From The Editor's Memo Pad:  

FDA STILL IN TROUBLE

The July/August 1977 issue of Ethics and Medics contained an article mentioning some of the problems facing the Food and Drug Administration in its regulation of the drug industry. On the one hand, the FDA is perceived by some as hindering the introduction of effective, new drugs into the market; on the other hand, it is criticized by others for yielding to pressures from the drug industry by permitting the sale of drugs that produce unexpected and harmful side effects. A recent proposal of the Carter Administration, largely written by officials at the FDA, promises to increase the agency's difficulties.

In the May/June 1978 issue of The Sciences, FDA Commissioner Donald Kennedy argues strongly for the necessity of changing our current drug laws, asserting: "I see this kind of law as one that can only be in the best interests of the public, the physician and other health professionals. It will certainly also be in the long-term interest of the pharmaceutical industry and drug development generally."

Three features of the new bill (H.R.11611 and S.2755) have already attracted severe criticism from various groups. One provision of the bill would lower some of the requirements confronting pharmaceutical companies in their introduction of "breakthrough drugs," drugs that provide significant improvement in the treatment of hitherto intractable illnesses. This proposal has received support from the drug industry. C. Joseph Stebler, president of the Pharmaceutical Manufacturers Association, has said that "excessively burdensome regulation serves to delay innovation and force continued reliance on the more expensive sectors of the health care system. Society cannot turn to antiscience, to holdbacks on technology, and expect to gain."

But Dr. Sidney Wolfe of the Health Research Group, an organization affiliated with Ralph Nader, has charged that this lessening of requirements is unnecessary, that it is a product of the myth, perpetrated by the drug industry, of an obstructionist FDA which needlessly hinders the introduction of new and valuable drugs.

A second proposal now receiving criticism would require that drug companies submit data pertaining to a new drug's relative efficacy: drugs would be evaluated partly on the basis of whether they represent a significant improvement over existing forms of therapy. A requirement of this type has long been desired by consumer interest groups and opposed by drug manufacturers. Representatives of the drug industry have argued that the effectiveness of many existing drugs has not been fully appreciated for years after their introduction, and that compounds are later found to be useful in treatments not originally approved by the FDA.

A third proposal is perhaps the most controversial of all, one that would require the publishing of data relating to the safety and efficacy of new drugs, information that has long been regarded as trade secrets. This requirement is strongly supported by public interest groups which have argued that trade secrecy is used as a tool by the drug industry to hide many of the harmful effects of the new drugs. These groups have wanted access to these data in order that they might more effectively oversee the findings of the drug companies and of the FDA. But the drug industry is vehemently opposed to any such revelation, contending that premature disclosure would help competitors, particularly in countries where patent laws are weak.

Dr. Louis Lasagna, Professor and Chairman of the Department of Pharmacology, University of Rochester School of Medicine and Dentistry, in a recent article in Science (26 May 1978) notes in this connection "that since the current laws allow the FDA to demand evidence for both safety and efficacy of new drugs, and the means to take any drug that is an 'imminent hazard' off the market forthwith, the fault seems less with the law than with the way it has been implemented."

The Freedom of Information Act (FOI) was enacted in 1966 on the assumption that it would be used primarily by private citizens in order to obtain information about the activities of their government. Nevertheless, the FOI also permits individuals to gain access to files kept by federal regulatory agencies on companies and their products, and extensive use has been made of this provision. Indeed, the federal law has given rise to a number of new companies, the best known of which is F.O.I. Services, whose business consists in obtaining information for clients from the federal government under the provisions of the FOI. F.O.I. Services initiates more than 5000 requests each year to the FDA alone. Many of its clients are interested only in knowing what requests have been made by their competitors; and stories are told of how F.O.I. Services has notified one of its clients that it was seeking information on the client at the request of another client.

The drug industry fears that the new proposal will simply compound an already serious problem. Once again, the FDA is in the position of being able to please no one, with neither the consumer activists nor the drug manufacturers finding the bill acceptable. (Chemical and Engineering News, 5 Dec. 1977, p. 18 and 24 April 1978, p. 16; Science, 27 Jan. 1978, p. 409.)

The above discussion makes it evident that there are strong and differing opinions as to what kind of a drug law is needed by this nation. The ethical concerns transcend the questions of efficacy and safety. There are ethical issues regarding human experimentation during drug development. There are questions regarding promotional policies and methods. The prescribing practices of some physicians have been questioned on ethical grounds. In our society, companies can justly expect suitable gain for their legitimate activities. Not beyond question are some of the practices of regulatory agencies. As laudable as their motives may be, the zeal of some of the consumer advocate groups may lead to tactics of an ethically questionable nature. Consequently, much patience and the willingness to understand and appreciate differing viewpoints will be necessary to arrive at a revised drug law which deals justly with all interested parties.