

In addition to the lists sent to some 6,000 agencies and interested parties, which I have previously mentioned, the Food and Drug Administration publishes periodically the FDA Drug Bulletin to provide timely information to physicians on actions, uses and labeling of drug products. The latest issue dated May 1972 contained the final labeling approval for oral hypoglycemic drugs, methadone for heroin addiction, and others. These bulletins provide to the extent possible unbiased scientific information to assist the physician in his drug therapy. About 600,000 copies of each issue of the Drug Bulletin are mailed to physicians, pharmacists, dentists, third and fourth year medical students, State and national medical and pharmacy associations and medical and pharmacy journals.

The pharmacists in the Department's hospitals publish newsletters containing information on drug use and costs on drugs in a particular category for distribution to physicians and nurses. Many pharmacists in hospitals throughout the country publish periodically information on the use of drugs in the treatment of disease for distribution to physicians.

The Food and Drug Administration on May 4, 1972, proposed detailed plans to clarify and formalize the agency's policy on public disclosure of information. FDA is a major depository of original, scientific, and technical information relating to drugs, foods, and other products.

The Food and Drug Administration files contained vast amounts of scientific data which have been developed over the years to prove safety and effectiveness for a variety of drugs and other products. Much of these data can help eliminate duplication of costly scientific research if it is more widely known and applied. However, there are valid reasons why some of the vast technical information in our files should remain confidential. It is not our intention to make public any data from any manufacturer that would give competitors an unfair advantage or reduce incentives for future research.

Mr. GORDON. What do you mean by unfair competition, unfair advantage? How do you determine whether competition is fair or unfair?

Mr. SEGGER. Well, the point is that we don't want to give away any trade secrets, I guess that is the general term used, and thus vitiate the advantage that a given company gains from its own research and development.

Mr. GORDON. That is covered by the law anyhow and it would include the processes and the methods of manufacture.

Mr. SEGGER. Yes.

Mr. GORDON. But you talk about giving an unfair advantage to competitors.

Dr. FINKEL. The clinical trials themselves are frequently rather sophisticated, and were developed under a contract with consultants, so that firms frequently feel that the clinical protocols which they have developed are confidential information.

Mr. GORDON. Generally, the firms have a patent, which gives them a 17-year monopoly. Is this going to give them a perpetual monopoly?

Dr. FINKEL. I believe after the drug is approved for marketing that the clinical data on the basis of which the drug was approved will be made public, also the preclinical data, unless the firms can show