Science and the News

The Drug Hearings: To No One's Surprise, Kefauver and the AMA Do Not Agree on What Should Be Done

Senator Kefauver resumed his subcommittee's hearings on the drug industry last week, and two days of testimony from officials of the American Medical Association revealed, to nobody's surprise, that the AMA is unenthusiastic about the bill Kefauver has introduced to reform the drug business.

The first phase of the hearings was described here in two reports a year ago (*Science,* 29 April and 17 June 1960). These took the form, pretty much, of an exposé of what Senator Kefauver and his staff felt to be abuses by the major companies of their economic power which led to excessively high prices for drugs. Kefauver issued a lengthy report, signed by the Democrats on the committee, summing up his indictment of the industry. The Republican members, Dirksen of Illinois and Hruska of Nebraska, added a briskly worded minority report summing up their indictment of Kefauver's investigation.

Kefauver has produced a broad set of charges against the industry that ranges from misleading advertising to suggestions of illegal price fixing; but the heart of his complaint is that the major firms, through the use of exceptionally heavy promotion expenses, have been able to persuade the medical profession to write their prescriptions in terms that assure the companies exceptionally high profits (about double the average for other industries) without offering the public any important health benefits. The public ends up paying both for the high profits and for the heavy promotion that makes the high profits possible.

For the minority, Dirksen and Hruska answered with an equally wide-ranging set of charges against the way Kefauver ran the investigation and the conclusions he drew from it. But the essential point, in their view, is that the drug industry is providing the public with the best drugs available anywhere in the world; that the cost of these drugs is perfectly reasonable, and indeed cheap, compared with the good they do; and that Kefauver's proposals amount to an unwarranted attack on the free-enterprise system.

Current Hearings

The current phase of the hearings is being held to consider specific legislation. Technically, at least, the investigation is over, although Kefauver has taken the unusual step for a legislative (as opposed to an investigative) hearing of ordering several advertising agencies and medical publications to appear at the hearings along with their records. (Normally the witnesses at a legislative hearing appear voluntarily to give their views on the bill under consideration.) The hearings, under these circumstances, will probably begin producing headlines again as Kefauver seeks to document the extent of the industry's promotional effort, and the possible effect that the advertisers have on medical publications, from which the doctors are expected to receive unbiased information about new drugs.

The bill Kefauver has introduced is a so-called "omnibus bill" in which a variety of legislation bearing on the same general subject is combined into a single bill. The Kefauver bill includes amendments to the patent laws, the antitrust laws, the Food and Drug Act, and several other pieces of basic legislation, all of which are intended, directly or indirectly, to reduce the market power of the major drug firms.

Kefauver, for example, would amend the patent laws in two important ways. One would require a drug manufacturer to license his competitors to produce any drug on which he holds a patent. The licensee, of course, would have to pay for permission to market the patented drug, but the license fee would be limited to some small percentage (in the draft bill, 8 percent) of sales. The intent here is to meet the situation now common in which a patented drug is available only from the patent holder and perhaps two or three other firms, all of which charge essentially the same price. In Kefauver's view this price is usually unwarrantedly high. In Kefauver's view, if the drug were widely licensed there would be far more likelihood that competition would force the price down to a reasonable level.

The second change in the patent laws is intended to meet the problem of what is called "molecule manipulation." Kefauver has produced evidence that a sizable proportion of the new drugs patented and put on the market are not in any significant way new. They involve merely minor changes in the molecular structure of an already available, and perhaps unpatented, drug; their only advantage is that they can be patented, promoted as a new drug, and thus be relieved of direct competition with similar drugs identical in their medical effects. The Kefauver bill would require that a drug be significantly different in its effects as well as in the details of its molecular structure in order to be patentable.

AMA Testimony

The AMA testimony last week offered no comment on several of the provisions in the draft bill on the grounds that they involved economic rather than medical considerations. The patent licensing requirement was an example. On the provisions more directly connected with the AMA's professional field, the AMA spokesmen found nothing they could approve. Kefauver wants the government to have the power to decide what the generic names of drugs should be, on the grounds that the drug companies prefer to have the generic name sufficiently awkward to make it easier for the doctor to remember the trade name and use it when he writes a prescription. The AMA sees no need for the government to get involved in this, for the AMA has a committee to make recommendations in this field. Kefauver argued that there is need for someone outside the drug industry to have more power than merely to make recommendations.

On a more important point, Kefauver wants the Food and Drug Administration to be able to require proof of efficacy as well as proof of safety before it authorizes the marketing of a new drug. To some extent the FDA already has this power, for most drugs carry the possibility of harmful side effects, and a judgment on safety necessarily involves some balancing of the

benefits of the drugs against the possibility of side effects. But FDA has argued in the past that it should have direct power over efficacy on the grounds that any ineffective drug, even without side effects, is harmful since its use deprives a patient of treatment by another, perhaps more effective, drug.

