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The Doctor, The Patient, and The FDA

Herbert L. Ley, Jr.*

EDITOR'S NOTE: The four articles immediately following represent the Proceedings of the annual convocation of the American College of Legal Medicine, held in New York City in 1969. Founded in 1960, this society has sought to bring together those physicians and attorneys with a special interest, and/or expertise, in the legal aspects of medicine. Further information on this organization may be obtained from their main offices at 60 East Scott Street, Chicago, Illinois. The Editors of the *Cleveland State Law Review* are gratified that this periodical has been honored by being designated as the vehicle for publication of the papers of the ACLM Proceedings since shortly after the society was organized. The four writers whose papers follow are typical of the high calibre members of the American College of Legal Medicine.

There have been considerable charges and counter-charges recently about the United States Food and Drug Administration's role in protecting the consumer, at least as far as the medical profession is concerned.

The FDA has absolutely no intention nor desire to assume the role of the physician or to interfere with the *bona fide* practice of medicine. The physician's primary concern is for the patient as stated in the Hippocratic Oath which he subscribes to; and in Plato's statement about physicians more than 2,000 years ago:

No physician, insofar as he is a physician, considers his own good in what he prescribes, but the good of his patient; for the true physician is also a ruler having the human body as a subject, and is not a mere money-maker.

The FDA and the physician possess in common a determination to protect the ultimate consumer, the patient. The FDA's purpose is spelled out in the Food, Drug and Cosmetic Act;¹ and the FDA's actions to implement it over the past half century have been upheld repeatedly and consistently in the courts. The physician's purpose is evident in the training, the dedication, and the single-minded devotion to what has been described as "the only profession that labors incessantly to destroy the reason for its own existence."

With so much in common, why then, the complaints by some persons that the FDA's actions on drugs, including drug labelling, drug recalls

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¹ 52 Statute 1040, June 25, 1938, 21 U.S.C.A. 301.

and the withdrawal of certain drugs from the market, constitute attempts to interfere with the practice of medicine? It is possible that one of the reasons, and perhaps the principal one, for this misunderstanding is the FDA's failure to communicate adequately its responsibility under the law to protect the patient and inform the doctor.

It is vitally important for the physician to have the most accurate and up-to-date information on drugs at all times. Similarly, it is the FDA's duty to see to it that this kind of information is available to the physician, promptly and without the distortions and exaggerations that so often appear in drug advertising and promotion.

The FDA's authority to do this is clearly provided for in section 705 (b) of the FDC Act.² It states in part:

The Secretary may also cause to be disseminated information regarding food, drugs, devices, or cosmetics, in situations involving, in the opinion of the Secretary, imminent danger to health, or gross deception of the consumer.

Significantly, the FDA has been upheld by the courts in several cases in the last ten years in which this authority was challenged. In the *Hoxsey Cancer* case³ the FDA issued public warnings in 1956 and 1957 against the quack Hoxsey Cancer Treatment. Mr. Hoxsey filed suit calling for the withdrawal of the warning which had been displayed in Post Offices throughout the country. The Federal Judge in Washington dismissed the case on a finding that section 705 (b) was constitutional even though it does not provide for a public hearing before the warning is issued. Again in 1964 a District Court Judge in Illinois said the FDA was authorized to issue publicity concerning its investigation of a cancer drug. And in 1967 a District Judge in Connecticut commended the FDA for its publicity concerning a seizure of an electronic device. The judge noted that Congress had imposed a duty upon the FDA to inform the public against the use of certain treatments.

The FDA has issued "Dear Doctor" letters and has required drug firms to issue such letters; and it has required changes in drug labelling along with corrections by drug firms in their advertising and promotion campaigns. It has issued newspaper releases, written magazine articles, and its staff has appeared on television and radio in an effort to carry through its basic responsibility to keep the public informed of the possible health hazards and to keep the medical profession informed of drug developments.

In my own testimony, I made clear the FDA's determination to exercise its responsibility in protecting the consumer. I stated:

When safety is not an issue, we do not plan to remove a drug from distribution until the hearing is completed. But in those cases, we

² 52 Statute 1058 Sec. 705(b), 21 U.S.C.A. 375(b).

³ *Hoxsey Cancer Clinic v. Folsom*, 155 F. Supp. 376 (D.C., D.C., 1957).

will insist that the companies include in all promotional material an affirmative disclosure of the Academic findings, and FDA's agreement that the product is ineffective. This information is essential to provide physicians with information that is highly relevant about the drugs they prescribe for their patients.⁴

This referred to the National Academy of Sciences/National Research Council findings on approximately 3,000 drugs marketed after 1962. The Kefauver-Harris Amendments⁵ to the Food, Drug and Cosmetic Act required that all drugs be effective, as well as safe.

Thus, in requiring drug companies to print the National Academy of Sciences judgments on those drugs which the NAS/NRC finds are ineffective, the FDA is following the Congressional mandate expressed seven years ago. In those seven years, the drug companies have had more than adequate opportunity to develop and present the kind of substantial evidence that is needed to show that the drugs are, indeed, effective for the diseases for which they are prescribed. Evidence is lacking in the case of almost every drug which the NAS has found to be ineffective.

