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Food·Drug·Cosmetic Law JOURNAL

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THE EDITORIAL POLICY of this JOURNAL is to record the progress of the law in the field of food, drugs and cosmetics, and to provide a constructive discussion of it, according to the highest professional standards. The FOOD DRUG COSMETIC LAW JOURNAL is the only forum for current discussion of such law and it renders an important public service, for it is an invaluable means (1) to create a better knowledge and understanding of food, drug and cosmetic law, (2) to promote its due operation and development and thus (3) to effectuate its great remedial purposes. In short: While this law receives normal legal, administrative and judicial consideration, there remains a basic need for its appropriate study as a fundamental law of the land; the JOURNAL is designed to satisfy that need. The editorial policy also is to allow frank discussion of food-drug-cosmetic issues. The views stated are those of the contributors and not necessarily those of the publishers. On this basis, contributions and comments are invited.

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TO THE READER

About This Issue.—We are pleased to present two of the papers which were presented as part of the program of Food Update Midwest Highlights—1963. The first, by *Harvey L. Hensel,* describes how the food law division of a law department works. In an informative article beginning on page 132, he describes his experiences as head of the Commercial Division, Law Department of Swift & Company.

Dealing with a difficult subject, *Marion A. Hoy,* an Oak Park, Illinois attorney, gives manufacturers some worthwhile advice on the handling of a food seizure case. The beginning of this article is at page 142.

A discussion on the effect of the investigational drug regulations on drug research and development concluded the nineteenth annual meeting of the New York Bar Association Section on Food, Drug and Cosmetic Law. This paper, by *Augustus Gibson,* Director of the Medical Research Division of Schering Corporation, appears on page 153. The other papers from this meeting were published in the February 1964 issue of the JOURNAL.

William F. Weigel, of the New York City law firm of Rogers, Hoge & Hills, spoke at the annual Research and Scientific Development Conference of the Proprietary Association. He commented on labeling problems which have confronted proprietary manufacturers since the enactment of the Kefauver-Harris Drug Amendments of 1962. He predicts that the future will bring more regulation in the field, in the article appearing at page 162.

Although there has been some discussion of applying less stringent requirements to small drug manufacturers, *Winton B. Rankin* feels that the possible advantages would "be greatly overshadowed by the disadvantages to all segments of our society." Mr. Rankin, Assistant Commissioner of the Food and Drug Administration, discussed problems which face the small drug manufacturer at the January 30, 1964 meeting of the Drug and Allied Products Guild, Inc. The paper begins on page 172.

"Products Liability Under the Uniform Commercial Code in New York and Other States" is the title of an article by *Warren Freedman,* which starts on page 178. Mr. Freedman, a New York City attorney, declares that the adoption of the Code "has altered many of the traditional notions of products liability, as had been delineated under the Uniform Sales Act." "Accordingly," he points out, "products liability, particularly to the extent that it depends upon the rules of warranty as set forth in the Uniform Sales Act, must now be carefully reviewed."

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Food·Drug·Cosmetic Law
Journal

How the Food Law Division of a Law Department Works

By HARVEY L. HENSEL

Harvey L. Hensel, Head of the Commercial Division, Law Department of Swift & Company, Delivered This Talk as Part of the Program of Food Update Midwest Highlights—1963, in Chicago on November 5, 1963.

I REALIZE that I am talking to a group of people who are not lawyers. I also realize that I am going to talk about the functions of one division of a law department, and most of the people I am talking to neither work in a law department nor plan to work in a law department. These facts might provide a sufficient basis for many of you to decide to close your eyes and get a little rest until the next speaker arrives. Before you succumb to this thought, and it may not turn out to be a bad idea, I would like to suggest two reasons why there may be something I can say which will be of interest to you:

(1) The very good possibility that you will, some time in the future, have to work with your law department on some phase of a food legal problem.

(2) The fact that there are many ways your law department can help you and you can help your law department if you are only aware of how this can and should be done.

I might add that I am going to make a point of trying to stress the ways in which the scientific fraternity and the legal profession in the food industry can work together.

As you may know, my subject this afternoon is how the food law division of a law department operates. I am going to be describing my experience as head of the food law division of Swift & Company. We happen to use the term "Commercial Division" instead of "Food Law Division," but the subject matter covered is the same plus some additional areas of responsibility.

Guidelines for Proper Operation

First, I would like to mention the general principles that should be followed to properly operate a food law division. The first principle is that of knowing your company's business. In a large and diversified corporation, as many of the food corporations are, this is not an easy assignment. It means not only knowing what products your company now makes but also having sufficient communication with all departments to keep abreast of the new products being developed and merchandised.

In the past there have been several times when food and drug matters have developed which I felt had no bearing on my company and which turned out to definitely affect us. As an illustration, I can mention the cranberry food and drug problem of not too long ago. I was absolutely certain that Swift & Company did not sell cranberries. What I had forgotten, until food and drug inspectors showed up at our ice cream plants, was that we produce cranberry ice. When the recent standard for carbonated beverages was issued, I paid little attention to it, as I was very sure that we did not manufacture soft drinks. Later I found out that we do manufacture an ingredient used by the soft drink industry. Thus it is a constant problem of a food lawyer to know his company's business, both present and future, in order to know when a new development in the food law field does affect your business.

The second basic principle that must be followed to operate a food law division is familiarity with the basic statutes and regulations. These statutes include the Federal Food, Drug and Cosmetic Act, the Federal Meat Inspection Act, the Federal Poultry Products Inspection Act, and the many state acts concerning food.

These above statutes and regulations must be available to you for convenient, constant use. We use the CCH Food Drug and Cosmetic Law Reports for the federal law. We have a separate notebook for each state where we collect the various food laws of

each state. These are only examples of the periodical tools that must be available.

Federal Register Is Important Tool

It is not enough to merely become familiar with the present law. The more difficult problem is to keep up to date on the changing laws, regulations, announcements coming out daily from the Federal Food and Drug Administration and other federal and state agencies. To do this, it is absolutely necessary to read the daily *Federal Register.* I might also add that we have a policy of having a separate copy of the *Federal Register* examined by one of our top scientists in the Research Laboratory each day. In addition to the *Federal Register,* I receive copies of all of the various federal food and drug releases and the new state laws and regulations as they are passed.

Meetings and Publications Are Useful

Another useful way to keep up to date on the many changes is to attend meetings such as the excellent one you are attending now. I recommend attending the National Meeting of the Association of Food and Drug Officials of the United States, and, if you have time, one or more of the regional Food and Drug Association meetings. I also highly recommend the annual fall meeting in Washington that is jointly sponsored by the Food Law Institute and the FDA.

These meetings not only have the advantage of keeping you up to date on current subjects, but they also afford the opportunity of personally getting to know various federal and state food and drug officials. In my opinion, this type of personal contact is extremely important.

I do not know if any of you have any need to contact state food and drug officials, but if you do, I recommend to you a book that lists the various officials of each state, their name, title, address and phone number. The book is entitled, *Directory of State Officials Charged with Enforcement of Food, Drug, Cosmetic and Feed Laws.* It may be obtained free of charge by writing to James C. Pearson, Division of Federal State Relations, Food and Drug Administration, Washington 25, D. C.

Regardless of how many publications I read and meetings I attend, quite often a member of our research laboratory calls me and tells me of a development which I should know about but do not. This is one of the ways you can help your law department.

It is obviously not enough for the lawyer to know of the various changes in laws and regulations, but appropriate and timely steps must be taken to communicate this knowledge to the individuals in the company who need to be informed of the changes. Sometimes they need only be advised of the proposed change. Other times, views are requested as to whether they desire to file a written protest concerning a proposed new regulation or change in regulation. Often mailing a copy of the pertinent section of the *Federal Register* is an effective method of communicating on the subject.

Methods of Communication

While we are on the subject of communication, I would like to mention several methods of communication that we use in the law department.

(1) Twice a week we have a morning meeting of the four members of the food law division. We use this opportunity to discuss the more important pending matters, to share interesting experiences, and to keep all members of the division where they can, with some degree of familiarity, answer questions about work being handled by other members of the division.

(2) Once every three weeks all of the division heads in the law department meet with the general counsel and assistant general counsel to discuss the various important matters being handled in the law department.

Up to now I have discussed general rules of operation which we follow and which probably any organization should follow. They can be summarized by two words—"good communications."

Basic Philosophy in Handling Legal Problems

Before I discuss some specific food problems, I would like to spend a moment on our basic philosophy in handling legal problems. We feel it is important that our clients understand our basic approach to problems presented to us. While our first approach to a problem is to determine if the course of action suggested by a company representative is legal, we do not necessarily stop at this point. If the approach suggested is illegal, it is up to us to be ingenious in suggesting alternate methods that will accomplish the desired goal and still comply with the law. Our law department cannot be and is not "soft" in applying the law to a given set of facts. At the

same time we do not desire the title of "obstructionists." A spirit of cooperation plus constructive suggestions goes far toward eliminating this undesirable title, while at the same time we are properly performing our function as lawyers.

Helping the Company Merchandise a New Product

Now let us discuss how specific problems are handled. Let us consider for a moment how the food division of the law department functions in helping the company merchandise a new product. Suppose the law department is advised that our company desires to sell a frozen product somewhat similar to ice cream that contains 900 calories. These are some of the food law problems that must be solved before the product can be marketed:

(1) What is the proper name of the product? Must it be called ice cream or ice milk, or is this a new product for which there is no common or customary name?

(2) Is this a standardized product? Is there a food and drug standard which must be met which would require that certain butterfat, etc. must be in the product and which would also require that certain ingredients must be in the product?

(3) If this is a dietary product, as it obviously is, what dietary information must be contained on the label?

(4) What general information, such as net weight, name of manufacturer, list of ingredients, must be contained on the label?

(5) Is the size of type and the contrast, in color on the package sufficient to comply with federal and state laws? This is an important current question. While the federal Hart Bill has not yet passed and may never pass, the publicity given the Hart Bill has prompted numerous states to pass new regulations on the subject of conspicuousness of labeling. The importance of uniformity of laws and regulations on type size to a company that distributes nationally cannot be overemphasized.

(6) I have already assumed that the product will be sold in interstate commerce, but in what states will it be manufactured and/or sold and will the product be in compliance with the state laws where it is manufactured and sold?

Practically all of the potential problems we have discussed concerning the marketing of a new frozen dessert apply to any other new product our company wants to market.

While we are discussing the subject of marketing new products, I would like to suggest that anyone working on a new product consult with his food lawyer *early* in the development of the product. Such a consultation may well result in a product being changed or work on it being stopped. For example, if a commercial department is advised that a product must be labeled "imitation," they are often no longer interested in it.

FDA Inspections and Hearings

Now let us consider the question of FDA inspections and hearings. If an FDA inspector arrives at one of our plants, it is our instruction to have the local manager cooperate with the inspector, accompany the inspector on the tour of the plant and obtain duplicate samples of any samples obtained by the inspector. Instructions are issued as to what type of information should be furnished to the inspector. If the inspector requests information not covered by the instructions, the plant manager is to call the law department for further instructions. No statement is to be signed without our department's specific approval. When the inspection has been completed, the local manager forwards to us a copy of the inspection report. This is a very important guide to what future action should be taken. If the report shows few or no items, this means that there has been a good inspection. If many items are listed, this usually means that prompt action should be taken. In an extreme case, this could mean promptly closing a plant so a thorough clean-up can be made. In other cases, a contact, by phone or in person, might be made with the FDA District Office having jurisdiction over the plant inspected. If the inspection is unfavorable, it is very important to have the duplicate samples analyzed. It is also important to determine what results the FDA Laboratory obtains on the samples picked up by the federal inspector.

In some cases, after the District Office has reviewed the inspection report and obtained the results from the FDA Laboratory, they will send a notice of hearing to the company, requesting that the company appear at the District Office and show cause why a charge should not be filed by the United States District Attorney in the local federal court. When such a notice of hearing is received, it is necessary for the lawyer who will represent the company at the hearing to consult with operating personnel and scientific personnel of the company in order to gather together the best facts and arguments for presentation to the FDA. Usually a trip is made to the plant that has been in-

spected. At the hearing the lawyer is usually accompanied by the local plant manager and possibly a representative from the General Office. At the conclusion of the hearing, the District Food and Drug Office reports the facts presented by the company to the Washington Office of the FDA, along with the recommendation of the District Office. From then on, no news is good news. If the Washington Office decides not to start action in court, the matter will never be heard from again.

Food Additive Petitions

Another subject handled as a combined effort of the law department and our research laboratory is that of Food Additive Petitions. The scientific material in these petitions is usually gathered together by a member of our research laboratory. A member of the law department may write part of the petition or may compile the entire petition. The law department always checks to be sure that the petition complies with the various legal requirements of the FDA regulation for such petitions. We then file the petition and keep a check on its progress until such time as the petition is granted.

Subject of Food Standards

One of the subjects in which we are constantly interested is that of food standards. Our approach may be in the form of the filing of a petition for an experimental permit so that we may temporarily deviate from a present standard. We may try to change an old standard or try to shape a new proposed standard so that it will contain satisfactory provisions. A current example of the latter classification is the present proposed standard by the federal government for peanut butter. Most of the peanut butter industry feels that the percentage of peanuts proposed by the government is too high and that many appropriate optional ingredients are not permissible under the standard. As a result, comments have been filed by most peanut butter manufacturers and a hearing on the standard will be held in Washington in the very near future. At this hearing, witnesses from many companies will testify concerning what standard should be set for peanut butter.

Net Weight Violations

Another type of problem that our division handles is that of alleged net weight violations. When a violation is charged, it is necessary for us to determine whether or not the product was actually below the net weight, and, if below, whether or not this was due to

natural shrinkage. It is a known fact that most products lose moisture when exposed to air, and consequently lose weight. Most state laws provide that a variation from net weight caused by ordinary and customary exposure does not make the product illegal. However, there are no exact standards as to what constitutes a variation caused by ordinary and customary exposure, as this depends on the type of product, how it is packaged and how it is handled. Some weights and measures officials feel that this type of variation must be offset by manufacturers overpacking. Industry generally has strongly resisted this incorrect interpretation of the law.

Handling of Product Complaints

Probably the type of work handled by our division that consumes the greatest portion of our time is the handling of product complaints. As is customary in our industry, our company does not have product liability insurance on food product complaints. Our division of the law department handles all product complaints involving illness, injury or property damage, with the exception of foreign substance complaints involving less than $100, these complaints being handled by the local plant manager. In the handling of product complaints we are primarily guided by two principles: (1) keeping our total cost as low as possible, and (2) not paying a claim if we feel it is fraudulent.

Our procedure is to make a prompt and thorough investigation of each product complaint. This investigation includes wherever possible the obtaining of a sample of the product involved in the complaint for the purposes of laboratory examination. After the investigation has been completed and the sample tested, we then form a judgment as to what, if any, settlement should be paid.

