UNFINISHED BUSINESS IN CONSUMER PROTECTION OF FOODS, DRUGS, AND COSMETICS

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In 34 years with the Food and Drug Administration I do not recall a time when we have been as well informed about our "unfinished business" as we are today. We do not know the answers to all the present and future problems of consumer protection in regard to foods, drugs, and cosmetics, but we do know what many of the problems are.

Much of this knowledge was put on record in the comprehensive study made by the Citizens Advisory Committee on the Food and Drug Administration, published in June 1955 as House Document 227 of the 84th Congress. This is the report, you may recall, which made numerous recommendations for the improvement of our administrative, enforcement, and educational activities, but concluded there was not much wrong with the Food and Drug Administration which money couldn't cure. And you may also recall that this distinguished committee recommended a three- to four-fold expansion of the Food and Drug Administration to be accomplished in a period of five to ten years.

There is no doubt that this expansion program is the most important of all the FDA's unfinished business in consumer protection. Substantial progress has indeed been made, but we are still far short of the goal recommended by the Committee.

Some kind of yardstick is needed to measure the progress of any program, and to attain a four-fold expansion of our staff in a period of ten years would require an increase of approximately 15 percent per year. We actually exceeded this rate of growth for two years -- the fiscal years of 1957 and 1958. In fiscal 1959 our progress was considerably slower, and the 7 percent dollar increase provided in the contemplated budget for 1960, while substantial, will not get us back on schedule for a four-fold increase in ten years. We will be, roughly speaking, at the four year mark in the fifth year of the program. Meanwhile, the job of protecting the food and drug supply of the nation is growing.

A new law to assure the safety of food additives has increased our administrative and scientific responsibilities very considerably. Under this law the manufacturer is required to establish the safety of additives which have not previously been found safe. But the Food and Drug Administration must determine whether this research is adequate to insure safety. Futhermore, we must determine what amount of an additive may safely be permitted and in what foods. Our inspectors and chemists have the responsibility

of determining whether additives are being used according to the regulations. We asked Congress for a supplemental appropriation of $378,000 for 61 new people in 1959, and for $954,500 in our 1960 budget for an additional 60, or a total of 121 to carry on this work in the fiscal year of 1960. Scientists who are experienced in this kind of work are not easy to come by, so the protection of the consumer in this field may depend to a considerable extent on whether we are able to recruit as well as pay for the needed personnel.

Many people have the idea that when Congress passes a law dealing with a problem, it is all taken care of. Perhaps this is the reason that over the years the Federal Food, Drug, and Cosmetic law has seemed to grow faster than the organization employed to enforce it. Everybody is against sin, but it costs money to hire the policemen. An improved way to protect the consumer -- perhaps the best way -- is to set up machinery that will prevent violations of the law. This may actually cost more, but in terms of results may be cheaper than a system which depends entirely on punitive methods. Information and education play an important role in this type of law enforcement. Both industry and consumers must be informed if we are to do an effective job with this method of regulation.

The trend toward a preventive law is a continuing one. The Department is now drafting a new color additive section which will control the use of these materials in much the same way as food additives and pesticides are now regulated. Under such a law the amount of color that would be safe and the foods in which it may be used would be set by regulation. At present the law provides only that a color must be harmless in whatever quantity it is used. Many articles of ordinary diet, as well as colors, cannot comply with such a requirement.

Here again the cost of protecting the consumer would be likely to increase. Instead of having merely to determine whether a food manufacturer is using certified colors, the FDA inspector would be insterested in how much color is being used and in what foods. He would need to obtain samples of finished products so that their color content could be checked in our laboratories. Today the expense of testing and certifying individual batches of color is charged to the color manufacturer. Under a color additive law there would be the additional expense for monitoring the use of the colors.

The point I wish to make is that the costs of food and drug and cosmetic law enforcement are going up because the job is becoming bigger and more complicated. The products and processes of production are more complex, and the new laws are more complex and expensive to administer. The big overriding problem of consumer protection is that of adequate funds for research, administration, and enforcement.

Preventive legislation is also being discussed to strengthen the existing laws on cosmetics and therapeutic devices. Such legislation would require safety to be established before a new article, or one of uncertain safety, could be put on the market. Bills to require pretesting of cosmetics have been introduced in the last two sessions of Congress, but no hearings have yet been held. A bill to require safety testing of devices is currently being drafted by the Department.

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Now I should like to speak briefly on some of our "unfinished business" in regard to scientific problems. The Food and Drug Administration is basically a scientific institution. The facts we need to apply the law for consumer protection are obtained by scientific investigation. We are constantly in need of new facts and new methods and techniques that will enable us to deal with new problems of consumer protection.

