probably wished to be) mere passive agents administering a law that fell with blind impartiality on everybody, the case of Krebiozen was bound to be exceptional. For one thing the Department of Health, Education, and Welfare, parent organization of both FDA and the National Cancer Institute, had been involved far too long for simplicity to be possible. For another, FDA was already waist-deep in its in-

vestigation into Krebiozen's clinical and financial past. Although, in theory, the investigation is to facilitate the testing of Krebiozen by the Cancer Institute (stalled about a year ago by the inability of Ivy and Durovic to supply the desired data), in fact it may lead to a less pretty climax. FDA officials have admitted privately that the material they have seen so far has not only opened up some doubts about the legality of past distribution of Krebiozen as an experimental drug but has reinforced what seems to be the innate skepticism of many professionals where Krebiozen's claims of effectiveness are concerned. (The preliminaries have already produced one surprise—and a hint that it will not be easy to close the books on the Krebiozen story: Stevan Durovic, on 27 June, named Secretary of Health, Education, and Welfare Celebrezze, the latter's special assistant for medical affairs, Boisfeuillet Jones, and three FDA officials as defendants in a suit enjoining the government from harassing him. Depending on FDA's response, this could lead to a long court battle and further complications in the case.)

Two Smudged Slates

But if it was difficult for FDA officials to approach the 7 June deadline with a clean slate, smudges were visible on the slate of the drug's sponsors as well. Ivy and Durovic approached the deadline with two goals that were beyond the scope of the new regulations—to keep distributing Krebiozen to the 125 or so patients who at present believe their lives depend on continued treatment, and to increase pressure on the government to sponsor a "fair test." To attain these goals they used a variety of means with which the government was ill-prepared to cope. Doubting that their application for continued experimentation would be viewed by FDA with an unprejudiced eye, Ivy and Durovic stalled on filing, causing great alarm among the patients, who feared that their supply of Krebiozen would be cut off, and thus bringing a new, highly public, tension into the controversy. A few weeks before, on 15 May, some Krebiozen patients and their families, already growing anxious over the nearness of the cut-off date, traveled to Washington to tell their stories to government officials in an informal substitute for a meeting Ivy had proposed a few months before. Ivy's offer to bring patients and their records to

Washington for evaluation by government physicians had been turned down by HEW on the grounds that patient "testimonials" would "contribute nothing at all toward the solution of the scientific question of Krebiozen's merits." But the patients, mobilized by Mrs. Laine Friedman, a New York woman whose husband is a Krebiozen patient, thought otherwise and appeared anyway. Senator Douglas arranged for them to meet in the Senate Office Building; several congressmen, or members of their staffs, in addition to HEW officials, were in the audience.

Although to press Ivy and Durovic into filing would have been in the patients' own interest, for the most part they shared the sponsors' view that there was a "conspiracy," and they were sympathetic to the legal reasoning; they hoped the government could be made more flexible. As was discussed here last week, Ivy and Durovic believed that a New Drug Application they had filed in April 1961 could be activated to keep Krebiozen in distribution; but they also believed that the public pressure would be great enough to forestall FDA's seizing or enjoining distribution of the drug. On its side, the agency flatly disputed the claim of effective new-drug status for Krebiozen, refused to be intimidated by a popular uprising, and is in fact reported to have had its agents in Chicago quite prepared to seize the first shipments of Krebiozen that left Illinois after midnight on 7 June. FDA's position was that it could make no advance commitments regarding the application, and that if no application was forthcoming, the law would take its inexorable course.

Ivy and Durovic did not organize the uproar that enveloped Washington on 5 and 6 June, but they used it nonetheless. It was partly spontaneous, partly supervised by a skillful conglomeration of public relations firms, a few newspaper and radio commentators, some businessmen, and some private citizens, all dedicated to exposing what they genuinely believe to be the conspiracy against Krebiozen. It consisted of a long picket line in front of the White House, composed of patients and their families and friends, whose placards begged for Presidential intercession to stave off the application of the law and the banning of Krebiozen; of the arrest of Mrs. Friedman, who (by mistake or not) sat down in territory on which White House

pickets are forbidden to tread and got her cause in the newspapers as a result; of full-page ads in strategic newspapers, not only in Washington but elsewhere in the country, pointing a finger at "Cancer, Krebiozen and Our National Shame." And since the uproar involved heavy political pressures, most persistently from Senator Douglas, but increasingly from other senators and congressmen responding to an outpouring of mail from their constituents, the 7 June deadline, and what FDA would do about it, became a major test of the integrity of the new laws as well as a showdown on Krebiozen. Having played cat and mouse for over a decade, Krebiozen and the Department of Health, Education, and Welfare were finally caught in the same trap.