The AMA argued that the FDA's powers should not be broadened, on the grounds that it is only through wide use that a clear idea emerges of the value of a new drug, and that there should be more cause for concern over keeping a possibly useful drug off the market than of allowing a useless drug to be sold. The AMA argued that it is just beginning an extensive program to keep the profession better informed on the latest evidence on the effects of new drugs, alleviating the need for government action in this field, and that except in very clear-cut cases, no one, not even the government, should have the power to interfere, as by keeping a drug off the market, with the judgment of the doctor as to what is the best treatment for a particular patient.

Kefauver professed to be unimpressed by the AMA testimony. The AMA, in assessing the efficacy of drugs, could not, like a government agency, require the drug companies to cooperate by supplying all the pertinent information from their files, including what might be unfavorable. On a broader question, Kefauver doubted whether it was reasonable to assume that the AMA could do a proper job of policing the advertising and promotional policies of the drug industry when it was dependent on the industry, through some $4 million annually of advertising in AMA journals, for over half its annual budget.

The debate comes down to a judgment on the degree of sanctity with which the partisans view the free enterprise system. To Kefauver, and to liberals generally, the situation in the drug industry is peculiarly offensive, both because the extra cost of drugs under the present system, although not particularly significant when viewed on a nationwide per capita basis, falls especially heavily on the comparatively small part of the population that is faced with heavy medical bills, and because of the peculiar nature of the business, in which the person who pays the bills has little chance to look out for his own economic interests since he has no choice over what to buy: the prescription is written for him by the doctor. This led Kefauver to open the hearings by announcing that so far as he was concerned his bill was a moderate one, involving changes in the ground rules as a result of which the pattern of competition in the industry would tend to move naturally in a direction more in keeping with the public interest. The alternative, Kefauver suggested, would be direct federal controls.

To conservatives the extra cost of drugs is not significant enough to warrant another step in the increasingly large role of the federal government in the economy. They are concerned that this legislation, aimed at a particular industry, would lead to demands to change the ground rules in other particular industries. This tendency suggests to many conservatives a more intimate degree of federal interference, as opposed to the bulk of the business regulatory legislation which has grown up since the turn of the century, which tended only to lay down ground rules for business competition generally. The AMA naturally finds itself sharing the views of the conservatives, not only because the leaders of organized medicine are themselves conservative, but because their greatest political interest is in opposing the development of socialized medicine, and they cannot help feeling, probably correctly, that any increase in the federal role in medicine weakens the resistance to a national health service. This may be especially true here, for the professed aim of the bill is to alter the circumstances that make the industry's heavy investment in promotion profitable. It would make the drug business less profitable, thereby reducing the economic power of a principal political ally of the AMA. It would, if it serves its purposes, sharply reduce the amount of promotion, and this would reduce the AMA's own resources, since the AMA, in fighting the increasingly expensive battle against a government-financed health service, has come to rely heavily on the money its journals earn from drug advertising. For all these reasons a far more intense controversy surrounds the bill than a casual reading of Kefauver's bill would suggest. For the bill, on a casual reading, appears to contain nothing more than a series of minor technical changes in laws of whose existence the public is scarcely even aware.—H.M.

News Notes

Micrometeorites

Three attempts were made recently by U.S. scientists to study micrometeorites, a potential hazard to manned space flight because of the damage they may cause to space vehicles on impact. The tiny particles move at speeds of over 47 miles a second.

The Air Force succeeded in collecting what may be the first micrometeorite samples with an Aerobee-Hi research rocket nosecone dubbed the "Venus flytrap." The particles were caught in plastic traps which were exposed as the cone opened when it reached an altitude of 47 miles. The exposure was maintained during the cone's ride up to 102 miles and was cut off at 65 miles as the cone returned to earth (see cut).

Scientists from the Air Force Cambridge Research Laboratories who examined the traps said the contents showed the existence of a dense band of micrometeorites which envelops the earth somewhere between these extreme altitudes. The traps were struck by ten particles per square centimeter each second.

Two types of micrometeorite detectors or traps were used: one made up of three physically separated layers of plastic, the two top layers of Mylar film 1/4000 and 1/1000 of an inch thick, respectively, and a ⅛-inch sheet of Plexiglas; another of relatively thick films of three harder plastics, Millipore, Formvar, and Lucite. The particles passed through the Mylar film layers, leaving holes, many visible to the naked eye. When they struck the Plexiglas, small craters, some also visible, resulted. Craters also were detected on the Lucite film, but most evidence of micrometeorite contact was apparent only through microscopic examination. Few micrometeorites themselves were collected since they apparently vaporized on contact with the detecting surfaces.

AFCRL scientists are interested in the residual bits of the space dust lining the walls of the craters in the plastic as well as in the meteorites themselves since it is believed the particles may provide new clues concerning the origin of the meteorites and, perhaps, the origin of the earth and the solar system. Complete anal-