For example, we have a pressing need for simpler and faster methods to detect and identify pesticide residues on foods. Pesticides are necessary in the production of our crops, but virtually all pesticides are toxic to humans in some degree. Prior to World War II the problem of regulating the use of pesticides was relatively simple. There were only three basic types -- compounds of lead, fluorine, and arsenic -- all quite easy to detect. Since World War II we have seen the introduction of the synthetic organic pesticides such as DDT and the organic phosphorous compounds like parathion. Today over two million farmers are using about 600 million pounds of such products annually on literally every food crop. Due to the potency of the newer chemicals only very minute quantities of some of them can be allowed to remain on foods. Many require safety tolerances as low as one-tenth part per million. The need of accurate methods for detection and measurement is obvious. Since many of the foods are perishable, such methods must be fast. And because we should be able to check a great many samples, they should also be simple and economical to perform. We have a number of research scientists working on the development and improvement of these testing methods, but we need to accelerate this program.

With such a large number of grows applying pesticides it is obviously impractical to have an inspector on every farm. Safety depends on the grower's carefulness in following approved directions for each pesticide and crop. A continuous educational program is needed to remind growers always to read the label and follow directions exactly. By doing this he protects the ultimate consumer and avoids possible seizure of his crop. Last year we had 14 seizures of vegetables which were contaminated with pesticide residues. I am glad to say that the pesticide industry is cooperating in our educational efforts to promote the safe use of pesticides.

Another of our current scientific problems is the possibility of toxic properties in reheated fats. It has been known for some time that commercial practices involving the continuous heating and reheating of fats and vegetable oils under a wide range of temperature bring about structural changes in the basic chemistry of these substances. New processes being developed by industry to find more uses for fat and its by-products involve such changes. There is a serious need for investigative research to identify and isolate any toxic substances produced by such processes and to determine whether they are harmful to man. Last year more than two million chickens died as a result of consuming a tarry residue from commercial distillation of fats. Our chemists are still working on the identification of the particular constituent of the material which killed the chickens.

Everyone who enters a modern supermarket is aware of the great changes which have taken place in the processing and distribution of foods. More attractive and efficient packages and containers are constantly being developed, utilizing new plastics and other materials. New forms of wax coating are being utilized. As in the case of most innovations in food marketing, they represent progress. The Food and Drug Administration has a job to evaluate the new packaging materials to determine whether or not they may contaminate foods and drugs to the point of becoming a source of danger. In part the food additive law will help to resolve such problems, but we need to conduct additional research of our own.

Frozen foods also raise some new questions which require answers. For example, does quick freezing alter the nutritional quality of certain foods? Are present processing methods adequate to prevent bacterial development?

Generally frozen foods are prepared on an assembly line basis. Processing usually consists of heating and quick freezing. Under present practice most of the foods are not sterile at the time of final processing and packaging. The use of ingredients which serve as ready hosts of bacteria (such as sauces and gravies), thawing and refreezing, and the lack of a final high temperature cooking process in the home, can combine to make such products a potential source of bacteria and toxins. Our microbiologists are now studying samples of frozen foods collected during processing, packaging and distribution. These studies have shown extreme variation in bacteria counts, including bacteria which can bring about illness. More research and investigation is needed in this area to assist industry and to safeguard public health.

So much has been reported lately on the question of radioactivity in foods that there is very little that I can add to the discussion. By law it is the Food and Drug Administration which is responsible for removing any harmfully radioactive food product from the interstate market. But the sources of radioactivity are

largely beyond our control. Some is natural, some from weapons testing, and there are other potential sources. With the limited funds at our disposal the Food and Drug Administration has been carrying on studies to find out which foods are affected by radioactive contamination and to what degree. Much more research must be done before we will have sufficient information to provide an adequate basis for dealing with the problems of radioactive contamination. Some of the research being done by other agencies will doubtless be helpful to us, but much of it is not directly applicable to the problems confronting the Food and Drug Administration. Granting that any radioactivity is undesirable, we have fortunately not encountered as yet any food with a dangerous level of radioactivity, nor do we think this is likely in the immediate future. But we need to be prepared.

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Our unfinished business also includes some deficiencies in our routine or basic programs. Particularly important to the consumer are food standards, which according to law are established to "promote honesty and fair dealing in the interest of consumers." We believe this covers any kind of sophistication which would cheat, deceive or confuse the consumer and interfere with her right to get what she expects when buying the standard article under its common name. Standards also benefit the food manufacturer by encouraging fair competition.

Where no standard exists, the way is open for the development of imitations, substitutes and "gimmicks" which may not be in the interest of consumers. For example, substitute fats are being added to peanut butter and ice cream. Once the use of such substitutes becomes widespread, competition usually forces other firms to follow suit with the result that an inferior product preempts the market. Prompt action may be necessary to forestall such developments.