What FDA did was what, legally, it had to do: it waited—waited until, at the very last minute, mounting pressures, a helping hand from an emissary of the White House, and an ad hoc meeting of the disputants persuaded Ivy and Durovic to file an application. But if all the participants felt relief, it was a short-lived and sadly misguided sensation. The old patterns instantly reasserted themselves. In press releases after a private meeting the two sides issued conflicting interpretations of their agreement. Ivy and Durovic tied their decision to file to a supposed assurance that Krebiozen patients would continue to get the drug and that "all efforts would be made to speed an impartial test . . . in the near future." In HEW's view, however, no one had been assured of anything, except that the law would follow its natural course where investigational use of Krebiozen was concerned; this included distribution of the drug while the application was under review. In its press release HEW again stressed its position that the application and the test were entirely unrelated questions. Senator Douglas has already taken a different view and issued a statement which begins, "Now that Dr. Ivy and Dr. Durovic have filed a plan . . . there is no excuse for the National Cancer Institute and the Food and Drug Administration to delay further a fair test of Krebiozen."

As matters now stand, the application has been received and is under review—amid authoritative rumors that its rejection is imminent—and the patients have been receiving the drug. Under the terms of the law, Ivy and Durovic, if notified that their appli-

cation is inadequate, may call a conference with FDA to discuss the deficiencies, but it seems doubtful that such a conference would be productive.

If the application is rejected, although several delaying battles might be fought, FDA would be forced by law to attempt to ban further distribution of the drug that Ivy claims has (i) decreased the size of tumors for varying periods in from 20 to 70 percent of 4200 patients; (ii) reduced or abolished pain for varying periods, depending on the type of tumor, in from 33 to 74 percent of the patients; (iii) lengthened the ambulatory life of previously bedridden patients in 51 percent of the cases; and (iv) prolonged for from 4 to 12 years the lives of 10 percent of the patients whose doctors had expected them to die in 1 year or less. Although these figures have not been verified by any independent authorities, the fact remains that they have been publicly asserted. There will be many people aside from the Krebiozen "true believers" who feel that a drug with claims such as these behind it should under no circumstances be removed from circulation without a definitive test, however difficult it is to obtain the test, and however many unresolved mysteries still remain. If the FDA, either in applying the new laws, or in some other way, attempts to ban further distribution of Krebiozen, a renewal of the uproar is inevitable.

Re-enacting the Krebiozen drama, though it may be costly in more ways than one for all the participants, will not be difficult: many of the actors, onstage since 1951, appear to know their lines by heart.—ELINOR LANGER

Announcements

Provisions of the 1962 Kefauver-Harris Drug Amendments became mandatory 20 June when the revised "New Drug" regulations were published in the *Federal Register*. The amendments refer to both the efficacy and safety of drugs. Topics covered include effectiveness of new drugs, hearings, manufacturing controls, drug names, submittal of mailing pieces and advertisements, records and reports, and notice of approval or withdrawal of approval. Copies of the new regulations are available free of charge from the Food and Drug Administration, Tempo S, Washington 25; attn: K. V. Sloan.

Scientists in the News

Quentin H. Gibson, formerly head of the biochemistry department at the University of Sheffield, England, has become a professor of biophysics, physical biochemistry, and physiology at the University of Pennsylvania.

Leon Z. Seltzer, chairman of the aerospace engineering department, West Virginia University, has been named dean of St. Louis University's Parks College of Aeronautical Technology, effective 1 August.

Harold W. Lewis, associate director of the Nuclear Structure Laboratory at Duke University, has been named dean of arts and sciences and vice provost at the school, effective 1 September.

The new chairman of the department of physiology at Tufts University medical school is **Walter L. Hughes, Jr.**, head of the biochemistry division at Brookhaven National Laboratory, Uptown, N.Y.

J. E. Falk has been appointed chief of the division of plant industry at the Commonwealth Scientific and Industrial Research Organization, in Australia.

Recent Deaths

Emil Goetsch, 80; professor of surgery at Long Island College of Medicine and surgeon in chief of the Long Island College Hospital; 23 May.

Frank Howard, 84; professor emeritus of psychology and education at Middlebury College; 23 May.

W. Bay Irvine, 70; president of Marietta College, Ohio; 18 June.

Donald F. Jones, 73; retired chief geneticist at the Connecticut Agricultural Experiment Station, New Haven; 19 June.

Romeo J. Mansueti, 40; senior fisheries biologist, Chesapeake Biological Laboratory of the Natural Resources Institute and research professor at the University of Maryland; 1 June.

Walter C. Muensch, botany professor at Cornell University; 20 March.

Frederick A. Saunders, 87; retired chairman of the physics department, Harvard University; 9 June.

Shiro Tashiro, 79; professor emeritus of biological chemistry, University of Cincinnati; 12 June.