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Food Drug Cosmetic Law JOURNAL

Concluding Papers Presented at the
1967 Annual Meeting of the
New York State Bar Association
Section on Food, Drug and
Cosmetic Law

Papers Presented at the
Meeting of the American Bar Association
Division on Food, Drug and Cosmetic Law

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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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Table of Contents . . . . . March, 1967

VOLUME 22 NUMBER 3

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REPORTS

TO THE READER

Twenty-Second Annual Meeting of the Section on Food, Drug and Cosmetic Law of the New York State Bar Association.—The concluding papers presented at the meeting are featured in this issue of the JOURNAL. The previous papers presented at the meeting were published in the February issue.

The concept of group litigation is presented as the subject of two articles which were delivered at the meeting. Beginning on page 136, *Paul D. Rheingold,* a member of Speiser, Shumate, Geoghan & Krause, examines the plaintiff's viewpoint in his article, "Multiple Drug Litigation—The Plaintiff's Viewpoint," while *Joseph M. Costello,* a member of Costello, Ward, Tirabasso & Shea, discusses the defendant's viewpoint in "Multiple Drug Litigation—The Defendant's Viewpoint," which begins on page 145.

"Observations on Recent Developments in the Food, Drug and Cosmetic Law Field" is the topic of the paper beginning on page 151. *A. M. Gilbert,* a member of Davis, Gilbert, Levine & Schwartz, contends that FDA has not been following its own precepts of late. He examines certain dangers to industry and the public implicit in recent food and drug legislation.

"The Issues We Face in Carrying Out The Fair Packaging and Labeling Act" commences on page 158. *William W. Goodrich* cites the difficulties which await the legislator whose task it is to frame the regulations required by The Fair Packaging and Labeling Act.

Charles A. Sweeny examines the preparations being made by the FTC for the implementation of The Fair Packaging and Labeling Act. The extent of product coverage, drafting of regulations, and needed co-ordination among the agencies of the FDA, FTC and National Bureau of Standards are discussed. Entitled "Packaging Responsibilities of the FTC," the article begins on page 165.

The legislative development of The Fair Packaging and Labeling Act is discussed in the article entitled "The Fair Packaging and Labeling Act of 1966," which begins on page 169. *Robert E. Giles,* General Counsel of the U. S. Department of Commerce, goes on to note the specific responsibilities which Public Law 89-755 places on the Department of Commerce.

1966 Annual Meeting of the Division of Food, Drug and Cosmetic Law of the American Bar Association.—Three of the papers presented at the meeting are published in this issue of the JOURNAL. Additional papers read at the meeting, which was held in Montreal on August 10, 1966, will appear in a later issue.

A discussion of the Federal Trade Commission, what it is doing and what it plans to do, is found in the article by *Paul Rand Dixon,* Chairman of the Federal Trade Commission. "Guidance and Enforcement" begins on page 177.

In "The Canadian Viewpoint," *R. A. Chapman,* Director-General, Canadian Food and Drug Directorate, discusses some of the problems existing in the food and drug areas in Canada. Mr. Chapman concludes with a few comments on current developments in the international field. The article commences on page 185.

"Trends in Drug Legislation Under the Food and Drugs Act in Canada" is the topic of the article beginning on page 189. *R. E. Curran,* Q. C., reviews the history of food and drug legislation in Canada and indicates certain trends that their present legislation reflects.

Vol. 22, No. 3 March, 1967

Food·Drug·Cosmetic Law
Journal

Multiple Drug Litigation— The Plaintiff's Viewpoint

By PAUL D. RHEINGOLD

This Article and the Following Five Were Presented at the 1967 Annual Meeting of the New York State Bar Association Section on Food, Drug and Cosmetic Law. Mr. Rheingold Is a Member of Speiser, Shumate, Geoghan & Krause. The Next Article, by Joseph M. Costello, Discusses Multiple Drug Litigation from the Defendant's Viewpoint.

THE WHOLE CONCEPT OF GROUP LITIGATION by plaintiffs in personal injury cases has emerged in the recent drug products litigation. While there are many precedents for group preparation and trial of cases arising out of mass disasters, such as explosions, plane crashes and ship sinkings, all of these are limited to a single event and the filing of cases in one or a few courts.

A. Introduction

The filing of hundreds of actions in 1962 and the years thereafter by persons alleging injuries due to the use of the prescription drug MER/29 broadened the horizons of group litigation perceptibly. All of a sudden the courts all over the country, state and federal, found MER/29 cases on their dockets. And lawyers representing the plaintiffs, most of whom were attorneys who had never handled a drug case before, found themselves with an urgent need to understand their cases and to prepare them properly for trial. Some group effort was called for, and this was so even though, unlike the previous mass disaster cases, not all cases were alike: different people had suffered different injuries after using different dosages of the drug for different durations.

B. MER/29 Group

I want to refer in some detail to the establishment and operation of the MER/29 group as representative of the good and bad aspects

of group litigation in this talk. The so-called MER/29 group was set up during a meeting of some 33 lawyers in Chicago, all representing plaintiffs. It is of note that this was not and is not a National Association of Claimants Compensation Attorneys (NACCA) [now The American Trial Lawyers Association (ATLA)] group. The group is not run by NACCA. The present majority of the MER/29 group are not members of that association; many are defense counsel whose old clients were injured by the drug.

Over the years the membership of the MER/29 group has grown to more than 300 firms, representing something over 700 plaintiffs. The primary purpose for its creation was to exchange information on the drug and on the litigation. A newsletter was put out for this purpose, of which there have been over 30 issues. (While it was intended that these reports be confidential, the defendant has breached the security. Of course, knowing this, the plaintiffs have been able to communicate with the defendant by plants through its own reports.)

Each member made an original contribution of $100 to the group. Later there was an assessment of $200, to be used to carry on the national discovery program. Still later an additional assessment was made to raise further sums, imposed upon members representing more than one client. About a year ago the group ran out of money but it had finished up the work that it had set out to do for its members.

Each side to the MER/29 litigation needed some sort of national direction. Naturally, the defendant had much centralization both in its own house counsel office and through its carriers. In addition, the defendant employed the services of one law firm to act as a sort of national counsel and to deal with the plaintiffs' group. Management of the plaintiffs' group gradually settled down into a national steering committee and the use of one firm, on the local scene here in New York, as day-to-day representative. Periodically, the MER/29 group would have national planning meetings.

The distribution of the cases is interesting. MER/29 cases turned up in most states and all large cities. Within the group, most of the members have but one or two cases, although a number had over 10 and at least one had more than 100 cases.

C. Preparation of Cases

Shortly after formation in 1963, the group determined to work out joint discovery in all of the group cases. It was proposed to the defendant, and its carriers, that all discovery be both voluntary and joint, in the sense that but one set of depositions would be taken

and but one set of documents would be produced for all cases. The benefits to the plaintiffs would be that they individually would be spared great time and effort, and the group could attract new members by offering to them a complete discovery package long since taken but fully applicable to their case. The benefit to the defendant was to minimize the harassment and lack of uniformity that hundreds of notices and motions would have produced, while at the same time the personnel of the company would be spared time in being deposed repeatedly. Whether one side stood to gain more than the other in this sort of voluntary joint discovery is difficult to answer. Perhaps Mr. Costello will have comment upon this from his standpoint.

At first, the defendant sought to resist the onslaught of group discovery. An abortive attempt was made to interest the Judicial Conference of the United States in taking control of the cases, as they had just done with the electrical price fixing cases. After due consideration, the defendant's national counsel agreed to voluntary discovery and the national program got under way in 1964. Interesting aspects of it were as follows:

1. Depositions of the defendant, by two vice presidents and a head of sales. These three were thus taken just once, in all of the cases.

2. A deposition of a scientist in another drug company which had independently experimented with MER/29, along with a group set of interrogatories to the other company. Here even though neither party had control over all the cases in the country, that one deposition has been used at most trials, and no person outside or inside the group has sought to take the same deposition.