I think it would be worthwhile to take a few minutes to discuss how our scientific personnel assist us in the handling of product complaints. Let us discuss for a moment an alleged ham food poisoning product complaint where we have obtained a sample of the ham that is alleged to have caused food poisoning. Our local investigator is instructed to very carefully wrap, refrigerate in dry ice, and ship the sample to our independent bacteriologist for examination. We are fortunate in having an excellent, well-qualified, independent bacteriologist who examines all of our food poisoning samples, and, where necessary, testifies as an expert witness in court cases. By examination of the sample, the bacteriologist can tell us:

(1) Did the sample contain any bacteria of the type capable of producing food poisoning?

(2) Did it contain bacteria sufficient in number to produce food poisoning?

(3) Were the bacteria alive or dead? This latter fact is significant in determining whether the bacteria came in contact with the product before or after the housewife cooked the product.

(4) Did the sample show any other evidence of contamination which, although not causing food poisoning, may assist in determining the type of handling the product received?

The bacteriologist reports the above findings to the law department. We also receive investigation forms completed by the complainant and his or her physician. We check these forms to determine the following facts: (1) When was the product purchased? (2) When was the product cooked? (3) At what temperature and for what period of time was the product cooked? (4) How soon after eating the product did the complainant become ill? (5) What symptoms did the complainant have? (6) Did the complainant become ill after eating the product the first time or after eating the product the second time? (7) Did everyone who ate the product become ill?

After checking the above information and the report from the bacteriologist, it is usually possible to determine whether or not our product caused the illness complained of, or, if it did cause the illness, whether it was due to the handling the product received after it was purchased by the consumer. Our investigations clearly show that a large majority of our food poisoning complaints are caused by the handling the product received after it was purchased by the consumer.

If a food poisoning complaint becomes a lawsuit, we often take the deposition of the housewife who cooked the product, in order to determine exactly with what equipment and at what temperature the product was cooked. We then conduct duplicate cooking tests and determine the internal temperature of the product when cooked according to the method used by the housewife. These tests are particularly important in trichinosis cases, where we know that if the product reached the temperature of 137° at the time it was cooked by the housewife, there would be no live trichina in the product at the time it was consumed.

In foreign substance product complaints, we have the alleged foreign substance examined by the Laboratory, usually under a micro-

scope, to determine just exactly what the foreign substance is and its size. We then check with the operating people to determine if it is possible for a foreign substance of this type and size to get into the product.

Conclusion

In conclusion, I would like to emphasize that in the field of food law the scientist is the lawyer's right hand. The lawyer relies on the scientist for (1) general information on new food developments, (2) accurate scientific information about new company products, (3) scientific information in connection with food standards and food additive petitions, and (4) examination of samples and testimony in connection with food product complaints.

On the other hand, I believe it is safe to assume that the scientist needs the help of his lawyer to obtain approval for products he has developed and to advise him concerning the application and effect of the many food laws and regulations.

It has been my experience that lawyers and scientists work well together as a team. This may be partially caused by the similarity in amount of education both groups have received. I have always found it to be a personally enjoyable and intellectually stimulating experience to work with a scientist on a project. I can only hope that after your next contact with a lawyer on a food problem, you will have the same type of feeling toward the members of my profession. **[The End]**

INSPECTION OF FACTORY HELD PROPER

A factory inspection of an establishment in which cancer drugs for investigational use were being prepared and delivered for introduction into interstate commerce was authorized by Section 704(a) of the Federal Food, Drug and Cosmetic Act (FOOD DRUG COSMETIC LAW REPORTS ¶ 2661), and such an inspection on a Saturday on which the factory was in operation was reasonable, the United States District Court in Chicago has ruled. Consequently, an action to enjoin employees of the Food and Drug Administration from conducting such inspections was dismissed. The manufacturer was not entitled to access to the reports made by the inspectors to their superiors, the court said.

The court also ruled that the FDA was authorized by Section 705(b) of the Federal Food, Drug and Cosmetic Act (FOOD DRUG COSMETIC LAW REPORTS ¶ 2673) to issue publicity concerning its investigation of the drug.—*Durovic v. Palmer*, FOOD DRUG COSMETIC LAW REPORTS ¶ 40,099.

What to Do About Food Seizures

By MARION A. HOY

The Following Paper Was Presented at the Food Update Midwest Highlights—1963, Which Was Held November 4-8, 1963 in Chicago. Mr. Hoy Is a Partner in the Oak Park, Illinois Law Firm of Duday & Hoy.

TO PARAPHRASE AN OLD SAYING, the best seizure is no seizure. I hope that none of you will ever have to learn from your own experience what to do about a food seizure. However, food seizures do not always fall on the small, or fly-by-night operator. A perusal of the judgments entered in any given period will soon convince you that seizures can happen "in the best of families." Therefore, none of us can assume that "it can't happen here." For the sake of argument, let's assume that it will happen here, and what are we going to do about it?

A seizure can be made on the ground that a food is either adulterated or misbranded. My experience in defending food seizure cases has been limited to those made on the grounds of adulteration, and more specifically, those made under Section 402(a)(3) and (4) of the Federal Food, Drug and Cosmetic Act, which read as follows:

> A food shall be deemed to be adulterated . . . (a)(3) if it consists in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for food; or (4) if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health.

These are the provisions of the Act with which you are likely to be most concerned and the ones around which I would like to direct most of my remarks.

I have never been involved in a seizure action in which I did not wish that I had certain evidence that could have been procured before the seizure took place, but wasn't. So, if you don't mind, I should like to start this discussion with what I think could be done before a seizure to enable your attorney to present the best possible defense at the trial of the seizure that is about to take place.

If the seizure is based, for example, on high mold count, worm and insect fragments, or fly eggs and maggots, then the only question

to be decided by the court or jury is whether or not the particular adulterant is present in quantities in excess of those permitted by law.

The first seizure case our office handled involved No. 2 cans of whole tomatoes, and the seizure was based on the charge of adulteration with fly eggs and maggots. The only question before the court was whether or not there were more fly eggs and maggots in these tomatoes than the law permitted. Fortunately, for the claimant, the judge decided "no."

So many seizures include the charge that the product was packed "under insanitary conditions whereby it may have become contaminated with filth." In such a case, it would be highly desirable to have pictures of key spots in your plant taken during the period in question.

Where the charge of insanitation is involved, our experience has been that the FDA will seize any merchandise packed two weeks before and two weeks after the inspection of the plant. They reason that conditions did not get bad suddenly, and will not be changed for the better suddenly. Hence, the reason for two weeks before and two weeks after the date of the plant inspection. Any pictures taken during this period which would better enable the court or jury to understand the testimony offered in evidence could be highly advantageous to the claimant.

I think that pictures taken every few days, twice a week or even once a week, of key spots in your line and plant, showing the good clean conditions that existed, and the high quality of the raw product being processed, would be of material assistance to a lawyer in defending any seizure action on the ground of insanitation. I would take them at regular intervals, however, rather than just hit and miss.

Principle to Keep in Mind

On this question of sanitation or insanitation, you and I know that the only safe way to operate a plant is to keep it in good sanitary condition at all times, just as though you knew that an FDA inspector was going to drop in on you today, or tomorrow for sure. Maintain good canning practices, good sanitary practices, and good laboratory control. Perhaps one person should work as a sanitarian and be held responsible for the plant being kept in such a condition that there would be no question that it would pass an inspection for sanitation at any time. This sanitarian should be looking for things that the FDA inspector will be looking for when he drops around today, or tomorrow for sure.

The sanitarian shouldn't be like the minister from a small town in Western Missouri of whom I once heard. The good man took a trip through the Ozarks. While there he came across a swimming pool in which girls and boys were swimming together. This shocked him no end. He just couldn't believe that any such thing could really happen. He was so disturbed about it that on the Sunday following his return to his home town he preached a sermon in which he mentioned this observation. In his sermon he told how shocking it was, and added, "And the bathing suits that those girls were wearing were so scanty that if you should wad one of them up, you could put it in a teacup." After the service was over, one of the lady parishioners said to him, "Parson, what were the boys wearing?" He thought for a minute, then said, "I don't rightly know." Sometimes we see what we want to see and no more. You should be your own worst critic. Then if you keep your plant conditions so that you are willing to accept them, I don't think you are going to have much trouble with the FDA.

Value of Exterminator's Testimony

Working in cooperation with your sanitarian should be an exterminator. The testimony of our exterminator in one case was one of the most damaging blows that we dealt the government. This exterminator was given a free hand to spray any time he felt that a spray would materially reduce the fly population. Before the canning operations began, he sprayed inside and outside the plant, as well as the surrounding area. When he felt that the residue from this spray was losing its effectiveness, he sprayed again, and so on until the canning season was over. He testified as to the dates he sprayed and the type of equipment he used. The spray formula he used had been approved for this purpose by the Department of Agriculture of his state, and our entomologist testified that it was the best formula known for keeping down the fly population. Our exterminator testified as to the amount of spray he used on each occasion and the size of the area he covered. I couldn't have asked for any better testimony from an exterminator. He was also qualified and licensed as an exterminator of rodents and other pests, and his testimony on these matters was equally good.

Be sure to use the services of a qualified exterminator, and give him a free hand to do whatever is needed in his field. In the event of a seizure on the ground of insanitation, you will find that his testimony will be invaluable.

What to Do When Inspector Is Present

Now, the FDA inspector has come to make an inspection tour of your plant. If he is equipped to take pictures, and you permit him to take pictures, I think you should have your own photographer go right along with him, and take a picture of everything that the inspector photographs. If he takes a picture of a particular place showing it up at its worst, you take a picture of the same place showing it as it really is. While he is taking a picture of a little pile of accumulated dirt under your sorting table showing how terrible things are, you take one of conditions on top of the sorting table, with which the food actually comes in contact, showing the clean sanitary condition that exists there. When he takes a picture of a lug box of cull tomatoes, you take a picture of that same box, and note the time, place and who was present when it was taken. Then, when the government introduces this picture in evidence at the trial, and testifies that the box of culls was typical of the tomatoes that were going over your line, you will have some real evidence with which to combat that testimony. I use this illustration because that actually happened in a case which I tried in Chicago in the summer of 1955. We were able to overcome that testimony, but we could have done it a lot more easily, and perhaps more completely, if we had had our own pictures of the same lugs and witnesses who could have identified them for what they really were. The claimant, my law partner and I would have gotten a little more sleep that night.

It could be that a picture such as this on the part of the canner would be good preventive medicine. If the FDA inspectors had known that we had pictures of those same lugs of tomatoes and witnesses who could testify that they were culls that were only on the premises until a sufficient number of boxes accumulated to make up a truck load that would then be hauled away. I doubt seriously that the government would ever have introduced those pictures in evidence. The same would have been true of a lot of other pictures that the government introduced against us.

Now, when the inspector is making a tour of your plant, if he has any reason to question the quality of any of your products, he may take a few representative samples of the product in question. If this happens, have your analyst, and perhaps an outside commercial analyst, go right along with him and take at least two samples of everything that the inspector takes. This, like the pictures, could be quite a deterrent to the government in starting a seizure action against you unless it really has a case.

Accompany the Inspector on His Tour

Don't sit back in your office while the inspector goes through your plant. Go through it with him and have one or two of your key men, including your sanitarian, go along. Note carefully everything the inspector does and says. While he will give you a report when he is through with his inspection showing the condition of your plant as he found it, you should also prepare your own report of that same inspection, covering the points the inspector covered, and any others that you think important. Prepare your report right away while the conditions, as they were during the inspection, are fresh in your mind.

Know the Provisions of the Law Regarding Inspection

Don't attempt to "guide" the inspector on his inspection tour of your plant. Let him go where he pleases, and make him feel that you are perfectly willing for him to go there. Let him inspect everything that the law gives him the right to inspect. Most of the professional men I know are well informed on what the law provides with respect to their particular professions. Food processors should be similarly well informed. Know what items the law gives him the right to inspect, and then let him inspect those items without objection. If he insists on inspecting something that the law does not give him the right to inspect, you can, of course, refuse to permit him to inspect that item. If he insists on inspecting it, you might say to him something like this: "I don't believe that the law gives you the right to inspect that item. Since you insist that it does, I shall ask my attorney for his opinion on the question, and shall be guided by his advice."

One of your biggest rights is to see to it that the inspector does only what he has a legal right to do. Remember, you are both working under the same law. There is not one law for the inspector and another law for you. The same law applies to both. And where there is some ambiguity in the law, and some basis for an honest difference of opinion (and there always will be), it does not follow by any means that the inspector's opinion is always right and yours is always wrong, any more than it follows that you are always right and he is always wrong. Don't ever be arbitrary or unreasonable in your attitude or your actions, and don't let the inspector be unreasonable with you.

Storage Problems

Before we get to the actual seizure, there is one other point that I want to raise, and that is the status of the merchandise in between the time the inspector says to the warehouseman "Don't you move this merchandise until you hear from me," and the time that the merchandise is actually seized by the United States marshal. While I thought I knew the answer to this question, there was no actual decision on it, so far as I could determine, and there was some doubt, at least, in my mind, until the question was squarely presented to the United States Circuit Court of Appeals for the Seventh Circuit in the summer of 1957.

We petitioned the trial court for an order awarding us storage charges which had accrued during this period. The trial court entered an order in our favor, but the government appealed from this decision. In the government's brief, they made this statement:

> Holding the food prior to service of the monitions was entirely voluntary. The Federal Food, Drug and Cosmetic Act does not authorize executive seizures or embargoes.

The government's position was sustained, and the Circuit Court of Appeals reversed the trial court on this question. We know now that until the United States marshal actually seizes the merchandise, it is not in the custody of the government, and remains in the warehouse in the discretion of the other interested parties.

While the period before seizure is the most important insofar as we are concerned, and the one on which I should spend most of the time allotted to me, I do wish to cover a couple of points about things to consider after the seizure.

I believe that the first thing to decide after a seizure has been made is: Do you have a good defense? Do you have a meritorious defense? If you, your microanalyst, and your lawyer feel that you have a reasonable chance of winning on the merits, then file your claim, appearance, and get into the case for keeps.

A Good Microanalyst Is Important to Defense

I am assuming here that the ground for seizure is adulteration of the kind in which microanalytical results are important. If the ground is insanitation, then a microanalyst, as such, would be of little help. But if it is because of high mold count, or any ground charging that the article is actually contaminated with filth, then your microanalyst is going to be a very important person in the trial of this case.

Be sure that you have a good microanalyst—one on whose results you can rely. It would be well to have duplicate samples checked by an outside independent laboratory. I am speaking from experience on this point, for I once got caught in just such a jam. On the strength of the first analytical results I was shown, the majority of which looked very favorable, I filed a claim, appearance, answer and interrogatories. I really jumped in with both feet. Then I had duplicate samples analyzed by an analyst whom I knew to be thoroughly competent and reliable, and on whose findings I would have been willing to have gone to trial, only to have him come up with answers which, I learned later, were almost identical with those obtained by the FDA analysts. If I had obtained this man's results before I filed my claim and appearance, I would never have filed them.

