Science in the News

The Drug Inquiry: A Curious Affair That Has Netted Some Solid Results

Senator Kefauver's investigation of the drug industry adjourned last week, after closing on a lively note with exposure of the financial affairs of Henry Welch, who simultaneously headed the antibiotics division of the Food and Drug Administration and held an unacknowledged partnership in several publications promoting the sale of antibiotics. The hearings will resume, probably in the fall, in order to look into the production and marketing of antibiotics, and to give the American Medical Association and other medical organizations a chance to present their views of the situation. But the testimony, during the last two days of the hearings, of Arthur Flemming, Secretary of Health, Education, and Welfare, and of George P. Larrick, head of the Food and Drug Administration, confirmed what was already clear: that whatever complaints can be made about the style of the investigation, no one can say that the hearings have been a waste of the taxpayers' money. Kefauver and his staff are coming up with some solid results.

These results have, for the most part, developed out of the publicity given the hearings, which the hearings won, in part, through the way in which they were conducted. The committee's chief counsel, Paul Rand Dixon, is a vigorous man and, as one FDA official put it, an "old-fashioned crusader." Kefauver himself, in his more reticent way, shares this spirit, and if they conducted an investigation that is more an exposé than a restrained inquiry, it must be noted that they have exposed some things which almost everyone, including, privately at least, some members of the drug industry, agree deserved to be exposed.

The burden of their case has been that the larger companies, through their ability and practice of spending enormous amounts of money on advertising and promotion, have put themselves in a position where they can and do set drug prices far above the basic cost of manufacture. Kefauver cites as an extreme example the case of reserpine; Ciba sells this drug to druggists under the trade name Serpasil at $39.50 per thousand tablets and at the same time has sold the same product to the government for 60 cents per thousand. This is possible, says the committee, because the government buys the drug under its generic name, forcing the company to meet the competition of smaller firms. The public buys the drug from the physician, who specifies the trade name, and since the company has a monopoly on the trade name it can charge whatever price it sees fit.

Monopoly versus Competition

The committee tends to regard this basic charge as an example of the evils of monopoly, but those members of the drug industry who concede that the investigation is probably a good, if for them an unpleasant, thing, say that competition rather than monopoly is the source of the problem, and probably most economists would agree with them. The committee, and particularly Dixon, tends to regard any questionable use of financial power as an example of the evils of monopoly, but few economists are likely to agree with this broad use of the word as a bogey-term with which to tag almost any questionable situation.

The industry people, as well as several of the witnesses critical of the industry, say the trouble is that a pattern of competition has developed in recent years that makes it necessary for even the most ethical of big companies to join in the high-powered promotion race if they want to maintain their position. They say this has developed out of the immense growth of the industry in the past 20 years, with hundreds of new, although not necessarily important, drug products being developed every year, making it necessary for a company to join the promotional race if it is going to bring its product to the attention of the doctors. There is pressure on every company to match the promotional effort of the least responsible companies. This leads to the spending of a great deal of money to develop new drugs whose principal value may be only that they offer a gimmick on which to peg the promotion, and it leads to a barrage of promotion that amounts to $5000 per doctor per year, much of which tends to be misleading, since its purpose is to sell goods rather than to inform the doctor.

All of this has been publicized in the past, but the value of the Kefauver investigation is that it has aroused the interest of the public by demonstrating clearly how much this pattern of competition costs the sick who have to buy the drugs. It is a pattern of competition that many would normally regard as a wonderful example of the virtues of the American way. It does indeed sell more goods to more people. The question is whether the philosophy of selling more goods to more people is an acceptable basis for running this particular industry.