3. Eight depositions of non-parties. The parties agreed that each side would take four depositions, all applicable to every case. Plaintiff deposed two ex-employees, a doctor at the Food and Drug Administration, and a doctor at the National Institutes of Health. The defendant chose to depose two other ex-employees, a former clinical investigator, and a scientist who had done MER/29 animal studies.

4. The defendant produced one set of documents for all members of the group. These were some 107,000 documents—the totality of the company's files on the drug. These were on microfilm and were readily readable by the usual sort of machine. Members desiring documents could then order them through the group, and were not to seek them from the defendant. The group read most of what was produced and culled out what

came to be known as the key documents, which are put into a package for members who were approaching trial to use.

5. There was also an agreed upon set of interrogations and answers submitted by the group to the defendant.

All of this discovery was governed by a number of stipulations and written agreements. One master agreement covered many aspects of the arrangements, including laying a foundation for the admissibility of the documents. The plaintiffs' members agreed in turn to produce all pertinent medical reports at a time before trial.

D. Trial and Settlement

In 1964 the MER/29 cases started to come to trial. They have been coming up ever since and will probably continue until beyond the end of this decade. The majority of the perhaps 1300 cases filed have been disposed of, mostly by settlement. Many settlements have been substantial. For those keeping box scores of the trials, of the ten tried through to completion, each side has won four and there have been two ties—two hung juries. Two verdicts have exceeded $500,000, and one exceeded $1 million, including punitive damages. Of the four won, three are or will be on appeal; one has been settled. Of the four lost, three were appealed. In the two that have been decided, the position of the plaintiffs' group was worsened not only by the affirmance of the defendant's verdict below but the creation of appellate opinions exculpating the company. In fact, the Supreme Court in Oregon stated that on the record before it a plaintiff could not win a MER/29 case based upon a warranty action as a matter of law!

Originally, the MER/29 group had no plans for direct effort at trial, nor in the coordination of trials. It has basically adhered to this. Its function has been preparation, together with the dissemination of information about trials. The philosophy was that while attorneys were going to utilize group data, they were also going to try their own cases in their own ways, without interference in their attorney-client relationship. Thus no effort was made to bring the best case in the group to trial first or to encourage lawyers to settle a weak case if it was coming up. As it happened, the first three cases were not only weak on their facts but also were tried without the benefit of the discovery product of the group. All were won by the defendant.

The defendant was in a natural and proper position to coordinate its trial, and I think it is fair to say that this they did. Whether their

initial three victories discouraged any plaintiffs' counsel is another question.

The individual members at trial were aided by the group in having a central clearing house of transcripts from previous trials, data on expert witnesses available to the plaintiff or being used repeatedly by the defendant, and by having a so-called trial package of data available, including an outline of previous trials. On the other hand, no one from the group went to trials to observe or aid, except where the member trying the case wanted to pay for the services of an attorney from the group personally. Members who wanted to come to New York for a "school" on MER/29 could also learn about the trial of a MER/29 in this manner.

Here again the defendant no doubt excelled in the preparation of guides for trial and in keeping local counsel informed of the course and outcome of previous trials. Still, of course, the defendant, too, had to rely upon educating its local counsel. It has used no national litigation team, even though it has experimented with sending counsel from its house staff or from its national firm to individual trials, to advise or participate actively. "Schools" for local defense counsel, including trips through the defendant's plant, were also held.

After the trials have come the appeals. Here again the defendant enjoys a natural and proper advantage in coordination. On the plaintiffs' side any member may take any sort of appeal he wants, on any sort of record, on any sort of appellate arguments, without regard to the impact that the possible resolution of issues raised may have on the group. In at least one instance, however, it should be noted that the group has filed an amicus brief.

Since 99% of the cases disposed of so far have been so by settlement, one main benefit that the group has been able to provide to members is guidelines to settlement. These arise naturally out of reports on settlements, setting forth what data is known about the injuries and liability in the settled case. Another guideline which has turned out to be of great interest to the lawyer is knowledge of what constitutes a perfect or classical MER/29 case, as compared to one that deviates from that pattern. Both in attempting to analyze the cases medically and in reporting on settlements, the group has consciously attempted to give only information, not advice. That latter is considered outside of its function. The resultant settlements have followed virtually no pattern—identical, classical MER/29 cataract cases have settled in the past for $2,000 and $120,000—a span of $118,000!

There have been all varieties of preparation for trial and settlement within the group. Some attorneys have prepared strenuously, even exceeding the group's work. At the other extreme there are those who have relied so completely on group effort that they have never even bothered to check exactly what it is the group has done for them. Perhaps some of them will be surprised when they find out! There has been little or no correlation between those who have actively prepared a MER/29 case for trial and those who are known as specialists in personal injury litigation.

E. Problems for Plaintiffs

It may be interesting to consider what problems group litigation has presented to both litigants. I take first the plaintiffs' problems. One problem is making the plaintiffs' group cohesive. By its very nature, trial practice attracts individualists. Their motto is something like "I have never relied upon preparation of a case done outside of my office." (Of course, some of them consequently have nothing at all to rely on.) In any case, it seems that a few of them fear that their identity as specialists will be diluted if they join in with other lawyers. Fortunately, this has not been much of a problem in the MER/29 group, at least not to the same extent as in others. In retrospect it seems to have been the factor that prevented the formation of what would have been a very logical group of cases arising out of the Corvair-General Motors litigation. There some of the lawyers had gone ahead on their own to such a degree that when talk of concerted action arose they felt that they would only be in a position of virtually giving away free all of the fruits of their work.

In a realistic sense, one cannot expect every plaintiff to become involved with a group of lawyers handling similar cases. Some counsel will never hear about the group. After all, there is no good way for a group to get its name and activities known to the bar generally. (I might say that the defendant is ultimately as good a broadcaster to non-members of information about the group as any.) Some lawyers will never pay the $200 or $300 that it costs to join a group, unless of course they can raise it from their client. And some, as noted above, appear to be too proud to join.

Another significant problem for a group of plaintiffs is coordination. No lawyer would ever be expected to sign over to a group full discretion of preparation, settlement or trial of his case. Thus the plaintiffs' group can never expect to be able to bring on a good, well-prepared case first for trial, nor to prevent appeals that are likely to

lead only to adverse appellate decisions. Fortunately, the problems of coordinating the group's other activities, including preparation, are not that difficult. This is true, however, only as long as the group agrees to allow important decisions and the conduct of the discovery to be run by one firm or one individual in whom some degree of trust is reposed. Any attempt to parcel out tasks among the various members of a group will not work, we believe.

F. Problems for Defendants

One major problem for the defendant today is a determination of whether or not to follow the path of peaceful cooperation with the plaintiffs' group. By failing to put up a stiff fight against everything that smacks of grouping of forces on the plaintiffs' side, the defendant may be allowing individual plaintiffs and their lawyers to have better-prepared cases than if each plaintiff had to get up his own case. Experience teaches that some simply will not. This is especially so, as with the MER/29 cases, where the individual injuries were relatively small.

The course of refusing to deal with the group as a group can have its drawbacks, however. The defendant is forever dealing with individual requests for differing groups of documents. The doctors in the company are being redeposed frequently. Each new plaintiff on taking the deposition of the defendant's scientist can use not only the fruits of all previous discovery but can go on and make new inquiries that would never have been asked had there been only a one-shot group deposition. The recent Aralen drug litigation, which has followed this pattern, indicates the hazards. When a case finally comes to trial, the defendant is confronted forcefully with the fact of its having produced different groups of documents for different plaintiffs, and its witnesses having given different depositions as the time went on.