The reason why it is advisable to determine that you have a meritorious defense before filing a claim is Section 304(e) of the Act, which reads as follows:

> When a decree of condemnation is entered against the article, court costs and fees, and storage and other proper expenses, shall be awarded against the person, if any, intervening as claimant of the article.

We, therefore, have a provision that the claimant shall pay "When a decree of condemnation is entered against the article," but there is no provision in the Act that the government shall pay when no decree of condemnation is entered against the article. Therefore, to file a claim and appearance without proceeding on to a successful conclusion means that you will not only lose the merchandise under seizure, but will pay the "court costs and fees, and storage and other proper expenses" in addition. Unless you feel that you have a fair chance of winning, there is little point in adding other costs to the loss that you have already sustained.

Make your decision on the basis of the merits of the case, and not on the basis that the government is on one side of the case, and you are on the other. Our courts are great neutralizers. When the government men step into the court room, they come as party litigants, just like you. If they can't prove their charges, they will lose.

On a number of occasions, I have urged that canners press for an amendment to the Act to provide something like this:

> "When *no* decree of condemnation is entered against the article, court costs and fees, and storage and other proper expenses, *including provable damages,* shall be *assessed against the Government* in favor of the person, if any, intervening as claimant of the article."

This would be the other end of that same stick. I think it would make for a very healthful situation.

How Good Is Government's Case?

Once a seizure action is filed, and you decide that you have a meritorious defense, and file your claim, appearance and answer denying the charges made by the government, your next step, then, should be to find out just how good a case the government has against you. Your attorney will know how to do this, using the means of discovery that are available to him. You will serve interrogatories on the government and learn from them just how strong a case they have against you. Once you have in your possession the documentary and other evidence that they are going to present against you, and you, of course, already know what you have by way of evidence in your own defense, you will be able to better evaluate your own chances of success. The government will, of course, be using similar tactics against you.

If you are successful in your defense, the merchandise will be turned over to you—that is unless the government takes an appeal. In this case, the goods will be held up for another year. If you are successful on appeal, you will no doubt then get your merchandise, for whatever it is worth.

But if it should be worthless, you will have no recourse against the government under the law. Even though your defense is successful all the way, which means that the government should not have seized your goods in the first place, you wind up with little or nothing economically and have no recourse against the government for wrongfully seizing your merchandise. This is certainly another instance of where the government has the power to destroy. One canner once said to me, after winning all the way through, but winding up with virtually nothing, "I guess it's worth something to be able to prove you were right." The satisfaction of proving that he was right was about all he got out of the case. And sometimes the claimant can't afford to pay the cost of that satisfaction. The amendment which I just suggested, making the government responsible for the claimant's provable damages if the government fails to sustain its case, would change all of this.

Two Alternatives if Defense Is Unsuccessful

Now, if you are not successful in your defense, and a decree of condemnation is entered, you have one of two alternatives: you can

either pay the costs and forget it, or you can get some salvage from the condemned merchandise by selling it to be used for animal food. People who raise mink or fox are usually glad to buy this condemned merchandise, at their prices.

In the event you decide on the latter, there are, naturally, certain items of expense. One such item that you may encounter is the cost of denaturing the product. In one such case that our office handled, the FDA insisted that before any canned merchandise could be released for use as animal food, it must first be denatured by puncturing each can adding to its contents a small quantity of fish oil, and then re-sealing the can. Now, if one had only a few cases, and they were going to be used within a few days, it might be all right to open them. But suppose you had 1,000 cases, and they would not all be used for six months, or perhaps a year. Then the only way you could keep them after once puncturing them would be to reprocess each can. That would render the whole salvage operation economically impractical.

That was the situation we had. I pointed this out to the FDA men, and tried my best to get them to agree to let us stamp on each can, in large black letters, with an ink that could not be removed, the words "FOR ANIMAL FOOD ONLY." However, they were adamant in their position that every condemned can had to be punctured and fish oil added. So I petitioned the court to let us proceed under the plan I have mentioned, pointing out to the judge what a needless expense it would be imposing on the claimant to follow the procedure on which the FDA was insisting. The judge agreed with me, granted my petition, and entered an order permitting us to proceed to dispose of the merchandise to an animal raiser by stamping on each can the words which I suggested. So if you ever have this problem, insist on using a stamp rather than opening each can.

Expense of "Good and Sufficient Bond"

Another item of expense could be the posting of "a good and sufficient bond" by the claimant to guarantee that the condemned merchandise will be used for purposes provided in the Decree of Condemnation, and will not find its way back into the channels of trade for human use.

Since the Act does not provide that a surety bond has to be given for this purpose, I argued with the FDA men that the claimant should be permitted to give his own individual bond, and thereby save the

expense of a surety bond. I thought that the canner had been penalized enough already and should not be penalized further by being forced to buy a surety bond, which the law did not require, but the FDA men would not budge from their position that a surety bond had to be given. So back to court we went, and again, the judge agreed with me, and we saved the expense of a surety bond, which, in this case, would have been considerable. If you are ever faced with this problem, I suggest that you do the same as I did.

The condemned merchandise which I have just described was seized because the product was contaminated with an adulterant which could not be removed. There was, therefore, nothing to do with the product except to destroy it, or use it for animal food.

From my discussion so far, you might have gotten the idea that when a shipment of merchandise is seized that it is all bad. This is not necessarily so. In fact, from my experience, very seldom is it all bad. By far the major part of the seized lot may be good. But if you are going to get back the good, you will have to do one of two things: (1) go in and defend the case so that the court will condemn only the part that the government proves to be adulterated within the law; or (2) permit the entire shipment to be seized, and trust that the FDA will give back to you that which they found to be all right. You are going to have to get into the case as a claimant to recoup anything under either method.

I have had no experience at getting back good merchandise after it has once been condemned. I have had experience, however, in trying cases in which there were both good and bad merchandise. In each of such cases, the court has refused to condemn any merchandise that should not have been condemned and has always released to the claimant that which the government failed to prove to be adulterated.

The first case I ever tried of this kind involved 20 codes of No. 2 cans of whole tomatoes, seized because of alleged adulteration with fly eggs and maggots. The government admitted that 16 of these 20 codes were all right, but they seized them also, and not once offered to release them to us until the morning we were ready to go to trial. That morning, in the lobby outside the court room, a government man said to me, "We are willing to give you back 16 of those codes now." My answer was something like this: "If you had made me that offer a month ago I might have accepted it, but now I am ready for trial, and I want them all."

So even though you know that only a small part of a seized shipment is bad, if you want to recover the part that is good, you are

going to have to get into the case as claimant, and, if you and the government disagree on what is good and what is bad, you are going to have to go to trial in order to get back those about which there is any disagreement.

As I mentioned earlier, a product can be seized because it is misbranded. In some of these cases, the product can be "brought into compliance with the provisions of this Act," in which case it can be put back into the channels of trade. For example, a packer could have his tomatoes labeled as "fancy" in quality, when, in reality, they are only "standard." This would render them subject to seizure, but there is nothing wrong with the tomatoes themselves. They are just not as good as the packer says they are. In such a case, the labels can be removed and other labels, which correctly describe the product can be put on in their place.

In any of these situations that I have described—whether the product is to be destroyed, used for animal food, or brought into compliance with the Act—it must be done "under the supervision of an officer or employee duly designated by the Secretary, and the expenses of such supervision shall be paid by the person obtaining release of the article under bond," according to Section 304(d).

Conclusion

In conclusion, I should like to say that the protection of the consumer, while at the same time giving to the consumer the safest, most flavorful, and most nutritious food supply possible for the lowest possible cost, is the objective toward which both industry and government are working. These must be accomplished within the framework of our law.

When anyone oversteps the legal authority that he is given, whether it be consumer, industry, or government, our entire legal structure is weakened. Here, of course, things are not all black or all white. There are always those varying shades of gray in between; and it is in this area that honest differences of opinion are to be found. If you, in industry, honestly feel that you are right in such a dispute, don't be too quick to give in. Remember that our laws and our courts are for your protection too. The fundamental purpose of our law is the protection of society, and not the persecution of any of its members.

I want to thank you for being so patient while I have dealt quite inadequately with a most difficult subject. **[The End]**

The Effect of the Investigational Drug Regulations on Drug Research and Development

By AUGUSTUS GIBSON, M.D.

Dr. Gibson Is Director of the Medical Research Division, Schering Corporation; Bloomfield, New Jersey. This Paper Concluded the Nineteenth Annual Meeting of the New York Bar Association Section on Food, Drug and Cosmetic Law, Which Was Held on January 28, 1964.

AS WITH MOST LAWS, no one can oppose the intent of the drug law of 1962 and its implementing regulations. As Hoover said of the 18th Amendment, it is "noble in motive." We are all in favor of safe and efficacious drugs. However, no law or regulation is self-enforcing and few are completely predictable in their ultimate effect. I hope, therefore, that an examination of the effects to date of the new law and regulations will not be construed as opposition to their intent.

Intent of New Regulations

Perhaps, however, this intent should be outlined more specifically so that we can consider in detail the extent to which it has been achieved. As I understand it, it was as follows:

(A) To insure efficacious as well as safe drugs. Others have been assigned this topic for discussion.

(B) To insure the safety, not only of the purchaser of the marketed drug, as was provided for in the New Drug Law of 1938, but also of the patient on whom its effects in man are initially determined. Specific measures designed to accomplish this end include: (1) Requirements for animal studies before any drug is given to man; (2) Administration only by qualified clinical investigators; (3) The formulation of adequate plans of investigation; (4) Notification of the subject that he is receiving an investigational drug unless, an

important proviso, the investigator believes it not to be in the best interest of the patient to so inform him; (5) Prohibition of the dissemination, for promotional purposes, of investigational drugs, a form of pre-marketing sampling; and (6) Requirements that adequate records be kept of distribution of the drug and the detailed effects thereof in each patient who has received it.

The new regulations have not been in effect very long. It is premature to assume that the present environment in which drug research is conducted will persist indefinitely into the future. Furthermore, I doubt if anyone really knows just what is now going on. However, for what it may be worth. I will present my own opinion on the present state of affairs. Even if it may be somewhat valid as of today, the situation is changing, hopefully for the better, and my comments on this occasion may be badly outdated within a year. One thing, however, may be said with some degree of assurance. The new regulations were not designed to expedite the marketing of new drugs, to increase their number, or to decrease the cost of their development. None of these objectives were intended. They have not come to pass.

How the New Regulations Are Faring

Have the other intentions been fulfilled? Taking them one at a time, the situation seems to be like this:

(1) The better companies have always carried out appropriate animal studies before going to the clinic. Now all companies must do so. Whether this has provided significant additional protection to the public is impossible to say. We don't know about the bad things that haven't happened since the new regulations have been in force and, even in the bad old days, few patients were harmed by investigational drugs. However, the value of animal studies depends on their ability to predict effects in man. There is a high degree of predictability for certain types of toxicity, such as acute lethal effect. There is much less for others almost equally important, such as teratogenicity. A great deal has been said on this subject; there are many opinions but not much research and few facts. We badly need better correlation of animal and human data and research on better methods of experimentation. This, it seems to me, is too big a job for the individual company. It is one on which government, the universities and foundations, and the industry should collaborate. The new regulations have resulted in very high mortality among experi-

mental animals. However, if such testing is considered an end in itself and is done in a routine fashion without thoughtful consideration of its significance and without efforts to improve techniques and understanding, these animals die in vain.

(2) The regulations provide that only qualified investigators take part in clinical investigation. This obviously is desirable. However, regulations do not train, provide, or reward investigators so that the supply has not increased to meet the demand. Drug investigation has never been considered a glamorous field and has been made even less attractive by the restrictive provisions which inhibit the initiative of the scientist and increase the number of forms which he must fill out. In spite of this, it is gratifying and slightly surprising that a larger number of investigators have not discontinued drug evaluation. There have been many statements to the effect that this has happened, and I can only speak from my own experience but, in general, it is still possible to find qualified investigators to study drugs with some promise of usefulness. On the other hand, the cost of drug investigation has gone up appreciably, since we are requiring more laboratory work, more secretarial assistance, and more of the time of the investigator himself. It is only to be expected that the average cost to the pharmaceutical company of a clinical study has increased and is continuing to rise.

Question of Qualifications of Investigators for Drug Testing

The regulations do not give us an answer to one of the most difficult questions which they pose: Who is qualified to do drug testing; what are the criteria for determining this; and by whom are these questions decided? The FDA has given us little guidance. Certification in a specialty, academic rank, and hospital staff positions are all factors which enter into the judgment of qualification, but I know of many people with eminent names in medicine who are poor investigators, and there are many young men just starting a career in clinical investigation who have not yet become known but who by native intelligence, diligence, and good basic training are well-qualified. As in every other field, an investigator is best judged by his performance. As you know from reading the daily papers, there probably have been rare instances of falsification of clinical records. It is, nevertheless, very easy to tell on examining an investigator's plan for research and the case reports and analysis which follow its conclusion whether he is truly qualified. The FDA has

always used these criteria in an informal way and has weighed drug research reports according to the internal evidence of their quality. This, no doubt, will continue to be the practice, and we who arrange clinical studies for the industry have used very much the same criteria. We are, however, tightening up our requirements and sharpening our critique in order to be able to present clinical data in our applications which will be acceptable to the physicians in the FDA.

One interesting by-product of the regulations is that a number of commercial organizations have sprung up throughout the country, offering to provide drug research for the pharmaceutical companies all the way from screening to toxicity studies to clinical evaluation. These are often well-staffed, and although I doubt if the large companies avail themselves of this service, these research institutes may be of help to the small firms which cannot afford large, full-time staffs.

Advance Protocols of Research Required

(3) The new regulations require that protocols of research be prepared in advance both by the drug company which sponsors the drug and by each individual clinician. Planning is always desirable, and probably has often not been as thorough in the past as it should have been. The chief objection to this provision is the fear that it will lead to loss of flexibility and that the clinician may be forced to carry out a study which experience proves unworkable or undesirable. We have been assured, however, by the FDA that reasonable flexibility will be permitted, and it goes without saying that a plan of investigation which proves to be hazardous may be abandoned. Changes in protocol, however, require further notification of the FDA.

Although our plans for investigation must be submitted to the FDA at the time that the clinical investigation is initiated, thus far we have received little or no comment on them, probably because the overworked staff in Washington has not gotten around to reading them. This is unfortunate, since it deprives us of the benefit of the judgment of the FDA on the suitability of our studies until we finally submit a New Drug Application. It is only then that we learn that they were inadequate in some respect. It is to be hoped that the prolonged period from the start of a clinical drug investigation to the submission of an NDA will be made more fruitful by an interchange of information and opinion between the physicians in the industry and those in the agency; otherwise, there will inevitably be great loss of time and delay in the availability of new drugs.

