Science in the News

Regulating the Drug Industry: Reports Ask for Reforms While the Industry Leaders Ask for Trademark Protection

Among the outgrowths of Senator Kefauver's drug investigation was the appointment, by Arthur Flemming, Secretary of the Department of Health, Education, and Welfare, of two committees to look into charges of lax performance by the Food and Drug Administration. One was a group of educators and scientists organized under the National Academy of Sciences, which was to look into the scientific side of the question; the other was a triumvirate of government officials with investigative experience who were to look into charges that decisions of FDA officials had been unduly influenced by their cordial relations with the industry they were charged with regulating.

For both committees the key case was that of Henry Welch, the now-retired chief of FDA's antibiotics division, who had earned a quarter of a million dollars in half a dozen years as a result of his interest in a number of scientific journals supported by advertising from firms marketing antibiotics. Welch's superiors at FDA knew of his association with the journals. He was openly the editor. They did not know the "honorarium" he said he was receiving for this service was a share of the advertising and reprint revenues, or that one of the reasons the publications showed no profits was that Welch's honorarium was running to $40,000 a year.

The National Academy committee was asked to see whether the decisions of FDA officials, particularly those in the antibiotics division headed by Welch, were scientifically sound. The committee was also invited to make any general recommendations it cared to make about the working of FDA.

The second committee, working out of the office of HEW Secretary Flemming, was to make sure, first, that there were no more Welches working at FDA, and second, whether the general relations of FDA employees with the drug industry were not cordial to the point where FDA was inclined to be unduly generous in seeing things from the industry point of view.

The National Academy committee filed its report in October. It found the decisions in the sample of FDA cases it had studied "acceptable," but went on to make 11 recommendations for enlarging the powers or revising the procedures for regulating the drug industry. The recommendations in general paralleled the recommendations made by FDA itself last summer (*Science*, 17 June) under the pressure of the Kefauver investigation, and Flemming endorsed all of the committee's proposals except one, regarding advertising, whose effects extended to other agencies of the government beyond his control. Flemming promised to study the feasibility of the proposal on advertising. The tone of the National Academy report was that FDA is doing a decent enough job considering the limitations of budget, of personnel, and of legal powers under which it must work, but that all of these will have to be enlarged if FDA is going to do a really satisfactory job.

Personnel Investigation

The second committee, investigating personnel, has yet to file its report, but it has leaked enough of its feelings to foreshadow its findings. These are that, although there are no more such blatant conflict of interest situations in FDA as Welch represented, the relations between FDA and the drug industry are indeed much too cordial. The committee would like to see a return to the arm's length stance of FDA that prevailed from the time of the New Deal through until about the end of World War II. Unlike the recommendations of the National Academy committee, this does not find much sympathy in FDA, where the official view is that FDA can now accomplish a good deal that is useful by enlisting the cooperation of industry, something which would be difficult to do if the position of FDA were changed from regulator to policeman.

Any major policy changes at FDA will have to be confirmed by the new administration, but everyone assumes that the FDA under the Kennedy administration will go at least as far in asking for legislative reforms as the FDA did at its testimony before the Kefauver committee last June. It is assumed that the new HEW secretary will reaffirm Flemming's endorsement of the proposals of the National Academy committee.

Whether the new secretary will move to carry out the recommendations of the personnel investigating committee over the objections of career officers at FDA is less clear. Much will depend on how convincingly the investigators can document their case. No one seriously supposes that Democratic and Republican leaders in Congress are any less determined in fighting for their points of view on controversial matters because their cordial relations allow them to work out informal arrangements for cooperating on numerous subsidiary matters. The same applies to attorneys on opposite sides of a law case and even to Soviet and American diplomats across an international conference table. Everyone, except the most naive, recognizes that such cordial relations not only make life pleasanter for the antagonists, but very substantially expedite the business at hand.

The problem at FDA, as at other government regulatory agencies, is that cordial relations are not on quite as reciprocal a basis as they are among attorneys and legislators and diplomats. The industry people have generous expense accounts with which to entertain the government personnel, and jobs to offer them in the event they should choose to leave government service. There is the danger not of cordiality between the regulators and the regulated, which is useful, but of the regulators' coming to forget that, despite the room for a great deal of useful cooperation, the regulators and regulated do, or should, after all, represent opposing interests and opposing points of view.

A good case can be made, though, that the effectiveness of an agency in safeguarding the public interest is more closely related to the tone set by the

Administration and top political appointees in an agency than by the personal relations of the career civil servants with their contacts from the industry.