A special problem for the defendant is whether to follow the course used in MER/29 and to produce all documents relevant to the drug, or whether to hand over discrete packages of documents individually, grudgingly and usually only after court order. The latter process leaves the plaintiffs with fewer documents and perhaps some helpful ones will never be discovered since the plaintiffs are unable to frame an adequate request for them. Once again, the sheer time and expense to a defendant of making such limited and coerced disclosure must be weighed against the saving of a one-shot, full house disclosure of all documents. To most plaintiffs, after all, the production of all documents is no godsend. The plaintiffs' group in the

MER/29 cases has to this day not been able to read through all 107,000 documents the defendant produced.

There is another more serious problem for the defendant in group litigation. This is an unfortunate state of mind which sometimes arises among drug companies when plaintiffs band together. What happens all too often is that a certain amount of unrealistic evaluation of the motives of the plaintiffs creeps into the defendant's thinking, what some might call delusions of prosecution. The plaintiffs are perceived not as out for restitution—they are seen as out to destroy the company. The reputation of the company is somehow now at stake.

Examples of this unfortunate state of mind can be found in recent talks given to assemblages of counsel representing drug manufacturers. In May 1964, a member of a New York law firm spoke to the law section of the Pharmaceutical Manufacturers Association (PMA). Apparently, he is hostile to plaintiffs' groups. He said that in the face of such groups the defendants—the whole industry—perhaps should band together. Three advantages he found were as follows:

> . . . We are, unfortunately, faced with an organization of plaintiffs' attorneys, National Association of Claimants Compensation Attorneys—N.A.C.C.A.—which does not see anything a bit unethical in passing among its members information on drugs, the side effects of which might be actionable; successful strategies; the names and addresses of expert witnesses; and other data pertinent to the trial of such a case. . . .
>
> Richardson-Merrell quite recently has won a signal victory against N.A.C.C.A. Not only did the N.A.C.C.A. attorneys pass information out among themselves, but they also banded together to try cases against The Wm. S. Merrell Co. arising out of alleged reaction to the drug MER/29. . . . .
>
> . . . Is there some way in which a united front can be presented not only for the purpose of protecting the companies involved but for the higher purpose of establishing a reasonable body of law in this area? . . . .
>
> . . . (3) The establishment of a clearing house for information about the activities of the 'enemy' (N.A.C.C.A. and its satellite attorneys).
>
> . . . (8) The financial ability to resist the intimidation of N.A.C.C.A.-oriented plaintiff's attorneys.
>
> (9) A central public relations voice capable of action on a national scale. . .

A few months later, a distinguished Cleveland counsel for drug companies told another PMA audience that something had to be done, and done fast, about the plaintiffs' groups in drug cases.

> . . . Now, what about them singling you out as a target defendant?
>
> . . . The business of A.T.L.A. is litigation. They always want a target defendant. A target defendant is a large, rich corporation, a soulless corporation. A target defendant is such a corporation that is in the public's displeasure. An angry public is an angry jury, and angry juries award much more money than they would normally.

By definition, then, your industry at the present time fits perfectly the target defendant of A.T.L.A.

More recently, the then general counsel for Richardson-Merrell spoke to this section and expressed the same theme— it is unfair for the plaintiffs to band together.

This imperceptive attitude is reminiscent of big business's attitude toward labor unions before the turn of the century. Early attempts at unionization were regarded as illegal and unethical. For a while, business was able to get the courts on their side in the fight against collective bargaining; it is a way of life today.

There are two very unfortunate consequences of this unbased state of mind. The first is that there may be a tendency among counsel for the defendant in a group situation to feed upon its client's attitudes, rather than to lead its client to a more objective and realistic appraisal of the pending litigation. The second is that both client and counsel may be led to seek other than the usual pathways of litigation to settle their problems.

G. Conclusion

What can be predicted for the future? It seems safe to say that from time to time groups similar to that of the MER/29 group will be voluntarily formed. This is especially so in products cases, which naturally involve the same product causing similar injuries over a national or even international area. Drug cases are especially logical products for grouping of efforts, in part because of the complexity of their preparation. Already, modeled on the MER/29 group, there are about six other groups in operation, for such drugs as Enovid and the other birth control pills, Parnate and other MAO inhibitors, Aralen, Sabin polio vaccine, Esidrix and other similar diuretics, and drugs that are allegedly teratogenic, including meclizine and cyclizine. Probably none of these groups will come to have the power or the direction of the MER/29 group, because the number of cases pending is much less and because in some instances there are multiple manufacturers of the same product. In fact one may well conclude this talk with the observation that while the group technique has proved successful and will undoubtedly be used in the future, we all hope that the need for such efforts will grow less, especially for the pharmaceutical product. **[The End]**

Multiple Drug Litigation—The Defendant's Viewpoint

By JOSEPH M. COSTELLO

Mr. Costello Is a Member of Costello, Ward, Tirabasso & Shea. Multiple Drug Litigation from the Claimant's Viewpoint Is Discussed in the Preceding Article by Paul S. Rheingold.

IN DISCUSSING THE VIEWPOINT OF THE DEFENDANT DRUG COMPANIES, there is no problem presented when we are talking about the isolated case, wherein a claimant in a lawsuit sues for injuries sustained as the result of the ingestion of a particular drug and that claimant, through his attorneys, seeks complete discovery to prepare for trial. We are concerned though, with a multiplicity of claims usually pending throughout the country, arising out of the ingestion of a particular drug. As a general rule, this occurs in the case of a relatively new prescriptive drug as opposed to those over-the-counter drugs or prescriptive drugs on the market a long time.

At the outset, I would state that multiple claims arising out of the ingestion of a particular drug, even though the alleged adverse side effect might be similar, should not be confused with the common disaster type of accident, such as the crash of an airplane or the sinking of a ship, resulting in multiple loss of life or injury. A perfect example of this was the collision of the Andrea Doria and the Stockholm a number of years ago off the coast of Rhode Island. In the type of accident resulting in multiple death or injuries, there is a definite need for a single all encompassing discovery proceeding to get the facts and circumstances surrounding the single act and, if necessary, a single trial to determine liability only. Once this is decided, then there is the sole problem of going forward and assessing damages if, in fact, any liability was found in the first instance. Although the Andrea Doria case never came to trial, it was agreed upon between the parties and the various insurance interests after discovery

proceeding as to where the relative fault lay. Once this was decided, the principals set up a fund and most of the claims were disposed of by way of settlement. Very few actually came to trial and all were settled without any appeal. On the other hand, with a prescriptive drug, the only thing that is usually common to the various plaintiffs is the actual ingestion of the drug and a possible similarity as to alleged side effects. This is as far as it goes, and under the circumstances, does not lend itself to either joint trial to establish liability or joint discovery proceedings.

Joint Discovery Proceedings

A quasi precedent for joint discovery proceedings was established with the MER/29 (Triparanol) cases, with which most of you are familiar, wherein a multitude of suits arose out of the ingestion of that drug while it was on the market for approximately two years. Our firm has personal experience with the situation involved there and would say that the circumstances were unique. At the time there was a Federal Government investigation and the possibility of criminal action by the U. S. Justice Department. Plaintiff's attorneys at the same time were clamoring, and rightly so, for their legitimate discovery proceedings so that they could get on with the individual claims. Because of the criminal proceedings, defendant's general counsel perforce had to be aware of whatever statements by way of testimony the corporate principal's officers would make, which would be impossible if depositions were being taken throughout the country in different jurisdictions. In addition thereto, the corporate records were in Washington under subpoena, and there was only available a microfilm copy of the record which comprised over 107,000 documents. At about the same time, as I understand it, the American Trial Lawyers Association (ATLA) formed what has become known as the MER/29 Group, of which Mr. Paul Rheingold is Trustee—and I might say the main architect of the group discovery proceedings in drug cases. After living with the results of the group discovery proceedings with MER/29, we feel that this type of proceeding inures entirely to the benefit of the plaintiff-claimant, with little or no benefit to the defendant in question. If anything, it is manifestly unfair to the drug company. As stated before, the MER/29 situation was unique due to the enormity of the discovery to be taken and the possibility of criminal action against the drug companies. Since that time, our firm, with the concurrence of the various drug companies we represent, has resisted this group discovery proceeding for the following reasons:

Dissimilarity to Common Disaster Type Action

1. Other than the possible ingestion of the particular drug and the resulting side effects, which may or may not be the same, the comparison of multiple drug claims with the common disaster type of action is unwarranted. There are so many facets to this—the date of the ingestion of the drug, the length of time the party was on the drug and the amount of drug taken over the particular period of time. The intervening cause is another factor; I refer to the prescribing doctor. Ask yourself the question—What was the doctor aware of at the time? Why did he prescribe the drug? What warnings, if any, accompanied the drug at the time it was given to the plaintiff? Needless to say, most of these claimants take the drug at different times and for various lengths of time, and in different dosages. The amount of drug taken and the resulting side effects vary in each individual patient. In short, there is no common denominator between each of the plaintiffs and the defendant drug company in question.