The FDA has divided clinical drug evaluation into three parts: Stage I, the initial trial in a few normal people to determine the probable dose and the immediate effects; Stage II, the first limited trials in ill patients to obtain some hint of efficacy; and Stage III, the prolonged and extensive studies in depth to delineate more accurately the dose, the efficacy in various indications, and the nature and incidence of side effects. It has for many years been the custom in a rather informal way to follow similar sequence of events, but there has been a tendency to pass gradually from one stage to another. The new regulations have emphasized Stage I studies in normal persons, since these require less preliminary data. The increase in such studies has resulted in much wider utilization of prisoners and student volunteers as subjects. This may, at times, present unusual ethical and medico-legal problems.

Notification of Patient

(4) The next provision is one which has caused a great deal of discussion and debate—the requirement that the patient be notified that he is receiving an investigational drug unless in the judgment of the clinician such notification is contrary to the best interest of the patient. Some investigators even prior to passage of the present law routinely notified their patients and, of course, now encounter no additional problems. Others have found this requirement a great handicap to accurate drug evaluation, since it is bound to introduce a large subjective element into the reporting of both relief of symptoms and side effects. This makes it more difficult to provide the objective evidence which the FDA requires.

A particularly difficult problem is raised in double-blind studies, where neither the physician nor the patient knows what drug is being administered. How can the patient give informed consent if the doctor cannot tell him whether he is getting an investigational drug, an old drug made up to look like it, or a placebo? Of course, the patient could be told that he is going to get one or another of these. In this case he might reasonably object to the possibility of receiving a placebo which could not possibly have any real effect on his illness. However, the placebo controlled double-blind technique has received a great deal of emphasis by the FDA. This in turn has created conflict with the legal requirement that drugs shipped in interstate commerce be labeled in such a way as to indicate their composition. Such a provision has been in the law for many years and, in spite of

it, double-blind studies have been carried out. However, the problem has been brought into sharp relief during recent months. There are, nevertheless, ways of complying with the regulations on labeling and at the same time providing for truly double-blind studies. However, they are both tedious and cumbersome.

Burden of Record Keeping

(5) Record keeping both as to the effects of an investigational drug and of its disposition is now required. In other words, if we send a doctor one hundred doses, at the conclusion of his investigation he should have a record indicating how many of these have been used, he should return to us the unused portion, and should report fully the effects in each patient. Such provisions are a useful measure of protection in case a drug is found harmful, since it is then possible to trace all outstanding supplies and to retrieve or destroy them. It does, however, provide an added burden of record keeping which the physicians do not always take to kindly. Most important is the requirement that there be adequate records of the effects of the drug on each pateint. If a doctor fails repeatedly to furnish adequate reports, he may be declared unacceptable as an investigator and no longer eligible to receive investigational drugs. It has always been difficult to get adequate, complete reports from physicians, since their secretarial facilities are usually overtaxed and their own records are often in a sort of illegible medical shorthand. However, I welcome this provision of the law, since it aids us as well as the FDA in making an accurate evaluation of a drug. We no longer have to rely on impressions which may not be backed by data, and we have the authority of the federal government in demanding complete reports from each clinician on each patient he has treated.

(6) The regulations prohibit the use of investigational drugs except for bona fide investigational purposes. A tacit exception to this is made for emergency cases where a patient may be dying of a disease for which a drug still in the investigational stage is the best treatment. In such a case we are permitted to make immediate shipment and to fill out the paper work later. Furthermore, the treatment of such an individual case is obviously not part of a planned investigation. Yet we will not be criticized for making a drug available to possibly save a life. However, the FDA does frown on supplying investigational drugs to marginal investigators whose chief function is to make the investigational drug better known to the medical

profession prior to marketing. There have, no doubt, been abuses in this respect, but the FDA regulations also make it far more difficult to carry out a legitimate, broad-scale drug evaluation, since this may be misinterpreted as semi-promotional distribution. Yet such broad-scale investigations often have a great value. A few cases carefully studied will, it is true, provide certain types of information more effectively than a large number observed more casually. Nevertheless, the true incidence of beneficial and harmful effects can only be determined on a broad statistical basis. The wider use of investigational drugs, once they are proved safe and probably effective should not be hindered, provided the results of such use are reported. Once a drug is on the market, we lose contact with the physicians using it and rarely learn about their experiences. There is, therefore, a real place for broad-scale studies which may point out the existence of unusual side effects or establish the degree of efficacy.

Having indicated certain specific areas in which the new regulations have altered the conduct of drug research, I should like to point out what I consider to be their more general effects.

More General Effects of New Regulations

First, there is little doubt that there is some inconvenience to investigators. This has made a few clinicians with borderline interest in the field of drug evaluation drop out of it and may well have kept others from entering it.

Secondly, the new regulations require paper filing and record keeping even in investigating an old drug for a new use or in altering a study of a new one just as they do for initiating the evaluation of an entirely new compound. As a rule these requirements are not difficult to fulfill but, nevertheless, this does prevent the independent investigator from lightly following up some educated hunch, new line of reasoning, or chance observation which may open up an entirely new area of medical usefulness. For instance, a drug introduced some years ago as an adjunct to the use of penicillin was found to be much more valuable in the treatment of gout. It is entirely possible that under the present regulations this use might not have been considered probable enough to justify even a modest amount of paper work. Thus, we may lose the important fruits of serendipity found by following faint leads or intuitions. Also, there are certain products which are of interest to only a few people either for academic purposes or the treatment of rare conditions. The average pharmaceutical com-

pany now does not find it possible to cater to such interests, since the effort required is almost as great as that for a large volume, highly profitable product.

Investment of Time and Money Increased

Above all, the regulations do increase the length of time necessary to introduce a drug. I doubt if many people realize how long this takes, even under the most favorable circumstances. From the time a new chemical structure is envisaged to its actual synthesis may take several months or even occasionally years. The first quantity produced is usually so small that it is only sufficient to provide the faintest hint of medicinal activity. Then comes the problem of producing enough for fuller evaluation in animals of possible usefulness and acute toxicity. This may take another three or four months. If the data up to this point are favorable, larger amounts are needed for chronic toxicity testing and for early clinical experiments. Fairly large amounts of material at high cost may be required and another six months or more may ensue in its preparation. One might ask "Why not make all of this in the first place?" The answer is that the cost would be prohibitive and the gamble not justified until we have some indication we are on the right track. The subacute toxicity prior to giving a drug even to the first human being requires six weeks or more of administration to animals and then several weeks for evaluation of results. After the first clinical pharmacology, which takes two or three months to complete, one must do additional animal studies prior to final clinical evaluation. The average drug is then in the clinic for anywhere from a year and a half to three or four years before a new drug application can be filed.

From the time of filing the new drug application until the first reply from the FDA is another six months, and it is the rare exception for a drug to be accepted on first submission. Refiling with correction of original deficiencies may occur in three to six months, and we may then get a final approval from four to six months later. After approval of the new drug application, preparation for full-scale production frequently takes another two or three months. It is only then that one begins to get some return on the successive investments of time and money. From the initial conception in the scientist's mind to appearance of a product on the market may easily take five years and often longer. The substantial investments of time and money make it more and more difficult for small companies to enter the pharmaceutical field

or to stay in it unless they have been so fortunate as to hit on a major successful product early in their career. The legislation bearing Senator Kefauver's name has not lowered drug costs nor helped the small manufacturer.

Even more important, the public may on occasion be denied the use of valuable agents for the prevention, alleviation, and cure of disease for many months or years by the serial time-consuming process of drug development. Much of the delay is quite unavoidable, but we should not unnecessarily add to that which is inherent in the discovery and adequate testing of valuable new drugs. The FDA, I am sure, does not wish to do this. The opportunities and temptations to procrastination and indecision, however, are great. A reasonable pace can only be maintained by insistence on the most rapid evaluation and decision consistent with safety. This present period of adjustment is difficult and exasperating for the manufacturer, the clinical investigator, and the FDA officials. By communication and cooperation in all phases of the drug development and testing process, we can keep it from also being costly to the health of the public.

[The End]

WIDE RANGE OF SOCIAL SERVICES AVAILABLE TO PREVENT ALCOHOLISM

Public welfare departments have been urged to provide a wide range of social services to help prevent alcoholism or to minimize its damaging effects on the family. Commissioner Ellen Winston, Welfare Administration, Department of Health, Education and Welfare, pointed out in a recent letter to state welfare directors that the federal government may pay 75 per cent of the cost of furnishing rehabilitative and preventive services to families and individuals whose social and economic conditions may contribute to alcoholism.

Commissioner Winston called attention to a new leaflet which suggests the kinds of specialized services that local public welfare departments can provide under the 75 per cent matching arrangement authorized in the Social Security Amendments of 1962. These services have "particular relevance to families in which alcoholism is, or is likely to become, a problem," she said.

The leaflet, "Alcoholism—A Preventive Approach Through Programs of the Welfare Administration," points out that the problem of alcoholism affects rich and poor alike, that it wastes family earnings, adds to the numbers receiving public assistance, and is responsible for a number of cases of abuse and neglect of children. It also notes that alcoholism among parents contributes to family breakdown and to juvenile delinquency and that it complicates the problems of caring for and protecting older persons.

The leaflet may be purchased for 5 cents per copy from the Superintendent of Documents, United States Government Printing Office, Washington 25, D. C.

Labeling of Proprietary Products–Current Problems

By WILLIAM F. WEIGEL

The Author, of the New York City Law Firm of Rogers, Hoge & Hills, Delivered This Talk at the Annual Research and Scientific Development Conference of the Proprietary Association in New York City on December 5, 1963.

IT HAS NOW BEEN MORE THAN A YEAR since the enactment of the Kefauver-Harris amendments to the Federal Food, Drug, and Cosmetic Act. As all of you must know, it has been a year of considerable activity in the drug industry, as well as one of confusion and uncertainty. It would be nice to be able to say that we now know just where we are and where we are going. That, however, is an impossibility. The Food and Drug Administration is still in the process of promulgating regulations. Some of these have been challenged by industry. Neither government nor industry purports to know the entire effect or meaning of the 1962 law. I, for one, feel less certain about my own comprehension of the law than I did a year ago just after its enactment. The state of affairs in the drug industry may be described as a bit chaotic. Nevertheless, we do function under a system of law and we must learn what the law is and conduct our businesses within its framework. Too many people in all segments of the industry seem to forget that Congress did pass the 1962 law and continue to argue its merits as if it were still pending. It's time to realize that the fight was lost and, even though the law is unsatisfactory, it is nevertheless the law.

What does all of this mean to the proprietary industry? At the time of the enactment of Kefauver-Harris we felt a bit smug. We felt that we had escaped the brunt of the new law. We got our "grandfather" clause; we avoided formula disclosure; we were exempted from the new advertising requirements; we prevented an extension

of factory inspection in proprietary plants, although we had agreed to accept considerable extension. We were included in the requirement of a premarketing showing of effectiveness on our new products, but by-and-large proprietary medicines are effective and, we felt that since we must prove it to stay on the market, we could prove it to get on the market. It thus did not appear that the new drug law would effectuate any major changes in the proprietary industry. That, however, has not been the case. The drug industry is an integrated industry and cannot be neatly segregated into proprietary and prescription segments. Many manufacturers are engaged in the production of both types of products. The promotion and distribution of many over-the-counter specialities more nearly resemble those of prescription items than those of proprietary medicines. There is a constant, although perhaps not abundant, switching of products from one category to another. Ethical manufacturers are looking to the proprietaries to add stability to their businesses. And, the proprietary manufacturers are looking to the ethical manufacturers as a major source of new products for the future. In essence, what affects one segment of this industry will of necessity have an effect on every other segment of the industry.

Manner of Interpretation Changes

The law with respect to the labeling of proprietary medicines has not undergone any substantial change since the passage of the 1938 Act. The manner in which that law has been interpreted, however, is constantly changing and will probably continue to change. Basically the food and drug act is a labeling statute and virtually everything which affects a drug product directly or indirectly affects the labeling.

Labeling consists of much more than the informative label that is placed upon your product before it moves in interstate commerce. Paragraph 201(m) of the Federal Act defines "labeling" as "all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article." The latter part of the definition has been given a very broad interpretation. It has been construed to include all promotional material which is used at or near the point of sale whether or not it was shipped with the article. It has included a number of books which have been used to promote the sale of an article, even where the article was not specifically mentioned in the book, and even where the book was not prepared, supplied or endorsed by the manufacturer. It has included

in-store promotional material and counter displays, even though they were not supplied by the manufacturer and even though the manufacturer had no knowledge of their use. In a recent case, involving a vitamin and mineral preparation containing "royal jelly," promotional leaflets were shipped interstate to a sales agent two months prior to and separate from the shipment of the drug to the same agent. The leaflets contained certain false and misleading claims with respect to the drug. Even though there was no evidence that the leaflets were even used to promote the sale of the drug, the court of appeals held that they constituted labeling, "since they were obviously *intended* to promote the sale of the drug and served no other purpose." The Supreme Court of the United States has been asked to review this decision, but there has not as yet been any indication whether it will. These decisions point up an important fact that should be borne in mind. Even though your label, package inserts, advertising and the like are correct and proper in every respect, your product may nevertheless become misbranded and subject to seizure by virtue of the promotional material used in connection with it. You will not be absolved from responsibility because the material is not your own, but has been prepared or supplied by some over zealous retailer without your knowledge. Nor, is it necessary that the material itself move in interstate commerce, if the drug article has. Although you are all anxious to have your products promoted at the retail level, you should be careful to make sure that you are aware and approve of the materials to be used in connection with such promotion.

The jurisdiction of the FDA, as you can see, has been extended by the broad interpretation which has been given to the term "labeling." This raises a question which has very frequently been asked concerning the respective jurisdictions of the FDA and the Federal Trade Commission. Theoretically the answer is a simple one—FDA has jurisdiction over labeling and FTC has jurisdiction over advertising. The 1962 Amendments, however, specifically withdrew FTC's jurisdiction over prescription drug advertising. No such change was made with respect to the advertising of over-the-counter drugs—either ethical or proprietary. Although the distinction is simple in theory, it becomes quite complex in reality. Either agency can probably find a basis for jurisdiction, if it has a mind to do so. As we have seen, FDA has extended its jurisdiction by a liberal construction of what constitutes "labeling." It has also exerted jurisdiction over false advertising by employing its so-called "squeeze play."

Roles of FDA and FTC Sometimes Overlap

It has been the position of FDA that, if a false claim is made for a drug in an advertisement, it is impossible to write adequate directions for use for the article under such conditions. Thus, contends FDA, the drug is misbranded. On the other hand, the FTC is jealous of its own jurisdiction and has taken steps to broaden it with respect to drugs. It takes the position that virtually all labeling also constitutes advertising, which is its concern. And, of course, the Commission has placed a mighty broad interpretation on what is "a false advertisement," particularly with respect to proprietary medicine.

We, thus, have overlapping, and, on occasion, concurrent jurisdiction by FDA and FTC. This is not a particularly satisfactory situation for the manufacturer or for the regulatory agencies. It may be that attempts will be made to invest one or the other agency with sole jurisdiction as has been done in the case of prescription drugs. It is difficult to predict which agency would be preferable and it would probably depend upon the individual philosophies of the personnel at the time. In the meantime we will have to concern ourselves with both agencies.