FDA Testimony

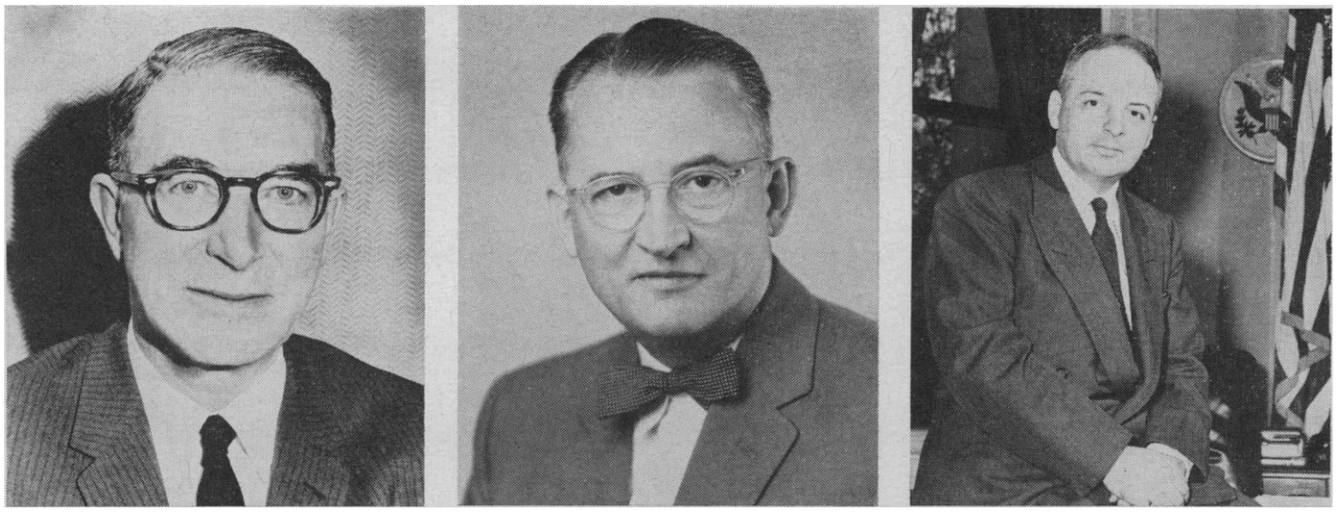
On the question of misleading promotional claims Larrick and Flemming said that FDA had legal, though indirect, means of forcing wayward advertisers to conform more closely to special standards of accuracy in promotion which the position of the industry demands. They promised to make more vigorous use of such powers in the future.

On the more basic question of the cost of drugs they said that FDA has no authority over the price of drugs, nor over the question of whether doctors ought to prescribe by brand name. But as they pointed out, "the activities of the FDA indirectly exert considerable influence" in the matter of generic versus brand name and thus, as the committee has made clear, over the level of prices charged the consumer.

The doctor wants to make sure that the patient gets no substandard drugs. Because of the limited ability of FDA to guarantee that all drugs are up to standard, the doctor tends to prescribe by the brand names of companies in which he has trust. The big companies encourage this practice, and their warnings about the danger of getting substandard products if brand names are not used are not entirely baseless.

Seizure Record

Larrick produced summaries of the FDA's drug seizures over recent years. They showed that during the past 10 years the FDA had to take action only



Senator Estes Kefauver with George P. Larrick, Commissioner of Food and Drugs, and Arthur E. Flemming, Secretary of Health, Education, and Welfare. Larrick and Flemming testified before the Kefauver Committee last week.

four times against any of the 28 largest firms, which produce 87 percent of the nation's drugs. Against the 1200-odd smaller firms, producing the remaining 13 percent of the drugs, the FDA had to take action 484 times during the same period; these figures provide a basis for the doctor's doubts about prescribing by generic names.

Food and Drug Administration officials point out that the situation may possibly be much worse than it appears. For although FDA inspects thousands of drug shipments every year, a statistical study made within the department suggests that the proportion of the hundreds of thousands of shipments annually which are inspected is not large enough to give a reliable index of the quantity of substandard drugs FDA ought to be keeping off the market.

FDA Recommendations

Flemming briefly summarized, and Larrick in a 53-page statement elaborated, the steps they thought ought to be taken. They said they agreed entirely with Kefauver that FDA should be in a position to assure the public and the medical profession that any drugs reaching the market are up to standard. But to do this, they said, FDA needs financial and legal support from Congress. They said that even though the FDA budget has been roughly tripled in the past 6 years, the agency can still maintain a staff of only 500 inspectors to police $70 billion worth of commerce in food, drugs, and cosmetics. As a result, the average drug plant is inspected only once every 2 or 3 years.