In addition thereto, from our own experience, the courts of New York have indicated that they do not consider these types of cases analogous to the common disaster type. This is evidenced by the fact that a local attorney who has many MER/29 cases, made a motion to consolidate a group of some seventeen (17) MER/29 cases with six others. Attorneys for the defendant, Wm. S. Merrell, cross-moved to deny the motion and in the alternative to separate all the causes of action. This cross-motion was granted. Subsequent thereto, it was taken on appeal to the Appellate Division with a cross-appeal by the defendant for the appointment of one judge mainly to handle and control all preliminary proceedings involved in these cases. The Appellate Division of the First Department appointed one judge to handle all preliminary matters relative to MER/29 and left the decision as to whether or not the cases will be tried as a group to that particular judge. Although this decision has never been rendered, I can state from personal experience that the judge in question assigned to all MER/29 cases pending in the First Department, has indicated that he does not feel that this is the type of case which lends itself to consolidated litigation. The Rule II judge appointed in the U. S. District Court for the Southern District of New York who, incidentally, has ruled on the questions in the Group National Discovery proceedings, has more or less voiced the same sentiments as the judge in the First Department. A MER/29 case has already been tried as an individual case in each of these courts.

ห้องสมุด กรมวิทยาศาสตร์

If this be true as far as trial is concerned, the same rationale should be applied to group discovery proceedings, namely, the deposition of witness and the examination of documents. Is not the pretrial discovery proceeding by way of depositions and examination of documents merely the prelude, the building up of the evidence which will eventually be used at the time of trial? If unlimited group discovery is agreed to in the drug cases, as would have to be the situation because there is no legal precedent for it[1], this would allow the plaintiffs' counsel, selected for his expertise, to go on an unlimited "fishing expedition" with no legal governor placed upon his action. There must be a relationship between the particular claim of the plaintiff and the acts of the defendant drug company allegedly causing the plaintiff's injuries. Plaintiffs' attorneys counter with the argument that if the drug company has nothing to hide, it should be willing to throw open its entire file to plaintiffs' attorneys. If we carry that argument to its logical conclusion, we might say that each attorney in a particular litigation should expose his file to the other so that they know exactly where each stands, and every intimate detail that has been said or written about the particular claim. Needless to say, neither plaintiffs' attorneys nor defendants' attorneys would ever go along with such an idea. If the group discovery proceeding were allowed in the first instance and made to cover the entire history of the drug from the date of its development to the date that the deposition was taken, there would be a tendency on the part of the local judge on the individual case to allow the broad deposition into evidence, even though certain parts of it are irrelevant and immaterial to the particular case, and, in fact, some of the evidence could easily be of a highly prejudicial nature. For example, if a person stopped taking the drug as of December 31, 1966, what the company did in relation to that drug subsequent thereto, would be irrelevant and immaterial to the particular claim of the plaintiff against the drug company, and could very easily be highly prejudicial.

Group Discovery—Contrary to Our System of Law

2. The very concept of broad discovery proceedings taken with no particular claimant in mind is alien to our common law heritage.

[1] Since this address was delivered, a motion was made in the local court, New York State Supreme Court, Special Term, Part I, wherein one attorney sought to force a defendant drug company to allow plaintiff in that case to participate in an examination before trial pending in another jurisdiction. The motion for group discovery proceeding in this particular matter was denied without opinion by the court from the Bench.

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We don't have that Civil Law concept wherein a charge is made which, in turn, sets in motion a complete unbridled discovery proceeding to see if there is any basis for the charge. Litigation in our civilized society is our last resort in the law and should be avoided. This has always been the tradition of the Judeo-Christian heritage and is manifestly carried forward in our common law precepts.

Practically speaking, we are engaged in an adversary proceeding and I see no reason why the drug company, from whom large monetary awards are being sought, should aid and abet claimants' selected experts to fish in its records and in a sense, help to possibly create litigation or, at the very least, to foster and nurture it. This very concept runs contrary to our system of jurisprudence. It is analogous to putting the cart before the horse.

Variance in Rules

3. Rules governing depositions and examinations of documents vary throughout the country, and very often between adjacent districts or departments of the very same court. The situation in the New York Supreme Court, Appellate Division, Third Judicial Department is a perfect example. In the First and Second Judicial Departments, medical records and the reports of examining physicians which will be used at the time of trial, must be exchanged between the parties. This, we understand, is not true in the Third Department. The rules in the various districts have been set, and properly so, by the judiciary to take care of the people within their district. This affords equal protection to all litigants. In the particular claim pending, both the plaintiff and the defendant should have protection of the local court rules and regulations governing depositions and discovery proceedings, if joint discovery is consented to. In the event of a dispute concerning what questions may or may not be asked, or what documents shall or shall not be produced, there would be no judge before whom the individual case would eventually be tried, to determine whether or not these documents shall be produced, or the questions answered.

As a practical matter, the plaintiff group could choose the most liberal jurisdiction in the country, have a complete discovery proceeding and then disseminate the information throughout the country, thereby subverting the local court rules. Perhaps we should have a uniform discovery proceeding throughout the nation, but this is within the province of the Judiciary or the Legislature, as the case may be.

We are aware of the fact that certain modifications have to be made to fit each individual case. We would go along with the idea that where one attorney has three or four cases in a particular jurisdiction and is acting as either the attorney of record or doing all the preliminary discovery proceedings, arrangements can be made to allow joint discovery proceedings to be taken and to apply at the time of trial to each particular case, reserving the rights as to relevancy and materiality to be determined by the judge sitting in that particular case. In that situation, we do have a control or governor, that is to say, the rules and regulations of the local court. **[The End]**

FIRST FAIR PACKAGING AND LABELING REGULATIONS PROPOSED

The Food and Drug Administration has proposed the first of the regulations required to implement the Fair Packaging and Labeling Act, which takes effect on July 1, 1967. The proposed regulations cover only the labeling of foods, while rules for the labeling of over-the-counter drugs, cosmetics and medical devices will be the object of later regulations.

The proposed labeling requirements include the listing as part of the name of a product the form in which it is offered, the omission of words that tend to exaggerate the amount of food in a package, and a declaration of the net quantity of each serving to accompany any statement of the number of servings in a package.

The net contents statement would appear in the lower twenty percent of the principal display panel of the package, with no other information below or to either side of it. The regulation would also fix minimum type sizes for the weight declaration on packages of varying sizes.

When net contents are expressed in weight, the label on packages of less than four pounds would give the total weight in ounces and, if applicable, in larger weight units as well. When liquid measure is used, contents of a gallon or less would be stated first in fluid ounces and then in quarts, pints and fluid ounces.

The Commissioner of Food and Drugs would be authorized to designate the manner of stating quantity when he judges that an existing practice does not facilitate value comparison. The continued use of decimal weight declarations would be allowed for commodities such as cheese, often packaged in random weights.

32 Federal Register 4172.

Observations on Recent Developments in the Food, Drug and Cosmetic Law Field

By A. M. GILBERT

Mr. Gilbert Is a Member of Davis, Gilbert, Levine & Schwartz.