The FDA thinks that the physician wants to know which drugs have been found ineffective and which present safety hazards. There are differences among physicians as well as drug companies concerning the NAS reports. The essential question is whether doctors should be informed by a responsible, objective government agency of drug findings by the top medical and scientific experts in the nation. The conclusion is that the FDA does have that responsibility under the law, and that physicians do want to receive that information.

With respect to curbing misleading and inaccurate drug advertising, FDA regulations state clearly and unequivocally that advertising aimed at physicians, and other health professionals, must be truthful, fairly balanced, and informative.⁶ Also, the FDA has published new Federal Regulations governing prescription drug advertising which became effective on June 16, 1969.⁷ The Regulations require that representations relating to the effectiveness of a drug must be balanced with information on side effects and contra-indications.⁸ The claims of usefulness for a drug may not exceed those permitted in the labelling approved by FDA. The Regulations also list twenty specific practices which would make a drug advertisement false and misleading, in violation of the law.⁹ Among the prohibitions are any suggestions that the drug is better, more effective, useful in a broader range of patients, safer, or has fewer or less

⁴ Statement made before the Intergovernmental Relations Subcommittee of the House Committee on Governmental Operations on May 13, 1969.

⁵ Drug Amendments of 1962, Public Law 87-781.

⁶ 21 C.F.R. 1.105.

⁷ 21 C.F.R. 1.105(e), Federal Food, Drug, and Cosmetic Act Sec. 502(n).

⁸ *Ibid.*

⁹ *Id.*

serious side effects or limitations than can be supported by clinical experience or other substantial and objective evidence.

An example of possible misleading advertisement in *Modern Medicine* concerned the drug Macrochantin, used for treatment of certain infections of the genito-urinary tract. The FDA asked the drug company to call the attention of all physicians in a letter to them, to certain misleading claims in the ad. The question remains, however, as to how many doctors actually read the letter.

The FDA took similar action against another drug company with regard to an advertisement for Ismelin. Again, the drug company notified all physicians of the portion of the ad which was regarded as misleading. Again, how many physicians read that letter?

Many of the complaints about faulty medical advertising come from physicians themselves; as well as from competing companies. In other words, the doctors themselves realize that they need accurate information on drugs, to provide the best possible patient care. They are upset when a drug company or drug detail man tries to deceive them about a product they might prescribe for one of their patients.

Unfortunately, communication is not a precise science. It is not like chemistry, where you can predict with considerable accuracy the reactions you will get when you mix two chemicals in a test tube. When the FDA sends out a "Dear Doctor" letter, or issues a press release, or makes a speech, it hopes to get a reaction. Rarely however, does it know with any degree of accuracy how much of a reaction or whether the reaction will prove to be the one anticipated.

The response to stimulus is what the communicators like to call "feedback." They base the effect of their public relations or communications program on the amount of feedback they get, sometimes in terms of letters or telephone calls, or hopefully in terms of some overt action in the form of a resolution by the target of the particular communications tool. This is the reason why the FDA is using every possible communications media to get their message through, in hope that one or two of them, or perhaps more, will elicit feedback. They are meeting with the editors of medical journals, including those published by the American College of Physicians and the American Society of Internal Medicine. The *New England Journal of Medicine* has been most cooperative in this matter, having published a recent white paper on drug efficacy.

The FDA has recently established, as part of the Education and Information Program, the position of medical communicator. It is his responsibility to prepare, implement and modify where necessary, a communications program with the medical profession through a variety of methods; including white papers, magazine articles, seminars, television and radio programs, etc. In short, anything which will transmit the information from the Bureau of Medicine to the physician.

The FDA has discussed unsuccessfully with AMA representatives the desirability of having the *AMA News* present a better balance of significant issues in the drug area. In our opinion the *AMA News* has devoted considerable space to statements criticizing either the FDA, the National Academy of Sciences, or both. An example of this is an interesting letter from a physician.¹⁰ He criticizes the FDA for proposing to remove certain fixed antibiotic combinations from the market. The physician ends his letter this way:

Surely, all wisdom does not emanate from the Food and Drug Administration, or the National Academy of Sciences.

The FDA would be first to agree with this writer, and nevertheless maintains its responsibility and duty to communicate its findings and those of its experts and advisors to physicians, so that they can have the information they need to use in the practice of medicine. An excellent answer to that type of criticism can also be found in the FDA's response to a request from the AMA staff to a statement concerning a particular antibiotic (Panalba).

As physicians, we are concerned—all of us, with life itself, with the protection of life and with the quality of life. To accomplish our side of this awesome responsibility, we need your (physicians') cooperation, your help, your understanding, your criticism, to guide us in carrying on our functions.

In sum, the FDA can continue to make sure that the American drug supply remains the safest and most effective in the world, and that the FDA can share with the medical profession the best information we have available on these drugs.

¹⁰ Letter appearing in the *American Medical Association News*, June 23, 1969.