Aside from more money, Larrick and Flemming said, the agency needs broader legal powers. They said that FDA needs broader inspection powers; it has the right to inspect a drug company's equipment but not its files. They said that the weak link that leads to substandard drugs is usually inadequate control procedures and that FDA "cannot appraise the control procedures unless it can examine control records and compare these with formulas showing what the firm's personnel are supposed to be doing."

They said that FDA needs the right to examine personnel files in order to see whether the people handling control procedures are qualified for their work. They asked for authority to keep off the market any drugs produced by a plant that did not have adequate controls.

They asked for authority to look at complaint files (usually letters from doctors reporting undesirable side effects), since "we cannot at an early date obtain evidence to evaluate the firm's experience with a new drug as to . . . safety if we are denied authority to review the firm's complaint files."

Flemming said that FDA asked for, and appeared to be getting, a comprehensive factory inspection law in 1953. The proposed law provided that drug factories had to be open to "reasonable" inspection, but as Secretary Flemming put it, "some elements in the drug industry did not want us to have this authority." These elements, sources at the FDA say, were predominantly the Proprietary Association (patent medicine manufacturers) and the National Retail Druggists Association, the latter a very powerful lobby that at the time was closely allied with the patent medicine lobby, although the two are currently quarreling with each other. The ethical (prescription) drug manufacturers were less active and indeed were officially in favor of the inspection law. In any case, senior members of the House Commerce Committee, which had reported the bill, were prevailed upon to hold a colloquy on the floor which, without actually amending the bill, effectively took the meat out of it.

"When this bill says 'reasonable,' " Congressman X would say, "does that mean that an inspector would have the right to look at the complaint files?"

"Why no, certainly not," answered Congressman Y, "I should think that would be entirely unreasonable."

The exchanges filled several pages of the *Congressional Record,* and when they were over it was clear that FDA inspectors had no reasonable right to examine formula files, personnel files, or complaint files.

An FDA official present at this performance says, "Here was a bill affecting the health of everyone in the country. There were about 200 members on the floor. No one questioned what was going on." The next day even the New York *Times* reported only that "the House conducted routine business yesterday."

Lack of Action

None of this explains why FDA has never asked for broader powers again in the years since this 1953 episode. Flemming said it was a mistake not to do so. FDA officials say it was because

they thought the case was hopeless. The public just wasn't interested because it didn't understand what was involved. The people who were most actively interested were against broadening FDA's powers.

Kefauver's Position

All of this is outside the legislative responsibility of Kefauver's Subcommittee on Antitrust and Monopoly. Kefauver cannot bring the remedial legislation to the floor of the Senate. It must come from the Committee on Labor and Public Welfare. But what he has done is to make a public issue of the whole business. If next year the FDA is granted the powers it is seeking, Senator Kefauver's name is not likely to be on the bill, but he and his staff will deserve a good deal, and perhaps most, of the credit.

School Aid Bill in Trouble

It became clear last week that there is a substantial majority in both houses of Congress ready to agree on a compromise school aid bill which the President would sign. Whether members will get a chance to vote the bill through remained very much in doubt. The Senate agreed to submit the bill to a joint conference to work out the compromise, but the House Rules Committee has not yet cleared the House bill for conference, and if it does the effort of House Republican leader Halleck to pack the conference committee with men opposed to school aid may prevent a compromise from being reached. If the bill gets by these hurdles it will then have to go back through the Rules Committee in order to get to the floor of the House for a final vote. HEW Secretary Arthur Flemming is clearly in favor of the compromise, but the White House, as in past years, seems to be making no effort to keep conservative House Republicans from killing the Administration's own proposal.

The compromise, if it gets through, will provide $325 million a year in aid for classroom construction. It will run for four years, with two-thirds of the money going to the neediest states. This is just about what the 1957 Administration bill asked for, but is a long way short of the billion dollar a year program passed by the Senate, which authorized aid for teachers' salaries as well as for classroom construction.