PLEASE LET ME EMPHASIZE that whatever I say today represents my personal feelings and concerns, and in no way represents the feelings or thinking of any other person, company or association. Let me also emphasize that what I say is meant to be helpful and constructive—all to the end that we will have a well balanced enforcement of the Act by the Food and Drug Administration (FDA).

I think we have had some very important developments in the last year or so, developments which could make our law stronger and more beneficial to the consumer than ever. However, depending upon how the law is enforced, there is also the possibility that, as stated by *Barron's*, "The medicine men of FDA, all unwittingly perhaps, are angels of death. The 90th Congress should clip their wings."

Of course, when industry does violate the Act, as in the case of salmonella infection, the product should be seized and FDA should take appropriate action. However, FDA's most important job is not that of being a tough policeman. I have been concerned with federal and state food and drug laws since 1930 and, like many of you, know from experience what the two Citizens' Advisory Committee Reports have urged: that merely wielding the big stick will not always get results which are in the best interests of the consumers in this country. More often this practice is self-defeating. Cooperation, education and reasonableness are essential. I know I am not saying anything that is new, but frankly, I am concerned that these essentials have not been given sufficient emphasis during the past year.

Misuse of Data

Let me cite just a few examples. On June 24, 1966, in testifying before the House Subcommittee on Public Health and Welfare of the Committee on Interstate and Foreign Commerce on H. R. 13886, Dr. Goddard submitted statistics as to injuries caused by accidental ingestion of children's aspirin. He said (page 14):

> The statistics lead us to one inescapable conclusion—every three days a child dies from an overdose of children's aspirin.

This made headlines in the papers. Dr. Goddard is a very prominent physician and government official, and when he makes a statement like this before a congressional subcommittee, people rely upon it and headlines result.

However, this is what was found when the facts were later checked. Mr. Harry B. Solmson of Plough, Inc., testified before the same subcommittee on August 29, 1966, and, in referring to Dr. Goddard's statement, reported that an inquiry had been made of FDA to determine the basis for the statement. He had been advised that the statement emanated from the figures accumulated by the National Clearinghouse for Poison Control Centers and issued by the Department of Health, Education and Welfare (HEW). Mr. Solmson then testified that the figures reflected the number of deaths due to accidental poisoning in children under 5 years of age for each of the years 1960 through 1964, that the figures included different types of substances, and that the figures for 1964 reflected a total of 125 children dead from poisoning due to "aspirin and salicylates." Quoting from Mr. Solmson's testimony,

> We know that 3 times 125 approximately equals the number of days in the year, but we feel it to be a grave injustice to the manufacturers of aspirin for children for this entire figure of 125 days to be equated solely with children's aspirin as a basis for saying that a child dies every third day from children's aspirin. As I have previously indicated, there are many drugs that contain aspirin that are not called aspirin, and there are many salicylates that are lethal in nature that are not aspirin.

On September 19, 1966, Dr. Goddard testified before the subcommittee and said that the types of salicylates involved in all the cases of death were not recorded and are not known.

Then there was placed into the record a letter dated September 27, 1966, from Dr. Goddard to Congressman Jarman, the subcommittee chairman, in which Dr. Goddard stated that the 125 deaths were attributed to accidental poisoning by aspirin and other salicylates. Dr. Goddard wrote: "Unfortunately, with only a few exceptions, the physician or medical examiner certifying cause of death did not specify whether or not children's aspirin was involved."

Incidentally, under the date of September 19, 1966, Dr. Robert D. Grove, Chief of HEW Vital Statistics, had written a letter to Charles E. Sullivan of Plough, Inc., wherein he listed 125 different types of entries on death certificates. An examination of these makes it quite obvious that many of the deaths were not known to be due to children's aspirin. Among other things, Dr. Grove wrote:

> The information from these death certificates provides no basis for drawing conclusions regarding the proportion of deaths due to children's aspirin. The data do indicate that some children's deaths are due to children's aspirin.

While there had been prominent stories in the papers following Dr. Goddard's original testimony, the "clearing of the record" was hardly noted by the press. The damage had been done—based on incorrect information furnished to the subcommittee— and it never should have happened.

In connection with this same hearing, FDA originally supported and testified in favor of the fixing of the maximum amount of children's aspirin that might be contained in a bottle. It was industry which opposed the fixing of an arbitrary maximum by statute and suggested that, as in the past, this should be accomplished through voluntary discussions and meetings among members of industry, FDA and competent scientists. We all know that Congress did not adopt FDA's position on this subject. Subsequently, the interested groups met and worked out a maximum that satisfied all parties.

Conflict over Dietary Supplements

As another example, consider Regulations Section 403(j), Foods for Special Dietary Uses. For some time, FDA had in the works certain amendments to these regulations. Following publication of a proposal to amend Section 403(j), an order was published last year establishing definitions and standards of identity for dietary supplements and vitamin- and mineral-fortified foods. To many of us, this so-called "order" did not comply with the applicable provisions of Section 701(e) of the Act with respect to promulgating identity standards. That a proposal for an identity standard had not been published, and that all interested parties had not been afforded an opportunity to file comments on this proposal in accordance with the requirements of the Act, is shown even by the opening language of FDA in this "order" published June 18, 1966, in the *Federal Register:*

> In association with the revision of the Regulations for Foods for Special Dietary Uses published elsewhere in this issue of the *Federal Register* . . . the Commissioner of Food and Drugs has concluded that definitions and standards of identity should be promulgated.

I think all of us would agree that the provisions of the law should be adhered to at all times by the government as well as industry. The government, like industry, should not be allowed to bypass or ignore applicable statutory provisions.

In this same so-called "order" there appears this statement:

> Vitamins and minerals are supplied in abundant amounts by the foods we eat. The Food and Nutrition Board of the National Research Council recommends that dietary needs be satisfied by foods. Except for persons with special medical needs, there is no scientific basis for recommending routine use of dietary supplements.

Under this "order," the foregoing disclaimer language would be required upon the main panel of the label of each dietary supplement.

Following publication of this "order," leading nutritionists said that their views had been badly distorted by FDA. Furthermore, letters from the Department of Agriculture and from members of the Food and Nutrition Board of the National Research Council stated that in setting vitamin/mineral allowances, FDA arbitrarily consolidated age bracket data collected by the Food and Nutrition Board and filled in blanks with its own figures. Furthermore, nutritionists and the U. S. Department of Agriculture denied any basis for this disclaimer.

The well known and highly regarded Professor W. H. Sebrell, Jr. of Columbia University, Chairman of the National Academy of Sciences-National Research Council Committee on recommended dietary allowances, admitted that the Food and Nutrition Board does recommend that dietary needs be satisfied with foods. But Dr. Sebrell added that the Board also recognizes that there are many situations in which dietary needs are not satisfied by foods. By proposing a disclaimer stating that the Food and Nutrition Board recommends that dietary needs be satisfied by foods, FDA used the authority of the Board to support a statement which, when taken out of context, creates a false impression. As Dr. Sebrell wrote:

> The generalization that vitamins and minerals are supplied in abundant amounts in the foods we eat has no relevance as applied to a particular individual, and there is abundant evidence that many individuals in the United States do not get all the vitamins they may need from the foods they eat.

Dr. Sebrell also wrote:

> These actions of FDA give a false value of validity and imply concurrence by the National Academy of Sciences-National Research Council in a way which would tend to reflect on the actions of the committee, of which I am chairman.

Disparity between Principle and Practice

In an address on November 28, 1966, to the Food and Drug Law Institute/Food and Drug Administration (FDLI/FDA) Conference in Washington, Dr. Goddard said:

> Americans must rely on one another, now more than ever before. This interdependence is nowhere more important than in the field of health.[1]

I am in wholehearted agreement with this. But my concern is that frequently FDA's conduct of late has not jibed with these words. FDA must act at all times in the best interests of the consumer and with a meticulous regard for fact and truth. Nor should FDA bow to the pressures of any congressional committee, or of any other group or individual, rather than fulfilling its responsibilities with the best interests of the American public in mind.