This is an area to which we have given relatively little time in the past several years due to the need for concentrating on more pressing problems affecting health. More needs to be done in enforcing existing standards, completing work on pending standards, and establishing new ones. We are hoping to issue a standard for ice cream and other frozen desserts within the next few months. With 23,000 pages of transcribed testimony and over 500 documentary exhibits, the ice cream hearings set a record. They cover in detail every phase in production of five frozen desserts, ice cream, ice milk, frozen custard, fruit sherbet, and water ice. The most difficult question of the hearings was whether certain synthetic emulsifiers should be allowed. Another difficult question is the milk fat content which should be required in ice cream in view of non-uniform state standards.

The newest food standard is one setting specifications for artificially sweetened canned fruits. Another recent standard is for frozen concentrates to make lemonade. Here we had to decide whether to require some proportion of unconcentrated lemon juice in order to produce the taste that consumers would expect in the finished product. The California citrus industry and the Florida industry were on opposite sides of the question. The matter was resolved when blindfold tests showed there was no distinguishable difference in the taste of lemonade made with concentrate alone or concentrate with some added straight lemon juice.

An amendment of the bread standards allows a small amount of gluten in rolls and raisin bread. This will make a stronger dough so that the hinge of your hot dog roll will not come open, and the raisins will be more evenly distributed in raisin bread.

A standard for vitamin and mineral enrichment of rice has been made effective in all respects save for the addition of riboflavin. Some rice millers object that the yellow coloring imparted by riboflavin will hurt sales. A hearing will be held to resolve this question.

Some food industry lawyers have contended the Food and Drug Administration standard-making activities are too restrictive on product improvements. We do not think the record will sustain this contention.

Labeling practices constitute an area in which we have much unfinished business. Enactment of the present Federal law in 1938 brought about great improvement in the labeling of foods, drugs, medical devices and cosmetics. Since that time there have been many advances in the art of packaging. Supermarket retailing has put heavy emphasis on the sales function of the package. Its function as a medium of consumer information is too often neglected or perverted. Information required by law for the protection of consumers, such as net weight and ingredients, it being relegated to the fine print and the far corners. Sometimes one can hardly find it. More needs to be done to enforce the requirement that such information be declared so conspicuously that it will be read and understood under ordinary conditions of purchase and use.

Colored wrappers are sometimes used on fruits and vegetables to make them seem fresher or better than they are. We are concerned about all such practices and to the extent of our ability we are trying to deal with them. Consumers could help, especially by reading labels more consistently and carefully, and basing their buying decisions on the pertinent facts. It is disturbing to hear of surveys which show that many consumers pay little attention to the information on the label and do their buying mostly by "impulse" or by brand.

We are trying to bring about some voluntary improvement of labels; for instance, there is an industry group working on the development of simpler and more informative names for food additives. Some of the chemical names now used could as well be ancient Greek so far as the average consumer is concerned.

When we turn to the labeling of drugs we are at once involved in the broad problem of medical and nutritional quackery. False and misleading claims for vitamin products, food supplements, drugs and devices are on the increase today and are being utilized to bilk the public on a tremendous scale. Many agencies and organizations are concerned about this. In the Government, the FDA is responsible for labeling, the Federal Trade Commission for advertising, and the Post Office Department for mail frauds. But there are forms of quackery not covered by any Federal statute, and much of it is local in character.

The big, high-powered promotions and rackets of today are much more sophisticated than the simple cure-all promises of the old-time snake oil peddler. The amount of investigation and research now required to prosecute a big-time medical swindle is many times greater than was formerly the case. Consequently the number of cases which we can undertake at any one time is limited.

Education, if sufficiently widespread, is no doubt the most powerful of all weapons for combatting quackery. This is being increasingly recognized by organizations concerned with health education. The American Cancer Society, the American Medical Association, and the National Better Business Bureau are all actively working to inform the public about fake remedies and treatments. The AMA, particularly, is now conducting an effective educational campaign against quackery in the sale of vitamin products and food supplements. An AMA motion picture, "The Medicine Man," currently being shown by television stations throughout the country, exposes the deceptive practices carried on by many so-called "health food lecturers" and door-to-door vitamin peddlers. It shows their use of the "big lie" technique to make sales; the harm this can do to persons who really need proper food or medical treatment, and how federal law is enforced against these operators and practices.

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This report may give you the impression that the Food and Drug Administration has a great deal of unfinished business. That is certainly true, and there is much that cannot be included in a brief talk covering only the highlights of the matter. I should like, however, to modify any impression that little progress has been made. Measured in dollars, our appropriation for this year is approximately double what it was five years ago, and we have had an increase of about 50 percent in personnel. More important, perhaps, are the signs of increasing public curiosity and interest in health matters generally and about the work of the Food and Drug Administration. This is encouraging.