FDA consumer protection

REPORT ON THE FOOD AND DRUG ADMINISTRATION

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During the past year a West Coast family became ill after eating a meal which included a new heat-and-eat frozen food product. They had bought two packages, one of which was eaten and the other stored in the home freezer. Two weeks later the second package was heated and eaten. Again all five members of the family became ill and one had to go to the hospital.

The hospital called the County Health Department. They in turn reported the occurrence to the San Francisco District of the Food and Drug Administration. Since no packages were left of the original purchases, the FDA Inspector collected samples from the local supermarket. Bacteriologists at the San Francisco FDA laboratory checked the samples and found staphylococcus bacteria in quantities sufficient to cause the reported illnesses. A seizure action was immediately filed in the Federal court against the remainder of the shipment in the hands of the local distributor and it was thus promptly taken off the market.

Meanwhile, the San Francisco District had reported its findings to the District where the manufacturer was located. Another FDA Inspector visited the factory and found conditions that would have led to the bacterial contamination of the product. Several other lots that had been distributed were seized and the company undertook a nation-wide recall of all of the suspected products. A total of $211,000 worth of this food item was destroyed. The company, now very much aware of the need for strict sanitary and bacteriological control of its operations, promptly made very extensive improvements in the plant and adopted procedural changes costing altogether almost a quarter of a million dollars.

This case history illustrates several important points. It demonstrates, of course, that when foods are prepared on a mass production basis to be served in many thousands of homes it is vitally necessary that safe practices be followed and that there be effective enforcement procedures to ensure this.

But this story makes two other important points about the present problems and responsibilities of the Food and Drug Administration. The first of these is the very great impact of industrial technology, shown in the development of a host of new products which frequently raise new questions and problems of consumer protection. This is characteristic of all the industries we are concerned with -- foods, drugs, cosmetics, therapeutic devices, and chemical products used around the home. We are continually confronted with the task of keeping up with the new technology of dynamic industries.

The second point of this story is the fact that consumer protection is not really achieved until industry has taken the necessary steps. We commonly say that the law protects the consumer, or that the FDA protects the consumer, but neither one is effective until the manufacturers comply with the law. In the last analysis, they have to deliver the protection. And the law puts the major responsibility on them.

This leads to another important and fundamental concept.

The consumer is better protected when steps are taken to prevent injury and law violations than by merely punishing violators afterward. This principle underlies a basic trend in the Federal Food, Drug, and Cosmetic law over the past 25 years. During this quarter century a series of major amendments have converted the law from a primarily punitive statute into one that contains many built-in procedures for assuring the safety of foods and drugs prior to marketing. Among these provisions are those requiring the certification of insulin and antibiotic drugs; the clearance of new drugs; and the Pesticide, Food Additive, and Color Additive Amendments to the Act.

The latest amendment to apply the preclearance principle is the provision in the Kefauver-Harris Drug Amendments of 1962 requiring that new drugs be shown to be effective, as well as safe, before they are marketed commercially. This law also imposes new safeguards on the investigational use of new drugs and new antibiotics to prevent injury while the drugs are being studied prior to their commercialization.

The Federal Food, Drug, and Cosmetic Act today reflects the complex industrial technology of our times -- an ever-increasing technology. It is an effort by our society and our law-makers to cope with this technology and to ensure that its benefits will to the greatest possible extent outweigh the risks and hazards. The law in fact is based on the same technology which brought it into being. It requires all producers to achieve standards which have already been demonstrated to be workable.

Such a technology and such a law requires far more in the way of communication and education than we once thought to be sufficient. The fact is that extensive and continuing communication is essential in securing industry compliance with this law.

Such communication is very much in the interest of consumers. Last month we had 700 people in this room which normally holds about 500, for a conference on the proposed regulations under the new drug amendments. We had 11 people on the platform answering questions, and the questions went on all day.

I sometimes think that if consumers were to become as interested in the Food and Drug law as industry, then all our problems would be solved--or perhaps just beginning! At any rate, we would be able to do a much better job. Certainly we need more communication with consumers than we have had in the past, and through our Consumer Consultants and our Division of Public Information we are taking some steps to accomplish this.

Here might be a good place to call your attention to our experimental museum which you will find on the third floor just opposite the elevators. The theme of this exhibit is:

"Science Working Through Law to Protect Consumers."

Here also we call your attention to our Monthly Report and our Memo For Consumers, which are available to all of you if you will request in writing to be put on the appropriate mailing lists.

Now I should like to report on recent developments that are of special significance to consumers.

All of us realize that a law like the Federal Food, Drug, and Cosmetic Act is neither static nor perfect. New developments frequently require changes in the law to meet new problems and conditions. The amendments I mentioned earlier were designed to meet such problems. But there are other needs which have not been met. For example, there is no requirement in the law that cosmetics be proved safe before marketing, or that new medical devices be cleared for safety and effectiveness. Our inspection authority is limited in ways which seriously handicap our law enforcement efforts. We are barred from seeing certain records which are required in determining whether or not firms are complying with the law, and that are essential to preventive rather than punitive enforcement. Another serious need is for stronger control over sedative and stimulant drugs which are widely diverted into illegal channels. I am speaking particularly of the so-called sleeping pills and pep pills which are involved in crime, highway accidents, and delinquency.