There has been a great deal of confusion with respect to the "grandfather clauses" in the 1962 drug law. In the future your labeling will depend to a great extent upon whether or not you can claim grandfather protection. This was probably the most important aspect of the new law as far as proprietary manufacturers are concerned. The FDA has long sought what amounts to complete licensing control over drug products. The 1962 Act gave it its desired control over prescription drugs; the amended new drug procedures, requiring affirmative approval, strengthened its control over "new drugs"; antibiotic certification amounts to a licensing procedure for drugs containing antibiotics; and investigational drugs are definitely licensed by statute and regulation. Proprietary medicines, however, avoided—for the time being—the fate of licensing by virtue of its "grandfather clauses." Already FDA is, in my opinion, attempting to by pass the obvious intent of Congress and render the "grandfather clause" a meaningless nullity.

The two grandfather clauses have been referred to as the absolute provision and the "two year" provision. The absolute provision provides, in effect, that, if a drug was on the market prior to the 1962 enactment, was not a new drug nor covered by an effective NDA (New Drug Application), it will not be considered a "new drug,"

even though its effectiveness may not be generally recognized, so long as no changes are made in the labeling claims. In order to challenge the effectiveness of drugs covered by this clause, FDA must institute a court proceeding by way of seizure, alleging the drug to be misbranded, and it has the burden of proving the lack of effectiveness. The only effect, although a very important one, of the grandfather clause is to maintain that burden of proof on the government. Contrary to popular belief, one may not market ineffective products because they are covered by the grandfather clause. They are, as always, subject to seizure and the manfacturer is liable under other sanctions of the Act.

Personal or General?

One of the first questions to arise under the grandfather clause was whether it was personal or general. That is to say, may one take advantage of his competitor's grandfather protection. The answer, in my opinion, is "yes." FDA has indicated that it concurs in this interpretation, although for some reason it seems to be reluctant to say so. If there is a product on the market, covered by this absolute grandfather clause, you may market a product of substantially identical formulation and make the same claims for it without going through the new drug procedures.

When Is Loss of Grandfather Protection Jeopardized

Another frequently asked question relates to the extent to which one may change his formula or label without jeopardizing a loss of the grandfather protection. The FDA has indicated that it may not permit any such changes no matter how inconsequential. Therefore, because of the seriousness of the risk involved, I strongly urge each of you to consult your own counsel before making any decisions in this area.

It seems to me that it was not the intent of Congress to freeze all established products in their present form and with their present labeling. Improvements can and should be made. It would appear that binders, excipients and fillers may be changed, comparable recognized ingredients may be substituted, the form of ingredients changed provided that these formulation changes are not substantial and do not result in a different end product. Labeling changes may be made provided that they do not consist of the recommendation of new or different uses. It would appear that the trademark may be

changed, new or different warnings employed and directions varied, as long as the drug is intended solely for use under the same labeling conditions.

Drugs which were subject to new drug control at the time of the enactment of the new Act were granted a two-year grace period during which the manufacturer may not be called upon to prove effectiveness to FDA. Of course, a seizure may be made for misbranding during that period, but such a course by FDA is not likely except in most unusual circumstances. FDA has already put a number of manufacturers on notice that they will be called upon to produce their evidence of effectiveness on October 9, 1964. If your product did have an NDA with respect to safety, but you do not know whether FDA will call upon you for effectiveness data, you may ask them for an advisory or informal opinion at this time.

The big question under this two-year grandfather clause relates to those drugs which went through the new drug procedures, but were not considered to be "new drugs" on October 9, 1962. The FDA contends that such drugs are grandfathered for two years only. An extremely technical interpretation of the statute might support this position, but I do not believe that common sense or the congressional history will. It may be that litigation will be necessary to resolve this question. Again, however, we should bear in mind that such litigation can only determine who has the burden of proof, since all drugs must be, as they always have been, effective.

As a corollary to its position on old "new drugs," FDA has announced that it feels it has the right to proceed against another manufacturer's brand of the same drug, even though the drug was considered to be an "old drug" when his particular brand was first marketed. I fail to find any statutory authority for this proposition.

The existence or nonexistence of the grandfather clause is only one aspect of the problem of determining whether or not you have a "new drug." So many of the provisions of the 1962 Act are restricted to prescription drugs that many of us overlook the fact that the new drug provisions are not so limited. Proprietary manufacturers have always been aware of the fact that their product must be effective. Both FDA and FTC have impressed this upon them for the past 25 years. Now, however, with new products they may have to convince the FDA rather than a court of law that such is the case. If one does have a "new drug," the time, effort and expense of going through the new drug procedures will often not be justified, unless

one is pretty sure that he has "a real winner." The small proprietary manufacturer may never be in a position under present law to introduce a truly new drug. In addition, there has grown up a double standard with respect to the labeling of over-the-counter drugs. Since affirmative approval must be procured for "new drugs" from FDA, the claims for such drugs are considerably curtailed and one may be placed at a competitive disadvantage with respect to a grandfathered competitor. FDA has shown an alarming tendency of late to disdain self-diagnosis and self-medication. Thus, those of you who must go through new drug procedures are likely to be precluded from making certain well-established and accepted claims for those products.

Caveat emptor was long ago written out of the law with respect to the sale of drugs. In addition to the general prohibition against any false or misleading labeling, all drugs must bear adequate directions for use and warnings against misuse. To assure that the public will be protected in every respect, both the Food and Drug Act and the Federal Trade Commission Act provide that in determining whether labeling or advertising is false or misleading, there will be taken into account not only the representations made or suggested, but also the failure to disclose material facts in the light of such representations. This is the basis for the present furor about so-called "affirmative disclosure." It has been in the law for 25 years, but it has only been recently that FTC has gone all-out to establish its own interpretations of what this provision means. As one of the Commissioners was recently heard to remark, "Affirmative disclosure has become a way of life." I have no objection to the principle of affirmative disclosure when it applies to warnings and contraindications when they are necessary for the protection of users. What I am discussing is the proposition that one should spend a good portion of his advertising dollar to tell the public that his product is really not as good as he says it is. This may be justified in rare instances, but not, in my opinion, "as a way of life."

It is difficult to tell just how far the regulatory agencies or the courts will go in requiring such affirmative statements. If your product will only be effective in a small percentage of the cases demonstrating the symptoms you purport to affect, you may have to so inform consumers. It is not sufficient to state that your product will help alleviate symptoms, if they are caused by a particular factor. You will probably have to go further and advise them that the symptoms usually are not the result of that particular factor. Both FDA and FTC evi-

dently would like to extend this philosophy, but I don't think that they are likely to be quite that successful except in extreme cases.

Proposed Vitamin Regulation

The big push for affirmative disclosure seems to be an outgrowth of the government's current attitude with respect to vitamin preparations. The regulatory agencies have taken the position that most people do not need to supplement their diets by the use of vitamins and minerals. I am advised that this thinking is based upon erroneous subjective impressions, not substantiated by sound medical opinion. Nevertheless, the FDA made a bold attempt to implement its vitamin crusade by proposing on June 13, 1962 labeling regulations under Section 403(j) of the Act. These proposed regulations would proscribe the use of certain ingredients and limit the amounts of others which might be included in these dietary supplement preparations. Formulae for over-the-counter preparations would be standardized and FDA would dictate their composition. This is done under the guise of labeling regulation. I understand that the proposed regulations were met with a deluge of criticism and to date FDA has taken no further action on them. If it is successful in its endeavors, however, there will be a very substantial change in the labeling of proprietary dietary supplements. Many products would have to change their formulae, come off the market or go on a prescription basis. This is another instance of the disturbing trend to place what amounts to licensing control over manufacturers of proprietary items. In opposition to the proposed regulations I have taken the position that a manufacturer has the right to market any food or drug, as long as it is safe, its labeling is truthful and informative and the claims made can be supported by competent proof.

Labeling of Antibiotics

As most of you know, the field of antibiotics is another area where government has attempted to control the end product through its power to regulate labeling. As a result of its authority to certify all antibiotics, FDA can control the composition and labeling of combination products. Although principally of interest to the prescription industry, FDA has proposed to ban the use of antibiotics in combination with analgesic substances, decongestants, antihistaminics or caffeine for use in the relief of symptoms and prevention of complications of the common cold. The FDA states that its proposal is based upon the recommendations of a panel of "medical experts" which it claims

found that there is no acceptable evidence that any antibiotic is of any value in the treatment of the common cold or in preventing bacterial complications in patients with common colds who are otherwise healthy. Thus, FDA is attempting to tell the doctor how to practice medicine and what medications his patients may receive. This has very far-reaching implications in the proprietary field. If the physician is incapable of diagnosing and prescribing, we can certainly expect comparable attacks on self-diagnosis and self-medication. Already FDA has threatened with removal from the market many over-the-counter antibiotic-containing drugs such as troches, nose drops, mouth washes and deodorants on the grounds of questionable effectiveness. Since antibiotic certification is not included in the grandfather clause, FDA may question the effectiveness of such products at this time. Unless one is in a position to prove his claims for such products, he must give serious consideration to a revision of the labeling.

One of the most perplexing labeling problems for the proprietary manufacturer has not emanated from any change in the law, but rather upon a more vigorous enforcement of old law. I refer to the activity with respect to the conspicuousness of labeling information which has been a major area of recent enforcement. Basically the law provides that all required labeling information must appear in a plain and conspicuous manner so that it is likely to be read and understood. One should review his labeling and eliminate those practices which do not satisfy the law. These might include such things as printing directions on the back of the front label so they must be read through the liquid, molding the information on plastic containers without the use of contrasting colors, and the use of unjustifiably small printing in relation to the size of the label. The states, notably Virginia and Pennsylvania, have also been active in this field and we can obviously look forward to more regulation and enforcement at both levels.

I have attempted to touch upon a few of the more important labeling and related problems which the proprietary manufacturer has faced during the past year. There are others and undoubtedly there will be more to come. Before I close I would like to make brief mention of a few things we can expect in 1964. We can certainly look forward to more regulation and not less. We are faced with upcoming efforts to enact at least two very important pieces of federal labeling legislation. The so-called "Truth-In-Packaging" or Hart Bill, if enacted would grant the FTC and FDA the right to dictate by regulation every aspect of packaging and labeling with no effective recourse to the courts. The proposal to extend some of the provisions of

the Hazardous Substances Labeling Act to drug products would require your including in your labeling warnings against every conceivable consequence of misuse or accidental ingestion together with pertinent first aid information. The resulting labeling and products liability problems are appalling to contemplate. **[The End]**

EFFECTIVE TREATMENT OF SCHIZOPHRENIA

New evidence of marked efficacy of drugs in the treatment of schizophrenia has just been released by Public Health Service and collaborating scientists. The comprehensive study, supported and directed by the National Institute of Mental Health, Bethesda, Maryland, shows that 95 per cent of drug-treated schizophrenics improved within six weeks. Seventy-five per cent showed marked to moderate improvement, according to results of the two and a half year study, reported in the current issue of *The Archives of General Psychiatry.*

This is the first large-scale study in which acutely ill patients were treated in varying types of psychiatric hospitals. They ranged from small private hospitals to large state institutions. Altogether, the Institute's Psychopharmacology Service Center enlisted nine hospitals for this Collaborative Study Group. Earlier studies have been limited to hospitals of a single kind.

These results, coupled with the findings from other Institute research, suggest these drugs will be highly effective tools for treating schizophrenics in comprehensive community mental health centers where the emphasis is on rapid and early treatment near the patient's home.

Patients in the study were young schizophrenics averaging 28 years of age, usually suffering either their first psychotic breakdown or first hospitalization, and whom participating clinicians judged to be "markedly ill." More than 400 patients were given either chlorpromazine, two of the newer phenothiazines (fluopheniazine or thioridazine) or served as controls and received no drugs. The phenothiazine family of drugs was chosen because it contains the tranquilizers with the greatest potency. Chlorpromazine is the oldest and most reliable drug of this type.

Other results of the study were: Nearly half of the improved patients were rated as having no symptoms or only borderline illness at the end of six weeks; the degree of improvement had not leveled off by the end of the study, indicating that improvement probably was continuing, and would have been observed if the project had been longer; 23 per cent of the patients in the control group showed marked or moderate improvement when no specific drug treatment was used—this represents the proportion of patients expected to improve with other standard forms of hospital treatment; all three of the phenothiazines were equally successful and showed a strong over-all effect against nearly all schizophrenic symptoms; the drugs alleviated the symptoms of hallucinations, thinking or speech disorders, bizarre motor behavior, inappropriate emotion, and helped improve personal relations—they were less effective against feelings of guilt, delusions of grandeur, and loss of memory; side effects generally were mild, limited to drowsiness, dizziness and dry mouth.

The study has important implications for the treatment of mental illness, one of the nation's major health problems.

The Small Drug Manufacturer

By WINTON B. RANKIN

This Paper Was Delivered at the National Mid-Year Meeting of the Drug and Allied Products Guild, Inc., in New York City on January 30, 1964. Mr. Rankin Is Assistant Commissioner of the Food and Drug Administration.

THE DRUG COMPANY OF TODAY is quite different from the drug company of a century ago. Then there were few manufacturers and most pharmacists compounded the bulk of the products they dispensed.

Here and there a pharmacist or physician who became quite skilled in formulating drugs began making his products available to others. These firms were the forerunners of today's giant pharmaceutical industry. But even the most successful of these early drug companies would be classified by today's standards as small manufacturers.

Laboratory control was relatively inexact, but fortunately most of the products were relatively innocuous. The better firms did use the best control measures available to them.

The drugs of that day had been subjected to a form of clinical trial through decades or even centuries of use in medicine. The development of new therapeutic agents progressed at a snail's pace and one really new therapeutic advance per generation was about average.

The advance of pharmaceutical science was so slow that as late as World War I many physicians found it possible to practice medicine quite successfully with five basic drugs—opium, mercury, quinine, digitalis and iodine. Of course the early analgesics, anesthetics and antitoxins were being employed too, but even so the average doctor relied upon less than a dozen drugs.

New Era in Pharmaceutical Field

Then came a new era in pharmaceutical development. Laboratory experiments were successfully applied to clinical medicine with greater frequency. The era of chemotherapeutics, started with the discoveries of "606" and insulin, was hastened by the development of sulfonamides just before World War II and penicillin during that war. It sprang into full bloom during the 1940's and 1950's and is still with us.

The national pure food and drug law of 1938 helped pharmaceutical houses to utilize advancing science profitably:

(1) The new drug section required manufacturers to prove their new drugs safe before marketing them. To meet this very proper requirement the firms had to add more scientists of many disciplines, and as a result they were in a position to reap a rich harvest from the outpourings of new science from World War II.

(2) Under the factory inspection provisions added to federal law in 1938, FDA was able to help the manufacturers develop much improved methods of manufacturing and laboratory controls.