A recent survey of FDA employees showed that half of them had considered leaving the agency in the past year. The problem of getting and keeping capable employees is especially severe with scientific personnel who in government have neither the salaries that go with employment in private industry nor the amenities that go with an academic career. Hedging them round with regulations implying they are not to be trusted does not help the matter, but neither, on the other side, does a feeling that their bosses, the Administration, or the relevant Congressional committees are interested in cooperating with industry, or in cutting the budget to the point where the staff feels that either budget paring or seeking cooperation has taken precedence over seeking to protect the public interest.

In at least one area the FDA cannot be accused of leaning over too far to see the industry's point of view. Several of the major companies have lately been encouraging publicity for the counterfeiting drug problem, partly in hopes of pressuring the FDA into expending more of its resources in combatting the problem.

"An insidious racket that threatens the health of every man, woman, and child is spreading throughout America," announced *Parade*, a Sunday newspaper supplement. "The racket," said *Parade*, "is a flourishing under-the-counter trade in fake and diluted drugs, stamped with the counterfeit trademark of reputable firms." In fact, so far as FDA officials can tell, the racket does not necessarily, or even normally, involve either fake or diluted drugs. It stems from the situation of which the Kefauver committee made so much: that a great many drugs are sold at a modest price under their generic names (e.g., reserpine) and at a much higher price under their trade names (e.g. Serapsil, the trade name under which Ciba sells reserpine). The economics of the drug industry which account for this situation are reasonable or unreasonable, depending on the analyst's point of view, but the mere existence of the situation places a great temptation before the retail druggist: the temptation to substitute unbranded drugs for all or part of a prescription specifying a specific brand. The druggist feels the patient is no worse off, having received the right medicine, while the druggist is a good deal better off, having pocketed the difference between the price of the branded and unbranded drug. (If the prescription had merely called for the drug by its generic name the customer might have gotten the unbranded drug at its proper price.)

Substitution is illegal, and there is a fair chance of the druggist's being caught unless the substituted pills happen to appear to be indistinguishable from the specified brand. Here the temptation extends to the small drug firms, most of which do not actually manufacture drugs, but simply buy the chemicals in bulk form and manufacture pills. A number of firms make a specialty of making pills that look like those of the higher priced brands. This is unethical but, in most states, prefectly legal, and the availability of such goods further increases the temptation of the druggist to substitute by reducing the likelihood of his being caught.

In the game's fully developed form, the risk and a share of the extra profits are passed from the retail druggist to the distributor, who assures the druggist that his pills not merely look like the high priced brand, but really are the high priced brand, obtained at a bargain price and therefore for sale at a bargain price. In the slim chance that the druggist is caught, probably by a detective employed by the large drug firm to make purchases and send the prescriptions to the plant for analysis, the druggist can stoutly claim that he has done nothing wrong, but must have been taken in by a deceitful wholesaler. One major drug firm says it found that 12 percent of all prescriptions written for its products were partially or wholly filled with unbranded substitutes.

An Old Problem

The problem has existed for years, but it is only in the past few months that the industry has begun to seek publicity. Until recently the major firms preferred to hush up the situation. They feared that talking about the problem would merely cause the public and the medical profession to lose faith in the extra assurance of first quality in a brand name. There would be no point in paying a premium for a well-known brand if in fact there was a good chance you would actually get not merely unbranded drugs, which are usually, but not always, as good as the well-known brand, but unbranded drugs handled and distributed by people whose ethics are highly questionable.

The new attitude of those firms that have been seeking publicity for the situation stems partly from the feeling that the problem has grown to the point where it is getting to be prohibitively expensive for the brand owners to finance a private policing system themselves. They would like to arouse the public to demand stricter enforcement by state and federal authorities and stiffer penalties for proven offenders, who now tend to get off with very light sentences.

Public Health

The companies make the point that the racket not only costs the legitimate manufacturers a good deal of money, but that the public health is being endangered since a man who is counterfeiting trademarks can hardly be trusted to make drugs at all. But the problem, from the public's point of view, involves more than cracking down on firms for counterfeiting trademarks. The same man with the same ethics and the same manufacturing procedures who is counterfeiting may also be selling legitimate unbranded drugs of inferior quality. The National Academy report endorsed the Food and Drug Administration's proposed legislation for strengthening its powers to regulate and supervise the manufacture of all drugs, a step which would help keep inferior drugs from reaching the public whether masquerading as well-known brands or not.

The curious aspect of this effort to arouse the public to a special phase of the problem of regulating commerce in drugs is that the sensationalist articles, illustrated by suitably horrendous photographs of the interior of a raided firm, arranged for by publicists for a drug company, may well do more good in the long run than the eminently sensible report of the National Academy committee. For the scientists' report, after all, only restates the sort of recommendations that knowledgeable people have been making for years. The publicity about drug counterfeiting may result in considerable pressure on legislators to do something, while the National Academy report is being read mainly by people who are already convinced that something ought to be done.—H.M.