In this connection, I can remember a situation many years ago when FDA had seized a batch of raspberries in upstate New York on the ground that the berries were filthy and decomposed. The Congressman representing the district of the shipper came to see the then Commissioner and said that there was nothing poisonous about the raspberries and the seizure should be lifted. It so happened that that Congressman was chairman of the House Appropriations Committee. The Commissioner told this gentleman that if he did what was requested of him he could not look any of his people in the eye again. I need not tell you what happened to FDA's budget. In fact, this event resulted in the coining of a word for "cutting the budget."

And let me add that while we admire the attributes of zealousness and fearlessness in a law enforcement officer, no official should go beyond the law he is charged with enforcing.

Many of you will recall the discussion we had when the American Bar Association Division met in Philadelphia years ago during the pendency of the *Nutrilite* case. In addition to the usual penalties for violating the Act, the government asked the Court to order that Nutrilite pay to the government all the money it had collected from the sale of merchandise which the Court found was misbranded. The law contained no provision for this action, as we in Philadelphia agreed, adding that if FDA felt this to be an appropriate remedy, it should go to Congress and ask that the law be amended to give FDA this remedy. Incidentally, it is interesting that, to the best of my knowledge, FDA has never sought such an amendment.

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[1] James L. Goddard, "Report from FDA," 22 CCH Food Drug Cosmetic Law Journal 2, 74.

Necessity for Specific Requirements

I think all of us were concerned with the recent FDA seizure of Upjohn's Lincocin. I will not attempt to discuss this at any length. I think the story in the November 14, 1966, issue of the *Pink Sheet* tells us the facts and points out the dangers in the government's action. The action was based on a far from specific set of requirements for the advertising of Rx products in medical journals, requirements which industry had not had sufficient opportunity to understand. As stated in that issue of the *Pink Sheet:*

> Whenever a government agency moves into a new area of enforcement activity, both the regulated and regulators face a period of uncertainty until a transition is made and the dust settles, so to speak. The uncertainty in the control of Rx drug ads is increased because enforcement operates in an atmosphere of creativity.
>
> For this reason, it is impossible to establish precise legal boundaries at the outset, and regulatory action tends to reflect subjective evaluations made by government officials.

Prior to the seizure, Upjohn had written Mr. Goodrich that it was already in the process of changing the Lincocin advertising and that it was willing to review other ads "generously." On the same day that Upjohn officials were in Washington for a conference with Dr. Goddard, the Lincocin product was seized because of advertising which FDA claimed did not comply with the Act.

We all know of the developments which followed. Upjohn cancelled all of its Rx drug advertising in medical journals. Later, Dr. Goddard stated that it was nonsense for drug firms to cancel their drug campaigns as a way of countering FDA action. I do not know whether Upjohn cancelled its drug advertising for any such reason. But had I been counsel for Upjohn, especially in the light of FDA's actions regarding Lincocin, I would have advised Upjohn not to advertise any Rx drugs in medical journals until it could determine precisely what FDA's position was. I think all of us will agree that in this area FDA has a very distinct obligation to be helpful, cooperative and educational, not only for the benefit of the manufacturer, but for the benefit of the medical profession and the consumer as well.

Conclusion

Let me conclude by quoting from Vin Kleinfeld's paper of last summer, which appeared in the November, 1966, issue of the *Business Lawyer.*

> Perhaps the most significant change of all, however, was the recent appointment of a new Commissioner and the creation of the new slogan, "By

Goddard, things are going to change around here." Certainly a transformation has taken place. Whether this will be good or bad from the viewpoint of the Agency and the consumer only time can tell. Whether attacks upon the drug industry as a whole render a service or disservice to the public is a debatable point. The effect (added to over-regulation) may be to terrify the industry, drive the small manufacturer out of business, raise the cost and therefore the price of drugs, cause the drug industry to fear to spend funds in the development of new products, and result in a growing tendency on the part of Government personnel to play safe by saying "No" (since Congressional Committees, the press and the fringe consumer groups will never criticize you for keeping a drug off the market inasmuch as side effects cannot possibly materialize). If this occurs, it can hardly be considered to constitute progress. If this tendency continues, more and more research and the addition of new weapons to the arsenal of the physician will be done outside this country. Could penicillin and chloramphenicol obtain approval in the present Washington climate? It is doubtful that aspirin could; at best it would be required to be sold on a prescription basis for many years.

We are familiar with Icarus, the son of Daedalus who, in escaping from imprisonment, fell into the sea when the wax of the wings which had been fastened to his body melted as he flew too near the sun. The constant attacks upon the manufacturer of drugs and the ever-increasing regulations and restrictions may well end in a slow but constant decline in the marketing of valuable and life-saving therapeutic products. This, in turn, may result most unfortunately in a deceleration in the constant progress throughout the years of the practice of medicine. **[The End]**

REVISED PATIENT-CONSENT POLICY FOR INVESTIGATIONAL DRUGS PROPOSED

The Food and Drug Administration has proposed a new patient-consent policy which gives the physician using investigational drugs in the final stages of clinical testing the option of obtaining the patient's consent either in writing or orally. This would not alter the requirement that consent, written or oral, be obtained "in all but exceptional cases" when an investigational drug is used in treatment.

Written consent still would be required when an investigational drug is used primarily for the accumulation of scientific knowledge and when such drug is in the early phases of clinical use. These early phases include the first use in human volunteers to determine toxicity and dosage range and the initial trial of the drug's effectiveness against a specific disease or condition.

The final phase is clinical trial, in which investigators use the drug as it would be used if approved for general medical use. It is in this phase that the physician should be allowed to judge which form of consent is necessary or preferable. In all phases of clinical trial, the physician would be required to give the patient pertinent information concerning the drug being administered.

The Issues We Face in Carrying Out The Fair Packaging and Labeling Act

By WILLIAM W. GOODRICH

Mr. Goodrich Is Assistant General Counsel, Food and Drug Division, of the Department of Health, Education & Welfare.

FEW MEASURES HAVE PROMISED SO MUCH as the Fair Packaging and Labeling Act. It is popularly known as the Truth-in-Packaging Law. The consuming public has high expectations that, because of the Act, better packaging and more informative labeling will appear in the very near future—about July 1, 1967.

The President, in signing this bill, said that it would help the housewife save money, that it would target labels that lie and packages that confuse, and that it would restore truth in the marketplace. The effect of the new law, he said, is to tell the consumer exactly what is in the package, who made it, how much it contains, and how much it costs in comparison with competitive packages. And he said it will eliminate the need for a slide-rule as a shopping aid, free the consumer from uncertainty in making choices, and protect her from being short-changed by a slack-filled box.

The January issue of *Changing Times* magazine reports that new government measures are about ready for announcement, with the result that package labels for foods, drugs and cosmetics soon will be easier to read and will tell you more. "The Months Ahead" column headlines the fact that help is coming to the shopper, that she can say good-bye to the "Jumbo-Pound" and the "Giant Quart," that slack-fill practices are soon to be eliminated, and that "cents-off" sales soon will be stringently regulated.

Our goals are thus defined, and for those of us who must mold the regulations to fulfill the promise of this new law and satisfy the

reasonable expectations of the purchasing public, busy days lie just ahead. The time for talking generalities is over, and we must now begin to deal with the specifics of labeling and packaging reform.

While the bill was strongly supported in the Congress by consumer interests, and just as strongly opposed by the regulated industries, it emerged from the House Committee hearings with unanimous support, and it passed both Houses of the Congress with hardly a dissenting note. Thus, everyone apparently wants labeling and packaging changes as soon as possible.

We now face the test as to whether the regulations called for by the bill can be swiftly devised and placed into effect, or whether protracted procedural delays will block early implementation.