There were some who felt that these newer requirements would drive the small drug manufacturers out of business. FDA received requests that some mechanism be developed to apply less stringent requirements to the small manufacturer than to the large. As you know, we did not find it possible at that time to change the requirements to meet the size of the firm. However, this did not force the small manufacturer out of business. On the contrary, some of the more successful large firms of today were struggling small manufacturers or distributors in the early 1930's. Despite, and perhaps in many cases, because of the more stringent requirements, they have made rapid progress in the development and introduction of new drugs.

At that time new drugs still did not have to be proved effective for the uses recommended on their labels. Effectiveness often was established by the old method of trial and error in general practice.

Evaluation of New Products

The flood tide of new products required newer, better methods of evaluating a drug's worth, so medical science turned to statistics which had already proved quite useful in differentiating and classifying disease. The planned clinical trial, bottomed on sound statistical methods, gained widespread acceptance. It has definite advantages over older procedures. It is possible to determine in relatively short

time and on relatively few subjects whether a drug will do what its promoter claims. The careful observations which most investigators make during the controlled investigation will reveal with greater frequency and assurance the undesired side effects of the new product.

The scientific capability of determining a new drug's effectiveness and general recognition of the advantages to society of such a determination before the product is marketed, paved the way for a significant event. The Kefauver-Harris Drug Amendments of 1962 required manufacturers to test their new drugs for effectiveness as well as safety.

Ethical considerations in the clinical trial of drugs—long recognized and accepted by the medical profession—were also reflected in this law.

The thalidomide disaster in Europe aroused public interest and it probably hastened the enactment of the new legislation, but a demonstrated scientific capability of achieving what the proposed law asked had to be present for the legislators or the President to agree that the proposal should become law.

Less Stringent Requirements Put Small Manufacturer at a Disadvantage

Since 1962 we have again heard questions about the possibility of allowing the small drug manufacturer to meet less stringent requirements than the large. While the idea is attractive in some respects, it does have obvious drawbacks. If we accept the principle that the government applies, even to the large manufacturer, only those requirements that are deemed necessary in the interest of public health and well-being, then there is no basis from the consumer's standpoint for allowing small firms to meet lesser requirements which would permit drugs of unproved safety or drugs with inadequate labeling to reach the market. How could a small manufacturer prosper in the market place if his competitors were in a position to point out in all honesty that his drugs were suspect because they did not have to meet full government standards? On balance, the possible advantages to small businesses of adopting and applying inadequate safety and effectiveness requirements to their products would appear to be greatly overshadowed by the disadvantages to all segments of our society.

Certainly we will make every effort to assist any manufacturer who needs help in meeting the requirements of the law. He should

feel free at any time to call our attention to problems confronting him and to suggest possible solutions that can be put into effect without curtailing the consumer protection intended under the law. We continue this open door policy and will welcome industry representatives for frank, informal discussions of the way that the federal requirements apply to their products.

If it is not feasible to allow the small manufacturer to meet lesser requirements than his large competitor, what chance does he have in today's highly competitive situation?

I am willing to suggest that he has just as much chance as before. Strong competition did not burst upon us in this decade. It was here when the 1938 Food, Drug and Cosmetic Act was passed, when the original pure food and drug law was enacted in 1906, and before that. It is a characteristic of our democratic society. The details of the competition may vary from one decade to another, but its presence does not.

Quality, Rather Than Quantity Is Emphasized

The ability of a manufacturer to make a truly significant contribution in the drug area would seem to depend more upon the caliber of the scientists he employs than upon the number he has on the payroll. Last November, Dr. Vannevar Bush pointed out that when scientific programs are judged by popular acclaim, we inevitably have overemphasis on the spectacular. That is just what we have today. The deeply important scientific advances moving today are not easy to understand. If they were, they would have been accomplished long ago. Dr. Bush also called attention to the facts that:

(1) The great scientific steps forward originate in the minds of gifted scientists, not in the minds of promoters.

(2) A man sitting at a desk and thinking is not an expensive proposition.

The gifted scientist working for the small company or the university may arrive at the profound drug discovery just as well as the gifted scientist working for the large manufacturer. When the discovery comes, history shows that the mechanism for applying it for the general good is made.

Industry's Suggestions Solicited

We believe the new law is a workable instrument. To put it into effect successfully will require understanding, wisdom and coopera-

tion on all sides. We want your suggestions and your help, and when we can conclude that new policies or procedures which you suggest are within the framework of the law and in the public interest, we will adopt them.

We have just adopted two suggestions made by the FDA Advisory Committee on Investigational Drugs, chaired by Dr. Walter Modell of New York City. The committee suggested procedures to help research investigators obtain chemicals employed as research tools in clinical studies and to help them obtain new dosage forms of drugs already commercially available for use solely as controls in clinical investigations. We agree that these steps are desirable and will not in any way compromise the safeguards afforded by the regulations.

It is our view that a drug available for commercial distribution in a particular dosage form, such as a tablet or a capsule, may be altered to another dosage form and shipped for use solely as a control in a clinical investigation of a new drug without filing a notice of claimed investigational exemption or a new-drug or antibiotic application covering such shipment:

(1) If the new form has the same qualitative composition as, is prepared in the same way as, and is administered in no higher dosage than the product commercially available, except that changes in manufacture that are in accord with good manufacturing practice, including changes in coatings, flavorings, and colorings, may be employed as necessary to make the new form a suitable control agent;

(2) If there is acceptable evidence on which the sponsor has concluded that the new dosage form is absorbed and otherwise handled by the body like the form commercially available; and

(3) If shipments of the new dosage form are accompanied by the full-disclosure labeling employed in making shipments of the dosage form already marketed, plus a statement that this is a control drug for use only in clinical testing.

The claim for exemption for the investigation in which the control will be used need only report the source and nature of the control.

The provisions of the existing regulations with regard to the clinical pharmacology phases of a drug test (phases 1 and 2) already permit submission of a *general outline* of these phases as the claim for exemption. We believe that a sponsor could meet this requirement by submitting notice to FDA of:

(1) His intent to use the compound or compounds proposed for study;

(2) The indentity of the compound or compounds, together with the facts that satisfy him that the agent may be justifiably administered to man as intended;

(3) The purpose of the use and the general program of activity proposed; and

(4) Appropriate background information, including a brief statement of the investigator's scientific training and experience and the nature of the facilities available to him.

Such a general outline would apply both to agents to be employed for scientific research to study normal function or altered bodily function in man, and agents being employed in early clinical investigations of therapeutic potential (clinical pharmacology). Of course, other parts of the regulations, such as the patient-consent provision and the need for reporting adverse reactions would still apply.

Conclusion

No doubt as we gain more experience with the new regulations adopted under the Kefauver-Harris Drug Amendments, the need for other desirable improvements will become apparent. We are ready to work with all interested persons in an effort to improve the administration of this far-reaching drug law. Such improvement will benefit the consumer, the government and both small and large drug manufacturers.

It is a pleasure to meet with you today. We look forward to continued mutually beneficial work with the Drug and Allied Products Guild. **[The End]**

DIVISION OF NEW DRUGS' STAFF INCREASED SUBSTANTIALLY

On March 24, 1964, George P. Larrick, Commissioner of Food and Drugs, appeared before the Subcommittee on Intergovernmental Relations of the House Committee on Government Operations. He remarked in part:

"In 1940 we had one medical officer working on new drugs; in 1950 we had two. I was interested recently when I saw a picture of our New Drug Branch staff taken in 1953. It consisted of two medical officers, two clerks, and two chemists. In 1960 we still had only six full-time and four part-time medical officers. I am pleased to report that today we have 41 full-time and three part-time medical officers in our Division of New Drugs. Over half of them have been recruited within the past 12 months. We are beginning to establish a staff which will be equal to the heavy responsibilities imposed upon us."

Products Liability Under the Uniform Commercial Code in New York and Other States

By WARREN FREEDMAN

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THE ADOPTION OF THE UNIFORM COMMERCIAL CODE by 28 states [1] has altered many of the traditional notions of products liability, as had been delineated under the Uniform Sales Act.[2] Between 1954 and 1964 15 states have put the Code provisions into effect, and by September 27, 1964, the date on which the Code becomes effective in New York, six additional states will have done likewise. The Uniform Commercial Code is advertised as a complete revision and modernization of the Uniform Sales Act, (which statute had been adopted in 36 states, including Hawaii and Alaska). Accordingly, products liability, particularly to the extent that it depends upon the rules of warranty as set forth in the Uniform Sales Act, must now be

[1] The states, adoption date and effective date are as follows: Pennsylvania, 1953, Original version—July 1, 1954; (Pennsylvania, 1959, 1958 Official Text, Jan. 1, 1960); Massachusetts, 1957, October 1, 1958; Kentucky, 1958, July 1, 1960; Connecticut, 1959, October 1, 1961; New Hampshire, 1959, July 1, 1961; Rhode Island, 1960, January 2, 1962; Wyoming, 1961, January 1, 1962; Arkansas, 1961, January 1, 1962; New Mexico, 1961, January 1, 1962; Ohio, 1961, July 1, 1962; Oregon, 1961, September 1, 1963; Oklahoma, 1961, December 1, 1962; Illinois, 1961, July 2, 1962; New Jersey, 1961, January 1, 1963; Georgia, 1962, January 1, 1964; Alaska, 1962, December 31, 1962; New York, 1962, September 30, 1964; Michigan, 1962, January 1, 1964; Indiana, 1963, July 1, 1964; Tennessee, 1963, July 1, 1964; West Virginia, 1963, July 1, 1964; Montana, 1963, January 1, 1965; Maryland, 1963, February 1, 1964; California, 1963, January 1, 1965; Wisconsin, 1963, July 1, 1965; Maine, 1963, January 1, 1965; Nebraska, 1963, March 1, 1965; and Missouri, 1963, July 1, 1965.

[2] The Uniform Sales Act was promulgated by the National Conference of Commissioners on Uniform State Laws in 1906.

carefully reviewed. The seven warranty sections (Sections 2-312 to 2-318, inclusive), in the Uniform Commercial Code present substantial changes in the present law of Products Liability.[3]

Basic to any review is the inquiry whether products liability situations are actually covered by the U. C. C. Section 2-715(2)(b), relating to the damages of the buyer, makes it abundantly clear that consequential damages of a seller's breach of warranty include, "injury to person or property proximately resulting from any breach of warranty." Section 2-719(3) declares that any limitation of consequential damages "for injury to the person in case of consumer goods" is "prima facie unconscionable." Under Section 2-607 various beneficiaries are given rights for injuries sustained by them because of the seller's breach of warranty. Further evidence of the applicability of the U. C. C. to personal injury and property damage claims arising out of the use of a product, is the fact that state laws applicable to warranty aspects have generally been repealed by enactment of the Code.[4]

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[3] Note that under Section 1-105(1) affirmatively states the right of parties to a multistate transaction to choose their own law, although that choice of law is limited to jurisdictions to which the transaction bears a "reasonable relation." See, generally, *Seeman v. Philadelphia Warehouse Company*, 274 U. S. 403 (1927).

[4] In New York, for example, Article 5 of the New York Personal Property Law has been repealed. This was the New York version of the Uniform Sales Act.

Relevant sections of the Code and the New York Personal Property Law (which is repealed by the U. C. C.) as discussed herein, are as follows:

UCC	N. Y. Personal Property Law
1-102(2)	....
1-104(1)	....
1-105(1)	....
1-201(19)	156(2)
1-201(25)	....
1-201(26)	....
1-201(27)	....
1-202	....
1-203	....
1-204	....
2-102	155
2-104(1)	152, 126(2), 96(5), (2), 97(c)
2-103	156
2-106(1)	82(1), 82(2)
2-201	85
2-202	....
2-204(1)	82, 84
2-207(2)(b)	82, 84
2-209	....
2-302	....
2-302(1)	....
2-312	94
2-313	93, 95, 97
2-314, 2-314(2), 2-314(3)	96(2)
2-315	96(1)(4)(5)
2-316, 2-316(1), 2-316(2), 2-316(3)	....
2-317, 2-317(c)	95, 96
2-318	....
2-607	....
2-607(3)(a)	130, 150
2-607(4)	....
2-607(5)(a)	150(6)(7)
2-714	150(6), (7)
2-715(2)(b)	150(7), 151
2-718	....
2-719	....

(Continued on following page.)

However, underlying both the Uniform Sales Act and the U. C. C., is a basic policy that imposition of liability does not rest upon any equitable theory of distribution of loss. In consumed products cases imposition of liability arises, if at all, upon commercial practices delineated by the implied intention of the parties at the time of sale.

The applicability of the U. C. C. to products liability is, however, limited to the *sale* of the product.[5] Section 2-102 declares that Article 2 of the Uniform Commercial Code (which incidentally is the longest Article, consisting of seven parts and a 104 sections, or about one-quarter of the Code), applies to all transactions in goods, except security transactions and statutory sales to special classes of buyers. Section 2-106(1) affirms by limiting the transaction to the *sale* of goods,[6] and Section 2-204 emphasizes the contractual basis of the sale.

Express Warranties

Express (and implied) warranties are delineated in the Code with the avowed design of consolidating and systemizing basic principles[7] but the net effect has been a radical departure from basic principles of products liability law.[8] Under Section 2-313 *express* warranties may be created (1) by affirmation or promise, (2) by description, and (3) by sample or model. The recognition of express warranties of description and of sample does, however, revert to older

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(Footnote 4 continued.)

UCC	N. Y. Personal Property Law
2-719(3)	....
2-725	....
2-725(2)	....
2-725(3)	....
2-725(4)	....
9-109(1)	....

[5] The significance, if any, of Comment 2 to Section 2-313, 1958 Official Text, is open to question although it does refer to bailments for hire.

[6] "A 'sale' consists in passing of title from the seller to the buyer for a price."

[7] The warranty of title under Section 2-312 is not designated under Subsection (1) as an "implied" warranty and hence is not subject to Section 2-316(3).

[8] Perhaps a pragmatic view of the trend toward change is best seen in a study of jury verdicts which was the subject of a recent study by Jury Verdict Research, Inc. (2056 E. 4th Street, Cleveland 15, Ohio). The average jury verdict throughout the nation in all types of personal injury actions was slightly in excess of $11,000, compared to an average jury verdict in products liability cases of almost $26,000. Household product injuries brought recoveries 73 per cent of the time; food and beverage had a 62 per cent rate for plaintiffs; drug and beauty preparations, 42 per cent; and industrial equipment, 43 per cent. The over-all plaintiff recovery rate in products liability cases was 53 per cent, 77 per cent of which verdicts were against retailers and distributors of the product. Actions against the manufacturer only resulted in a 41 per cent rate of recovery for plaintiffs, and actions against both retailer and manufacturer brought recovery to the plaintiff 42 per cent of the time.

case law. But it is no longer necessary for the seller to use words of art or formal words such as "warrant" or "guarantee" to create an express warranty; but, a mere affirmation of value or a statement purporting to be an opinion or commendation of the goods does not create an express warranty.