A New Journal of Maps: Biogeography of the North Atlantic

The American Geographical Society, working with a panel set up by the Committee on Oceanography of the U.S. National Academy of Sciences–National Research Council, proposes to publish a scientific journal of an unusual kind, tentatively called *North Atlantic Biogeography*. The journal will consist of maps, accompanied by such explanatory text as may be necessary, and will appear irregularly as contributions are received and accepted. It will be a medium for publication of studies of all kinds—biological, geological, physical, chemical—that will increase our understanding of the marine environment. In scope it will be limited to the Atlantic marine areas, from the equator to the pole, and will include the Arctic basin.

Base Maps Prepared

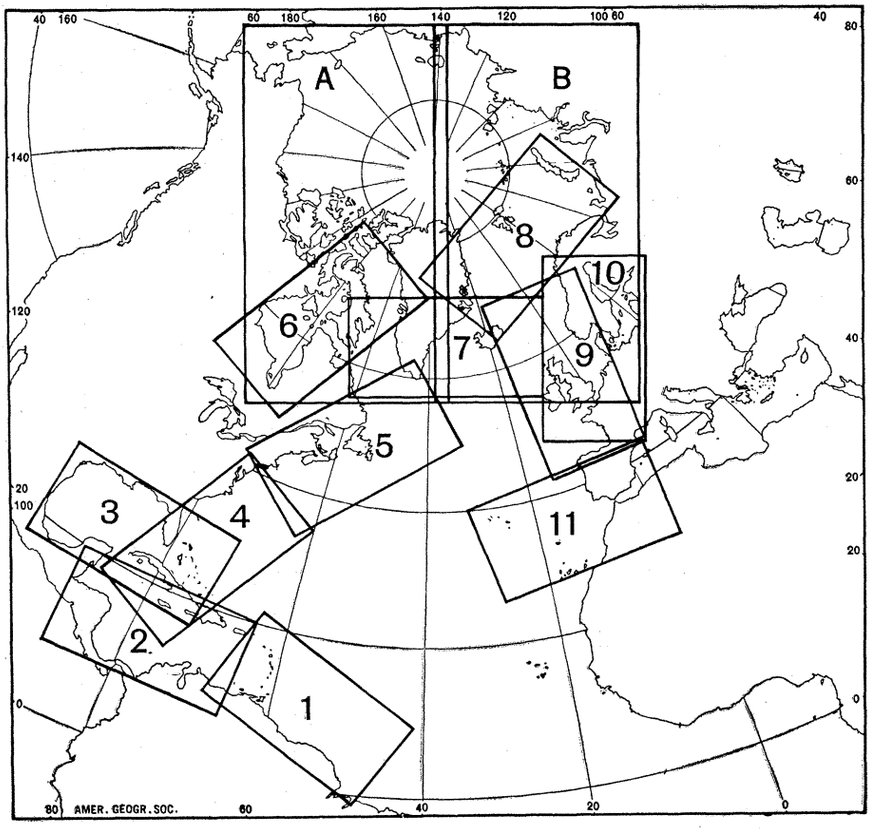
The American Geographical Society has already begun the production of work sheets or base maps for plotting data and has completed, as its first contribution to the project, two sheets covering the eastern North American seaboard from the Labrador Sea to the Straits of Florida. The master sheet, an oblique stereographic azimuthal projection specially prepared for the series, and the proposed layout of large-scale charts are shown in the accompanying figure. Scientists who contribute to the journal will be able to obtain these work sheets at nominal cost from the American Geographical Society (Broadway at 156th St., New York 32, N.Y.).

The journal will be published in atlas size, 24 by 15 inches. It will be available in two editions—on opaque paper or on a transparent material which will be of particular value for comparative studies—and will form an expanding atlas of the North Atlantic.

Journal Meets Growing Need

The new journal will meet a growing need in the study of the environment and of marine organisms and will offer a ready and standard means of recording and comparing distributions. It will be adaptable to almost any relevant purpose a particular author may have in mind.

Often in marine research, as elsewhere, correlations are found which seem significant, then the pattern falls



Sheet layout for the biogeographic atlas.