Contents of the New Law

Let me start my presentation with a brief summary of what is in this new law and how we are directed to proceed. Since Mr. Sweeny will speak for the Federal Trade Commission (FTC), and Mr. Giles for the Department of Commerce, I will deal wholly with foods, drugs and cosmetics. And I will leave completely to Mr. Giles the voluntary standards procedure insofar as it may affect food, drug and cosmetic packaging.

First, there are mandatory provisions for agency regulations. We are directed to require:

that the label identify the product and give the name and address of its manufacturer, packer or distributor;

that the net quantity of the contents be separately and accurately placed at a uniform location on the principal display panel; and

that any label which says anything about servings also say how much is in each serving.

Since the existing law for food, drugs and cosmetics has long required the name of the product and the name and address of its manufacturer, packer or distributor, we should focus our attention here on the "quantity of contents" provisions. These will require a basic overhaul of essentially all existing labels. We should also give attention to all required label information, whether called for by this new law or by existing law.

The Quantity of Contents Statement

The "quantity of contents" statement will have to have several new features:

it must be a featured part of the principal display panel;

for most packages, it must contain a dual statement of quantity expressed in total ounces (identified as avoirdupois or fluid ounces) and in pounds and ounces, or quarts, pints and ounces, with fractional ounces in common or decimal fractions;

it must be conspicuous, easily legible, and in distinct contrast to other matter on the label;

its type size must bear a fixed relationship to the area of the principal display panel;

the declaration must be in uniform type size for all packages of substantially the same size; and

the declaration must be generally parallel to the base of the package as it is to be displayed.

This is saying a lot. In a sentence, it means that the "quantity of contents" statement must become an important design feature of the label. We must decide where it shall appear—at the top left of the label, top right, top center, immediately above or below the most prominent feature of the label, or at some other uniform place. We must decide how large the print will have to be and how the required conspicuousness, legibility and contrast are to be achieved. And we must have uniformity in type size for all packages of essentially the same size, even though they may have different sized labels.

Foods, drugs and cosmetics already bear net contents statements, but now one must search several label panels to find them. And even where voluntary improvements have been made to meet rising criticism, further changes will no doubt be called for in front panel placement, uniformity and improved contrast.

As an example of what might be required, we may look to the labeling requirements for hazardous substances. Our regulations call for the signal word and the statement of principal hazard to be placed on the principal panel, distinctly apart from other wording or designs, and for prominence to be achieved by placement within the borders of a square or rectangle with or without a border line. We require suitable contrasts of background, achieved by distinctive typography, color or both. We specify the minimum point size for type, and we require a reasonable relationship with other label type on the front panel.

Further Difficulties

These are some of the possibilities for the net contents statements. What of other mandatory labeling declarations required by the newly enacted law and by existing law?

Do the name and address of the manufacturer, packer or distributor, the serving information required by the new law, or the ingredient information called for by existing law, also belong on the front of the package? If not, where does this information go, and what considerations of prominence, conspicuousness, type size and contrast will control?

Can, and should, exemptions be made for "quantity of contents" declarations for small packages? When do we call for weight declarations, as opposed to declarations by numerical count? When do we require avoirdupois ounces and when fluid ounces? What supplemental statements concerning quantity of contents will be permitted elsewhere on the label? Will a statement that the product yields one pint or makes a three-layer cake be allowed? Are express prohibitions required to eliminate the "giant quart?"

These are illustrative of our problems in taking the first steps toward satisfying the promise of the new law. But this is not all.

We are authorized to make some exemptions from full compliance with the law, to the extent that such compliance is impracticable or unnecessary, and to impose conditions on such exemptions.

Whenever necessary to prevent deception or to facilitate value comparisons, regulations are to be prescribed:

establishing standards for "large," "small" and "economy" sizes of packages;

regulating, but not prohibiting, "cents-off" and other bargain promotions;

requiring additional ingredient information on drugs and cosmetics which does not divulge trade secrets; and

preventing non-functional slack-fill.

Of all these, perhaps the most urgent need is for control over "cents-off" promotions and slack-filling. And perhaps the most controversial issue will be ingredient labeling for cosmetics.

"Cents-Off" Promotions

Only recently, representatives of a large coffee distributor called on us to urge prompt action concerning "cents-off" promotions. Ac-

cording to these representatives, their company had stopped the practice at the time of the recent Federal Trade Commission investigation, only to see an immediate loss of business to competitors who had not stopped. In short, they contended that this kind of competition was essential to survival as long as any important competitors were allowed to use it.

The Congress recognized, as we all did, that most Americans are bargain hunters. The job now set before us is to see that the promise of reduced price is not an illusory one: to see insofar as possible that any offer of "cents-off" is actually delivered to the consumer.

The guidelines we have are found in the House Committee Report. For example, we are told that the regulations may require the manufacturer to show that the wholesale price has been reduced enough to permit retailers to pass the "cents-off" saving on to the consumer. The regulations may limit the duration and the frequency of such promotions, and they may fix the maximum percentage of the annual output that may be marketed with "cents-off" labeling.

All of this requires the overseeing of pricing practices, which is an entirely new function for the Food and Drug Administration (FDA). Indeed, in our most extensive inspection authority—that over the marketing of prescription drugs—we are not allowed access to "pricing data." But we will have to examine pricing practices to carry out the obligation of making "cents-off" offers real price reductions.

Slack-Filled Packages

Thus far, controlling slack-filled packages has been a difficult operation for FDA. Operating under a law that declares misbranded any package made, formed or filled so as to be misleading, FDA has been notably unsuccessful in the courts. About all our efforts have yielded is a rule of decision to the effect that a person using a package too big for its contents may justify this apparent deception by proving that it is necessary to safeguard the product and that no less deceptive alternative method of packing is available.

The bill passed by the Senate, S. 985, did not contain authority to prohibit slack-filling. Instead, it provided for package standardization when proliferation of package sizes was likely to impair the consumer's ability to make price per unit comparisons. And the bill provided that such standards should not preclude the use of packages

customarily used for related products of varying densities, except to the extent that continued use was likely to deceive.

These standardization provisions, even though largely voluntary under that bill, were the rallying point for industry opposition. And their elimination by the House Committee in favor of completely voluntary actions to eliminate confusing package sizes opened the way to the final enactment of the measure.

The House bill, H. R. 15440, contained authority to prevent the distribution of packages of sizes, shapes or dimensions likely to deceive consumers.

This provision was not supported by representatives of the administration. Nonetheless, the House Committee retained a slightly modified slack-fill provision. The agencies were authorized to prevent non-functional slack-filling of packages, defined as filling the packages to less than capacity for reasons other than the necessities of protecting the contents or the requirements of machine filling. Thus, the agencies have authority to prevent such practices as the use of false bottoms or unnecessarily bulky packaging material.

The House Committee report is wholly consistent with the judicial rule that the burden will be upon the user to justify the use of a package that is too large for its contents.

Label Declaration for Cosmetics

Much has been said about the label declaration of ingredients for cosmetics. The original Hart bill contained provisions which would have required label declaration of composition for consumer commodities in general. As passed by the Senate, the bill called for regulations consistent with the requirements of the Federal Food, Drug and Cosmetic Act which would require composition information other than proprietary trade secrets. It was argued that this bill excluded the authority to require label declaration of cosmetic ingredients because the Federal Food, Drug and Cosmetic Act did not require it. But, again, the House Committee made its intentions clear: that cosmetic ingredient information could and should be required to assist the consumer in making value comparisons.

Procedure for Rule-Making

But nothing in this entire law can take effect until regulations are first promulgated. And these regulations are to be adopted through

the elaborate public procedures for formal rule-making found in the Federal Food, Drug and Cosmetic Act.

The procedure begins with a notice of proposed rule-making. After comments are received, the rules are adopted. Then any person who will be adversely affected may stay the effectiveness of the rules and precipitate a public hearing on his objections. After the hearing, a decision is made on the record and is subject to judicial review in the United States Courts of Appeals.