Traditionally, it has been said that express warranties rest on "dickered" aspects of the individual bargain. But in today's economy the buyer has little choice, for he must either accept the warranties as expressed by the seller, or purchase a product from another seller. Evidently no longer is reliance by the buyer upon such express warranties necessary, for such express statements have, under the circumstances and in the objective judgment of the parties, been deemed to be part of the sales contract.[9]

Implied Warranty of Merchantability

The implied warranty of merchantability is described under Section 2-314 as arising by implication out of (1) a contract of sale, (2) a course of dealing, and (3) usage of the trade.[10] However, before such an implied warranty can arise, the seller must be a "merchant" [11] with respect to goods of that kind. The service of food or drink to be consumed (where the service is for value) constitutes a sale; hence, an implied warranty of merchantability arises with respect to the food or drink—a distinct statutory change from the common law.[12] A dealer in second-hand merchandise or a repackager of a product, if the fact is known to the buyer, has an obligation merely limited to an implied warranty which is appropriate for such a second-hand or repackaged product. The seller's knowledge of defects not apparent on inspection of the product imposes, however, an obligation to disclose known, though hidden, defects in the product.

Reliance upon the seller's skill or judgment is still essential to the cause of action for breach of implied warranty of merchantability under Section 2-314, as it was under Section 15 of the Uniform Sales

[9] See, *Silverman v. Samuel Mallinger*, 375 Pa. 422, 100 A. 2d 715 (1953).

[10] Under Section 15(2) of the Uniform Sales Act the implied warranty of merchantability was limited to those situations "where the goods are bought by description from a seller who deals in goods of that description. . . ."

[11] Section 2-104(1). Obviously this qualification restricts the implied warranty to a much smaller group than everyone who is engaged in business and requires a professional status as to particular kinds of goods.

[12] *Nisky v. Childs Company*, 103 N. J. Law 464, 50 A. L. R. 227 (1927), and *Sofman v. Denham Food Service Inc.*, 14 NEGLIGENCE CASES (2d) 372, 181 A. 2d 168 (N. J. 1962), decided prior to effective date of U. C. C. in New Jersey.

Act. Reliance is evident in the requirement that the sale be made by a dealer in such goods and "by description."

There are six criteria of "merchantability" [13] in Section 2-314(2) including the requirements that the product be fit for the ordinary purposes for which such goods are used, adequately contained, packaged, and labelled, and in conformity to the promises or affirmations of fact made on the container or label.[14] While Subsection (2) does not purport to exhaust the meaning of "merchantable" nor to negate any of its attributes not specifically mentioned, the latter two requirements do not solve the problem presented where compliance with a federal labelling statute has not precluded a court from ruling that the product labelling was inadequate and incomplete in order to find that the injuries were proximately caused by the use of the product. There can be no quarrel with a seller's obligation not to sell a mislabelled or misbranded product, but Subsection (2)(e) does not define "adequately," nor even recommend a standard or measurement other than the implied "mercantile good faith" under Sections 1-201(19) and 1-203. Decisional law must fill the void of the statute.

The implied warranty of merchantability may be excluded or modified, as delineated under Section 2-316. It should be noted that this warranty is so commonly taken for granted that its exclusion may be a matter threatening surprise to the buyer and therefore requiring special precaution. Subsection (3) makes explicit that usages of trade and course of dealing can create other implied warranties of merchantability.

Implied Warranty of Fitness for Particular Purpose

The implied warranty of fitness for particular purpose is delineated in a very brief section, to wit, Section 2-315. No criteria nor

[13] In contrast to the Uniform Sales Act which did not define merchantability, the U. C. C. delineates these six standards at great length with Comments. See, *DeGraff v. Myers Foods, Inc.*, 18 Pa. D & C 2d 19 (1959).

[14] Section 2-314(2): "Goods to be merchantable must be at least such as; (a) pass without objection in the trade under the contract description; and (b) in the case of fungible goods, are of fair average quality within the description; and (c) are fit for the original purposes for which such goods are used; and (d) run, within the variations permitted by the agreement, of even kind, quality and quantity within each unit and among all units involved; (e) are adequately contained, packaged and labelled as the agreement may require; and (f) conform to the promises or affirmations of fact made on the container or label if any."

definition of "fitness" or "particular purpose" are given.[15] Indeed, it must therefore always be a question of fact to be determined by the circumstances as to whether or not this warranty arises. Note the two stringent prerequisites in Section 2-315; the seller must at the time of the sale have reason to know the particular purpose for which the goods are bought, and the buyer must rely upon the seller's skill and judgment. Proof of reliance on the seller's skill or judgment is an indispensable part of the buyer's cause of action for breach of this implied warranty. But "particular purpose" does differ from the "ordinary purposes" characteristic of the implied warranty of merchantability, in that the former envisages a specific use of the product by the buyer, which use is personal and peculiar to the individual buyer. Thus, in the area of an allergic reaction to a given product, no implied warranty of fitness for particular purpose can arise, unless the seller at the time of sale had reason to know of the buyer's idiosyncracy or predisposition to the product *and* unless the buyer then relied upon the seller's skill and judgment to select or furnish a suitable product. The allergic buyer need not bring home to the seller actual knowledge of the particular purpose for which the product is intended, nor of his reliance on the seller's skill and judgment only. Particularly is this true where the circumstances are such that the seller has reason to realize what purpose is intended, and that the buyer's reliance does exist.

The implied warranty of fitness for particular purpose is no longer negatived when the product is bought by its patent or trade name, as under Section 15(4) of the Uniform Sales Act. The designation of the product by its patent or trade name is now only one of the facts to be considered on the question of whether the buyer actually relied on the seller, but it is not of itself decisive of the issue. Thus, if the buyer does not, at the time he purchases the brand name product, insist upon a particular brand, he can rely upon the seller's skill and judgment, and hence the warranty results.[16]

In event of conflict with other express or implied warranties the implied warranty of fitness for particular purpose would appear to be controlling, as stated in Section 2-317(c).

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[15] Note that Section 15(1) of the Uniform Sales Act formulates this implied warranty in terms that "the goods shall be *reasonably* fit for such purpose." See, *Crotty v. Shartenberg's—New Haven, Inc.*, 11 NEGLIGENCE CASES (2d) 624, 147 Conn. 460, 467, 162 A. 2d 513, 516 (1960).

[16] See, generally, *Pabellon v. Grace Line*, 191 F. 2d 169 (CA-2 1951), cert. denied 342 U. S. 893 (1951).

It should be pointed out that, contrary to the 1931 interpretation of the New York Court of Appeals,[17] the warranties of fitness and of merchantability are not usually synonymous. Indeed, "dual warranty" is a pure fiction.

Extension of Benefits of Warranty

Extension of the benefits of warranties, as well as the concept of privity of contract, are described in Section 2-318. Herein a seller's warranty is extended to any natural person who is in the family or in the household of the buyer, or who is a guest in his home,[18] if it is reasonable to expect that such a person may use, consume, or be affected by the product and who is injured in person by breach of the warranty.[19] The seller cannot exclude or limit the operation of this Section; but a seller is not precluded from excluding or disclaiming a warranty, which might otherwise arise in connection with the sale, provided such exclusion or disclaimer is permitted by Section 2-316. Similarly, the seller is not precluded from limiting his own buyer's remedy, or the remedy of any beneficiary of the warranty, in any manner permitted in Sections 2-718 or 2-719. The exclusion or limitation forbidden pertains to liability of the seller to persons to whom the benefits of the warranties are extended by Section 2-318.

Implicit herein is recognition of the privity of contract doctrine, for only those named third party beneficiaries to whom the warranty is deemed to extend, can bring a direct action for breach of warranty against the seller. The language is not intended to enlarge the developing case law as to whether the seller's warranties extend to other persons in the distributive chain. However, in 1963 the Pennsylvania Supreme Court, construing this Section of the U. C. C. (which has operated in Pennsylvania since July 1, 1954), refused to extend the benefits of warranty "beyond a purchaser in the distributive chain. In fact, the inescapable conclusion from *Loch v. Confair*, 361 Pa. 158, 63 A. 2d 24 (1949) is that no warranty will be implied in favor of one who is not in the category of a purchaser." [20]

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[17] *Ryan v. Progressive Grocery Stores, Inc.*, 255 N. Y. 388, 175 N. E. 105 (1931).

[18] A guest in an automobile is *not* such a beneficiary under Section 2-318, *Thompson v. Reedman Motors*, 199 F. Supp. 120 (DC Pa. 1961). An employee of the purchaser does *not* fit into the category of a purchaser, *Hochgertel v. Canada Dry Corp.*, 14 NEGLIGENCE CASES (2d) 1549, 409 Pa. 610 (1963).

[19] See *Jacquot v. Wm. Filene's Sons Company*, 8 NEGLIGENCE CASES (2d) 162, 337 Mass. 312, 149 N. E. 2d 635 (1958).

[20] *Hochgertel v. Canada Dry Corp.*, cited at foonote 18. See also, *Wilson v. American Chain & Cable Company*, PRODUCTS LIABILITY REPORTS ¶ 5074, (DC Pa. 1963), and *Kaczmarkiewicz v. J. A. Williams Company*, 13 Pa. D & C 2d 14 (1957).

Thus, by restricting the class of potential plaintiffs as well as by not enlarging the class of potential defendants, Section 2-318 has given rebirth to the privity of contract doctrine.[21] It is self-evident that Section 2-318, in giving the plaintiff consumer a direct action against the seller, does not give the plaintiff consumer a cause of action against the product manufacturer, unless the plaintiff consumer had purchased the product directly from the manufacturer. Bystanders and other third persons who fortuitously are in the path of harm when the danger culminates in an accident are properly excluded. Such injury is not within the zone of foreseeability. Section 2-318 thus contemplates enforcement of the warranty only against the immediate seller.[22]

Disclaimers of Warranty Liability

All warranties may be disclaimed, not only by exclusion or modification as under Section 2-316, but also when the warranty is unconscionable. Under Section 2-302(1) a court may find, as a matter of law, that the warranty (or its disclaimer) is unconscionable, and

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[21] See, Warren Freedman, "Extension of Benefits of Warranty: A Rebirth of Privity of Contract in New York," 484 THE INSURANCE LAW JOURNAL 276, May 1963; 18 FOOD DRUG COSMETIC LAW JOURNAL 287, May 1963. See *Wilson v. American Chain and Cable Company*, 216 F. Supp. 32 (DC Pa. 1962) holding that privity of contract was essential except where the product was imminently dangerous or inherently deleterious. Also, see *Barnard v. Pennsylvania Range Boiler Company*, PRODUCTS LIABILITY REPORTS ¶ 5037, 216 F. Supp. 560 (DC Pa. 1963), applying Massachusetts law.

[22] Even in New York, the benefits of an implied warranty have been extended only against the retailer, not against the product manufacturer: An infant whose father purchased for him an allegedly defective pair of roller skates (*Donadio v. F. W. Woolworth Company*, N. Y. Civ. Ct., Queens Co., decision by Judge Fink on February 28, 1963). Recovery against retailer; The child of the purchaser of an allegedly defective bicycle (*Outwater v. Miller*, 3 App. Div. 2d 670). Recovery against retailer; The employee of a dentist who purchased an allegedly defective dental chair (*Thomas v. Leary*, 15 App. Div. 2d 438, 225 N. Y. S. 2d 137). Recovery in his action against the furniture dealer; The employee of the purchaser of an allegedly defective safety mask (*Williams v. Union Carbide Corp.*, 230 N. Y. S. 2d 476). Recovery in his action against the retailer; An infant whose mother purchased for her a highly inflammable dress (*Fournier v. R. H. Macy & Company, Inc.*, N. Y. Sup. Ct., Kings Co., decision by Mr. Justice Benjamin on March 27, 1961). Recovery against the retailer; A gentleman friend of the mother bought the child ice cream which contained a screw. (*Walker v. Hot Shoppes of New York, Inc.*, 200 N. Y. S. 2d 742, Albany Co. Ct., 1960.) Jury verdict had exonerated ice cream manufacturer; The employee of purchaser (also defendant) of the auto tire—the warranty was held to run from the retailer to the employee of the purchaser but not against the manufacturer of the tire. (*Davis v. United States Rubber Company*, N. Y. Sup. Ct., Bronx Co., decision by Mr. Justice Lyman, on November 23, 1962.)

thereupon refuse to enforce it. The court may also limit the application of any unconscionable clause so as to avoid any unconscionable result. Unfortunately, the Code does not contain any definition of the word "unconscionable," although its obvious reference is to the absence of good faith and fair dealing, the principle being the prevention of oppression, one-sidedness, and unfair surprise.[23] While provisions of the Code may be varied by agreement of the parties, there is an express statement under Section 1-102(3) that "obligations of good faith, diligence, reasonableness and care" may not be "disclaimed by agreement."

In the case of express warranties, Section 2-316(1) provides:

> Words or conduct relevant to the creation of an express warranty and words or conduct tending to negate or limit warranty shall be construed wherever reasonable as consistent with each other; but subject to the provisions of this Article on parol or extrinsic evidence (Sec. 2-202) negation or limitation is inoperative to the extent that such construction is unreasonable.

It thus appears that there is a presumption that express warranties are consistent with each other (or with other warranties), unless such construction is strained and/or unreasonable. This *modus operandi* is confirmed in Section 2-317. Therefore, a disclaimer, a negation, or limitation, which is inconsistent with an express warranty would appear to be inoperative. However, where, in good faith, the disclaimer is specific and conspicuously disclosed, even the express warranty must give way and be deemed to have been disclaimed. A reasonable construction of such disclaimer would effectuate the result that the seller had made no express warranty. The rules on parol or extrinsic evidence under Section 2-202, however, do allow for explanation or supplementation.

Under Sections 2-316(2) and (3), the implied warranties of merchantability and of fitness for particular purpose may be excluded or modified or disclaimed. In the case of the implied warranty of mer-

[23] The underlying basis of this Section is illustrated by the results in cases such as the following: *Kansas City Wholesale Grocery Company v. Weber Packing Corporation*, 93 Utah 414, 73 P. 2d 1272 (1937), where a clause limiting time for complaints was held inapplicable to latent defects in a shipment of catsup which could be discovered only by microscopic analysis; *Hardy v. General Motors Acceptance Corporation*, 38 Ga. App. 463, 144 S. E. 327 (1928) holding that a disclaimer of warranty clause applied only to express warranties, thus letting in a fair implied warranty; *Bekkevold v. Potts*, 173 Minn. 87, 216 N. W. 790, 59 A. L. R. 1164 (1927), refusing to allow warranty of fitness for purpose imposed by law to be negated by clause excluding all warranties "made" by the seller; and *Robert A. Munroe & Company v. Meyer*, 2 K. B. 312 (1930), holding that the warranty of description overrides a clause reading "with all faults and defects" where adulterated meat not up to the contract description was delivered.

chantability, the language of the exclusion, modification, or disclaimer must mention "merchantability." The implied warranty of fitness for particular purpose can be excluded, modified, or disclaimed if in writing and conspicuous.[24] Such express language as, "There are no warranties which extend beyond the description on the face hereof," is sufficient to exclude all implied warranties.