Bills dealing with these problems have been pending in Congress for years. President Kennedy summarized the need for such legislation in his message on consumer problems February 14, 1962. The legislation was combined in two so-called "omnibus bills" that were introduced in the last Congress. One of these bills dealt largely with prescription drugs and the other with cosmetics and therapeutic devices. Hearings were in progress.

Then, as you all know, the tragic story of thalidomide hit the headlines. A major medical disaster had occurred in Europe -- thousands of armless and legless babies had been born to mothers who had taken this supposedly harmless drug. But it had been kept off the market in the United States by the FDA Bureau of Medicine acting under authority of the New Drug Section of the 1938 law. Dr. Frances Kelsey, who reviewed the application, with the concurrence of her medical associates was not satisfied with the data submitted. She insisted on answers to her questions; more information. By so doing she delayed action on the application which would otherwise have become effective automatically. Months went by and then came the shocking disclosures in Germany.

The thalidomide experience dramatized for the American public the great importance of adequate controls for drugs. Congress responded

by enacting the legislation now known as the Kefauver-Harris Drug Amendments of 1962. This law is a major advance in consumer protection. I would like to summarize it briefly.

1. Drugs are defined as adulterated if they are produced in a plant that is not equipped and operated in conformity with good manufacturing practices that will result in all drugs being produced under conditions adequate to ensure their safety, identity, strength, quality, and purity.

2. From now on, before a new drug is approved for marketing, it must be shown that it will have the effect it purports or is represented to have. Heretofore, only clearance for safety was required.

3. When new information raises questions about the safety or effectiveness of a previously cleared drug the new law provides for the drug to be withdrawn promptly from the market. A new drug may also be required to be withdrawn if the manufacturer fails to maintain the required controls or keep the necessary records, or refuses to give FDA access to such records.

4. Manufacturers are required to report promptly to FDA any information they get regarding adverse effects from new drugs and antibiotics that are on the market.

5. Authority is provided for much tighter control over distribution of drugs for research pruposes before approval for marketing. Both patients and physicians who take part in clinical investigations will be better protected by these regulations, and they will likewise contribute to higher professional and scientific standards in medical research.

6. All antibiotic drugs for human use are made subject to testing in the FDA laboratories and new batches of these drugs may not be shipped unless they are certified by the FDA as safe and effective. Exemptions are directed if certification is found to be unnecessary.

7. Authority to inspect establishments manufacturing prescription drugs is strengthened to encompass access to many things previously immune to inspection.

Consulting laboratories doing work for drug firms on a fee basis are specifically included as establishments subject to inspection.

Federal courts are given jurisdiction to issue injunctions against refusal to permit inspection authorized by the Food, Drug, and Cosmetic Act. This applies not only to prescription drugs but to all articles covered by the Act. Previously, the only remedy for refusal to permit inspection was criminal prosecution.

8. Every drug manufacturing establishment in the United States, regardless of whether it is engaged in interstate or intrastate commerce, must register annually with the Department. We are directed to inspect them at least once every two years.

Manufacturing establishments in foreign countries may register. If they do not, a sample from each of their importations is to be made available to us for analyses.

9. Authority is provided to designate "established names" for drugs when this is desirable in the interest of usefulness and simplicity.

10. Advertising of prescription drugs must include (a) the established name in type at least half as large as the brand name; (b) the drug's quantitative formula to the extent required on its label; and (c) a true and non-misleading brief summary of information as to adverse side effects, contraindications, and effectiveness of the drug for the guidance of physicians.

The advertising provision is of special interest because, for the first time, an advertising law has been enacted that is enforceable in the courts by seizure, injunction, or criminal prosecution. You may recall that the 1938 Wheeler-Lee Amendment to the Federal Trade Commission Act dealt with advertising to the medical profession in a limited way. Only materially misleading statements could be challenged. In contrast, the Kefauver-Harris Amendments to the Federal Food, Drug, and Cosmetic Act require advertising to the medical profession to be not only free from false and misleading claims, but also to include affirmative disclosures concerning side effects, warnings, and precautions. Thus Congress has shown its intention to require that advertising matter, as well as labeling, shall provide physicians with vitally necessary information regarding the drugs they prescribe and administer to their patients.

As you can see, the Kefauver-Harris law is a very important advance in the field of consumer legislation. Likewise, it is a great challenge to the Food and Drug Administration and to the drug industry. We in the FDA are confronted with a most difficult task of administration that required the enlargement and strengthening of our medical staff to handle the greatly increased and more complex responsibilities. The drug industry is challenged with higher standards in both medical research and drug production. I believe that a good beginning has been made toward the accomplishment of these objectives.

There are many other topics which I could appropriately report on at this meeting but there is not enough time.

We have been delighted that the Council on Consumer Information decided to meet in Washington this year. Your organization is one of great importance today, and potentially even more so in the future. In these times, consumers need to be informed as never before. From many years of observation I can tell you that consumers have a habit of neglecting their interests except at those rare times when they get excited about something. It takes an organization to develop an effective, consistent program for informing the consumer. The Government is trying to do its proper share in this. We in the FDA are hopeful that consumers will continue to take an interest in their

problems as consumers. We hope you will be inquisitive and communicative. Let us know when you encounter anything that comes under our jurisdiction that you think is detremental to your interests. This often helps us to help you.