Section 2-316(3) sets forth other recommended exclusionary language for all implied warranties, including "as is" and "with all faults." Provision is also made for the exclusion or modification or disclaimer where the buyer had examined the goods, or where the course of dealing so demonstrates. After the buyer has examined the product or has refused to examine the product, there can be no implied warranties with regard to defects which an examination of the product ought to have revealed. If the buyer discovers the defect and uses the product anyway, consequential injuries or property damages will be found to result from the buyer's own action rather than proximately from a breach of warranty. Indeed, such tortious defenses as contributory negligence,[25] assumption of the risk, indedependent act of negligence, etc., are applicable. The doctrine of *caveat emptor* does not control, for liability depends upon numerous facets of the cause of action, including proximate cause and adequacy of instructions for the use of the product.

The "defect" in the product is itself a question of definition,[26] particularly where the "defect" is unknown and undeterminable by the present state of scientific knowledge and experience. The American Law Institute's draft of new Section 402(a) of the Restatement of the Law of Torts, under Comment (k), has indicated awareness of the problem,[27] and seemingly A. L. I. would approve exclusion, modification, or even disclaimer of warranty liability under such circumstances.

[24] Cf. *Holland Furnace Company v. Jackson*, 106 Pitts. L. J. 341 (Pa. 1958) and *L & N Sales Company v. Stuski*, 188 Pa. Super. 117, 146 A. 2d 154 (1958).

[25] See, *Barefield v. La Salle Coca Cola Bottling Company*, PRODUCTS LIABILITY REPORTS ¶ 5018, 370 Mich. 1, 120 N. W. 2d 786 (1963).

[26] In Restatement (Second Torts) Section 402 A (Tent. Draft No. 7, 1962) "defective condition" is defined as "in a . . . condition not contemplated by the ultimate consumer, which will be unreasonably dangerous to him." Under Comment (g) "unreasonably dangerous" is defined as "dangerous to an extent beyond that which would be contemplated by the ordinary consumer who purchases the product, with the ordinary knowledge common to the community as to its characteristics."

[27] "There are some products which, in the present state of human knowledge are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs. The outstanding example is the vaccine for the Pasteur treatment of rabies which quite commonly leads to very serious and even

(Continued on following page.)

Dominancy of warranties is the subject of Section 2-317. Where consistency of warranties is unreasonable, the intention of the parties controls as to which warranty is dominant according to three enumerated rules.[28] The basic policy of Section 2-317 also makes all warranties cumulative, in the sense that some conduct, either affirmative action or failure to disclose, is required on the part of the seller.

Notices of Breach

Conspicuous by its absence from the warranty sections of the Code is the necessity for notice of a breach of warranty by the buyer to the seller within a reasonable period of time thereafter.[29] The notice requirements[30] under Section 1-201 (25), (26) and (27) as well

(Footnote 27 continued.)
permanently injurious consequences when it is injected. Since the disease itself invariably results in a dreadful death, both the marketing and the use of the vaccine are fully justified, notwithstanding the unavoidable high degree of risk which they may involve. Such a product, properly prepared and accompanied by proper directions and warning, is not unreasonably dangerous. The same is true of many other vaccines, drugs and the like, many of which for this very reason, cannot be legally sold except to physicians, or under the prescription of a physician. It is also true, in particular, of many new or experimental drugs as to which, because of lack of time and opportunity for sufficient medical experience, there can be no assurance of safety, or perhaps even of purity of ingredients, but such experience as there is justifies the marketing and use of the drug notwithstanding a medically recognizable risk. The seller of such products, again with the qualification that they are properly prepared and marketed, and proper warning is given where the situation calls for it, *is not to be held to strict liability for unfortunate consequences attending their use* merely because he has undertaken to supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable danger." (Italics added.)

[28] "(a) Exact or technical specifications displace an inconsistent sample or model or general language of description.

(b) A sample from an existing bulk displaces inconsistent general language of description; and

(c) Express warranties displaces inconsistent implied warranties other than an implied warranty for fitness for a particular purpose."

[29] Yet, under *Greenman v. Yuba Power Products, Inc.*, 15 NEGLIGENCE CASES (2d) 35, 377 P. 2d 897 (1963), notice to the manufacturer as a condition precedent for an action for breach of warranty was deemed not required by Section 49 of the Uniform Sales Act if there was no privity between buyer and manufacturer: "(Section 49) deals with the rights of the parties to a contract of sale or a sale. It does not provide that notice must be given of the breach of a warranty that arises independently of a contract of sale between the parties. Such warranties are not imposed by the sales act but are the product of common-law decisions that have recognized them in a variety of situations." Indeed, such rare distinctions in judicially-made law are hardly supportable under the wishful thinking that the U. S. A. or U. C. C. should not be extended to the manufacturer-remote vendee situation!

[30] Under Section 1-201(27) relating to receipt of notice by an organization, notice must reach an agent or officer, the actual or apparent scope of whose duties include action upon such notification.

as the reasonable time conditions under Section 1-204 are simply definitions and have not been made expressly applicable to Sections 2-312 to 2-318, inclusive. The applicable notice requirements, however, are found under Section 2-607(3)(a): a buyer who has accepted the product "must within a reasonable time after he discovers or should have discovered any breach, notify the seller of the breach or be barred from any remedy." This section does not apply to third party beneficiaries, described under Section 2-318, since they have nothing to do with acceptance of the product by the immediate buyer. Yet the impact of Section 2-607(3)(a) is to require even third party beneficiaries to notify promptly the seller that an injury has occurred. In fact, any person allegedly injured by the use of the product can be properly held to the standard of good faith in notifying the seller, once he has had time to become aware of the legal situation.

The burden of proof[31] of any breach of warranty is upon the buyer under Section 2-607(4), and obviously the buyer must pursue his remedies with dispatch within the four-year statute of limitations.[32] Where the buyer himself is sued for breach of warranty for which his seller is answerable over, the buyer *may* give the seller written notice of the litigation under Section 2-607(5). If the notice states that the seller may come in and defend and that if the seller does not do so, the seller will be bound in any action against him by his buyer for any determination of fact common to the two litigations, then, unless the seller, after reasonable receipt of the notice, does come in and defend, the seller is so bound. Section 2-607(5)(a) can obviously be only recommendatory that a seller is bound if he does not come in and defend his buyer against suit by an injured consumer of the product. The absence of mandatory language is significant, and the problem is therefore solved under procedural statutes of the state.[33]

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[31] Notwithstanding the active campaign by plaintiffs for absolute liability in products cases, it is still true that in a breach of warranty case the plaintiff must prove; (1) the existence of a warranty in his favor, express or implied; (2) a breach of that warranty by the defendant, including proof that the product was defective when sold and that the product was harmful when used in the manner intended; (3) the defect was the proximate cause of the injury; (4) his reliance upon that warranty; (5) notice to the defendant of the breach of warranty within a reasonable time.

[32] Section 2-725.

[33] While Section 2-607(5) on "vouching in" is new to the statutes, this common law doctrine is recognized in New York, *Hartford A & I Company v. First National Bank*, 281 N. Y. 162, 22 N. E. 2d 324 (1939). See Note in 51 *California Law Review* 471 (August 1963).

Damages for Breach

The buyer's remedy against his seller for breach of warranty in regard to accepted goods is delineated in Sections 2-714 and 2-715. The described measure of damages is not intended as an exclusive measure, and consequential damages include injury to person or property proximately resulting from any breach of warranty. Consequential damages may be limited or excluded entirely under Section 2-719(3), but limitation of consequential damages for injury to the person in the case of consumer goods is deemed to be "prima facie unconscionable." "Consumer goods" are defined in Section 9-109(1) as goods "used or bought for use primarily for personal, family, or household purposes," and this definition is incorporated in Article 2.[34] Nevertheless, the seller may still disclaim warranties under Section 2-316.

Other Representations Concerning the Product

Under Section 2-209 which abolishes the requirement of consideration for "agreements" modifying a sales contract or a warranty, the door has been left open with respect to post-contractual assurances or representations as to the product, for which the seller may or may not have been authorized by the product manufacturer. Such assurances can rise to the status of an express warranty as additions or modifications not requiring consideration to be binding. However, such modifications must meet the test of good faith,[35] for the extortion of a modifications or assurances without legitimate commercial reason is ineffective, because it is a violation of the duty of good faith implicit in every Section under the Code.

Should the seller insert, without the awareness of the buyer, a clause negating the standard implied warranties, under circumstances in which such warranties normally attach, such a negation will not become part of the sales contract under Section 2-207(2)(b), because such a clause "materially alters" the contract by surprise or hardship. Furthermore, where the seller and buyer are not both "merchants," as defined in Section 2-104(1), the additional term or clause would not become part of the sale or the contract of sale. Such other product representations made after sale do not become warranties.[36]

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[34] See Section 2-103(3).

[35] Sections 1-102(3) and 1-201(19).

[36] See, generally, *Smith Company v. Fisher Plastics Corp.*, 76 F. Supp. 641 (DC Mass. 1948), and *Budrow v. Wheatcraft*, 115 Cal. App. 2d 517, 252 P. 2d 637 (1953).

Statute of Limitations

Section 2-725 delineates a special statute of limitations in sales and in contracts of sale, and thereby actions based upon sales contracts and breach of warranty are taken out of the general laws limiting the time for commencement of contractual actions. A four-year period is deemed to be most appropriate to modern business practice, and all actions must be commenced within four years after the cause of action has accrued. Although the parties may by agreement reduce the period of limitation to not less than one year,[37] they cannot extend the time. The cause of action is deemed to accrue when the breach of warranty or of the contract occurs, that is, "when tender of delivery is made," regardless of the plaintiff's lack of knowledge of the breach. Where the warranty extends to future performance, the cause of action accrues when the breach is or should have been discovered.

Subsection (3) is a saving provision permitting an additional short period of six months for bringing new actions where suits begun within the four-year period have been terminated so as to leave a remedy still available for the same breach.

The insertion of this special four-year statute of limitations for warranty actions poses a knotty problem in those states where the statute of limitations is either longer or shorter than four years. In New York the contract statute of limitations is six years, and in a majority of states it is equally long or longer.[38] On the other hand, in a lesser number of states it has been held by decisional law that

[37] See Section 10(1) of the New York Civil Practice Act, now Section 201 of CPLR.

[38] For contract actions the following *longer or equally-as-long* time limitations for commencement of the action are applicable:

Alabama, 6 years; Alaska, 6 years; Arizona, 6 years (except for 3 years for oral warranty); Arkansas, 5 years (except for 3 years for oral warranty); California, 4 years (except for 2 years for oral warranty); Colorado, 6 years; Connecticut, 6 years (except for 3 years for oral warranty); Florida, 5 years (except for 3 years for oral warranty); Georgia, 6 years (except for 4 years for oral warranty); Hawaii, 6 years; Idaho, 5 years (except for 4 years for oral warranty); Illinois, 10 years (except for 5 years for oral warranty); Indiana, 10 years (except for 6 years for oral warranty); Iowa, 10 years (except for 5 years for oral warranty); Kansas, 5 years (except for 3 years for oral warranty); Kentucky, 15 years (except for 5 years for oral warranty); Louisiana, 10 years; Maine, 6 years; Massachusetts, 6 years; Michigan, 6 years; Minnesota, 6 years; Mississippi, 6 years (except for 3 years for oral warranty); Missouri, 10 years (except for 5 years for oral warranty); Montana, 8 years (except for 5 years for oral warranty); Nebraska, 5 years (except for 4 years for oral warranty); Nevada, 6 years (except for 4 years for oral warranty); New Hampshire, 6 years; New Jersey, 6 years; New Mexico, 6 years (except for 4 years for oral warranty); New York, 6 years; North Dakota, 6 years; Ohio, 15 years (except for 6 years for oral warranty); Oklahoma, 5 years (except for 3 years

the shorter *tort* statute of limitations is applicable to all personal injury actions, whether brought in tort (negligence) or in contract (warranty).[39] Subsection (4) does not solve the problem by stating that Section 2-725 does not alter or modify the law in any respect on tolling of the statute of limitations as now prevails in the state. It would appear that an express repealer is necessary to bring the respective statute of limitations into line with the four-year period required under Section 2-725. However, the defense of the statute of limitations may be waived, either by failure to raise the objection [40] or by agreement of the parties.

New York and the other 12 states which will put the provisions of the U. C. C. into operation in the year or two ahead, should carefully note the court decisions construing the respective Sections by such states as Pennsylvania with 9½ years' experience, Massachusetts with over 5 years' experience, and Kentucky with 3½ years' experience. In the interest of uniformity, it is to be hoped that the Code provision on warranty, on notice of breach, on privity of contract, on disclaimers of liability, and on the 4-year statute of limitations, will be accorded essentially the same treatment, for products liability, as dynamic a field as it is, must keep its feet upon the same ground. **[The End]**

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for oral warranty); Oregon, 6 years; Pennsylvania, 6 years; Rhode Island, 6 years; South Carolina, 6 years; South Dakota, 6 years; Tennessee, 6 years; Texas, 4 years (except for 2 years for oral warranty); Utah, 6 years (except for 4 years for oral warranty); Vermont, 6 years; Virginia, 5 years (except for 3 years for oral warranty); Washington, 6 years (except for 3 years for oral warranty; West Virginia, 10 years (except for 5 years for oral warranty); Wisconsin, 6 years; Wyoming, 10 years (except for 8 years for oral warranty).

[39] The one (1) year statute of limitations under Section 340(3) of the California Civil Practice Act, has been interpreted as applying to all personal injury and death actions, regardless of whether they are based on tort or on contract. See *George v. Douglas Aircraft Company,* U. S. District Court for the Southern District of New York, dated July 2, 1963, citing *Rubino v. Utah Canning Company,* 266 P. 2d 163, 168 (1954); *Lai Wum Chin Mock v. Belfast Beverages Inc.,* 14 Cal. Rptr. 602 (1961); and, *Aced v. Hobbs-Sesack Plumbing Company,* 12 Cal. Rptr. 257, 263 (1961). In New York the mere fact that the pleading sounds in contract will not enlarge the period of limitation if the essential basis of the claim for personal injuries is negligence. See, generally, *Loehr v. East Side Omnibus Corp.* 259 A. D. 200, 18 N. Y. S. 2d 529 (1940), aff'd 287 N. Y. 670 (1941). But where the plaintiff purchaser would be entitled to recover for personal injuries on the contract theory of breach of implied warranty—without necessity of proof of negligence—the contract six-year statute of limitations has been deemed to apply, *Blessington v. McCrory Stores Corp.,* 305 N. Y. 140 (1953).

[40] In New York, the objection is raised either by motion to dismiss or by affirmative defense in the responsive pleading under CPLR Rule 3211 (a)(5). On waiver in New York, see CPLR Rule 3211(e).

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