These hearing procedures and the opportunity for judicial review assure protection of the rights of manufacturers, packers and distributors of consumer commodities. But they also have an important bearing on how promptly the public can expect to benefit from improved labeling and packaging practices. Hearings and review on the net weight regulations alone could cause protracted delays.

No doubt there will be very good arguments why the net weight statement should not be at the top of the front panel, at the bottom, on the right or on the left. Labelers undoubtedly can show the costs involved in making labeling changes, the difficulties involved in redesigning packages, and the interference of the new requirements with established brand labeling.

Conclusion

One need look no further than existing packages to see that there is no consensus about how or where to present the net contents declaration. And the same is true for most of the other issues that must be solved before this new law can have its intended effect.

But the public is expecting substantial changes—for the better. It expects these changes to show up about July 1, 1967.

We plan to announce very soon the initial draft of regulations dealing with the mandatory aspects of the new law: net weight, name of commodity, name and address of the manufacturer, packer or distributor, and labeling as to servings.

We hope to obtain a cross-section of views on the basis of which acceptable regulations can be promulgated and placed into effect by or shortly after July 1.

There is much to be done, and we must work together if the needs of manufacturers and consumers are to be reconciled within a reasonable time. We will have to have the full cooperation of the affected industries to meet this deadline. **[The End]**

Packaging Responsibilities of the FTC

By CHARLES A. SWEENY

Mr. Sweeny Is Director of the Bureau of Deceptive Practices, Federal Trade Commission.

IN SPEAKING ABOUT THE RESPONSIBILITIES of the Federal Trade Commission (FTC) under the Fair Packaging and Labeling Act,[1] the views expressed are my own, and not necessarily those of the (FTC). This disclaimer is more significant than usual because the Commission has not yet made any official determinations with respect to its administration of this Act. As you know, I cannot assure you that our five independent Commissioners, will follow my suggestions.

Seriously, though, we at the FTC are cooperating, at a staff level, very closely with personnel at the Department of Health, Education, and Welfare, and with others at the Department of Commerce to assure the highest degree of co-ordination and cooperation in packaging and labeling matters.

The new law becomes effective July 1, 1967. After that date a package should not be employed ". . . which does not conform to the provisions of this Act and of regulations promulgated under the authority of this Act." Regulations are therefore essential.

Before we can issue regulations, we must comply with the requirement of the Administrative Procedure Act[2] that rules of practice be issued to specify the procedures by which regulations will be promulgated. The Commission is currently engaged in formulating such rules, or rather amending the existing rules of practice to provide for issuance of regulations under the new Packaging and Labeling Act.

[1] P. L. 89-755, 89th Congress, approved November 3, 1966 (80 Stat. 1296).

[2] P. L. 404, 79th Congress, approved June 11, 1946.

Extent of Product Coverage

The next problem is the extent of product coverage under the new law. Legislative history is not too clear on this point. On June 2, 1966, Senator Magnuson stated that the bill then before the Senate, S. 985, would be generally concerned with items found in supermarkets and would not cover durable articles, textiles, paint, fertilizer, etc.[3] On June 9, Senator Cotton attempted to amend the bill so that it would extend to all consumer commodities, but that was rejected by a vote of 69 to 7.[4]

The important point to notice is that the House did not adopt the Senate bill. The House Committee on Interstate and Foreign Commerce, under Chairman Staggers, wrote its own bill, H. R. 15440. The House bill, which was later adopted by the Senate, differs from S. 985 in a number of important respects, including the treatment of "proliferation" problems and the coverage of goods which are sold by linear measure.

According to Congressman Springer, this would extend coverage to items such as string, scotch tape, and facial tissue.[5] When the Senate was considering final enactment of the bill agreed to in conference committee, Senator Hart said the House amendment respecting linear measure "could reach the size of paper napkins, tinfoil, wax paper and related commodities."[6]

The statute itself is quite broad, extending to:

". . . any . . . article, product, or commodity of any kind or class which is customarily produced or distributed for sale through retail sales agencies or instrumentalities for consumption by individuals, or use by individuals for purposes of personal care or in the performance of services ordinarily rendered within the household, and which usually is consumed or expended in the course of such consumption or use. . ."

Certain commodities are excepted, such as meat, poultry, tobacco, agricultural seeds, and alcoholic beverages; and the agency may exempt others when packaging disclosures are impracticable or not necessary for consumer protection.

It seems clear that the Congress intended the main thrust of the law to comprehend supermarket items, and intended that the administering agency be reasonable in determining the coverage and exemptions. It seems equally clear, however, that the Commission will be faced with some decisions as to whether certain specific products are within the contemplation of the statute.

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[3] *Cong. Record*, 6/2/66, p. 11504.
[4] *Cong. Record*, 6/9/66, pp. 12165-67.
[5] *Cong. Record*, 10/3/66, p. 23861.
[6] *Cong. Record*, 10/19/66, p. 26564.

Co-ordination Among Three Agencies

Before any regulations are issued under the law toward requiring disclosures or declaring which products are exempt, businessmen and all interested persons will be given ample opportunity to submit views, comments and objections. In the meantime, I would say that any thoughts which you might care to express at this time on the subject of product coverage would be most welcome, in order that my office might advise the Commission properly on this important aspect of the matter, when we submit proposed regulations to the Commission for consideration.

My office has not yet drafted any proposed or even tentative regulations. But we are looking to three principal sources for guidance: the packaging law itself, existing Federal regulations and the existing Model State Regulation for package marking requirements.[7] It seems elementary that bringing these three source materials into harmony, and especially harmonizing the latter two types of existing regulation with the superimposed requirements of the new Packaging Law, will be a first step in drafting regulations under the new law. Since the Food and Drug Administration (FDA) wrote the existing Federal regulations applicable to food, drugs, and cosmetics, and since the National Bureau of Standards plays a key role in keeping the Model State Regulation up to date, I would expect a considerable amount of assistance from those sources in complying with the new law.

I think the Commission, and the other agencies as well, must first be concerned with issuing the "mandatory regulations" provided under Section 4 of the new law to deal with identity of product, name and place of business of manufacturer, packer, or distributor, and net quantity of contents. It is in this area that I expect great assistance and guidance from the other Federal agencies, since so much of their experience has been in those areas.

When it comes to the "discretionary" portions of the law, authorizing issuance of regulations if the agency finds them necessary to prevent consumer deception or to facilitate value comparisons with respect to "cents-off" or other reduced-price labeling, slack fill of packages, characterization of package sizes (such as "small", "medium" or "large"), and disclosure of ingredients in order of predominance,

[7] "Model State Regulation Pertaining to Packages: Exemptions, Marketing Requirements, Variations," as adopted by the National Conference and Weights and Measures, 1966; available from National Bureau of Standards, U. S. Department of Commerce.

I am sure that even closer co-ordination and liaison among the three agencies will be necessary to achieve reasonable uniformity of results, and also to draw upon the full experience of the several agencies in dealing with problems of this type.

For example, the FTC has had considerable experience with so-called deceptive pricing, both in individual cases dating back to the very inception of the Commission in 1915, and in cases arising since "Guides Against Deceptive Pricing" were issued by the Commission in 1958. All of us can find assistance in the record of this experience as background in formulating policy to carry out the "cents-off" or reduced-price portion of the new law. The same can be said of slack fill of container.

I visualize that some of the "cents-off," slack fill and other such questions will bring into play a consideration of the residual responsibility of the FTC to prevent unfair and deceptive trade practices (15 U. S. C. 45). For example, there may be isolated examples of "cents-off" or reduced-price labeling which are not of sufficient prevalence or magnitude to warrant a finding that issuance of regulations is *necessary* under the new law, but which are susceptible to individual-case treatment under Section 5 of the Federal Trade Commission Act. In such a case the Commission may elect to institute an individual-case proceeding against one or a few companies to correct the practice in question, rather than to institute a regulation-making proceeding under the Packaging Law.

I have read and heard criticisms that nothing is being done by the FTC to prepare for these added responsibilities. That is probably due to the absence of press releases and other announcements. I should like to disagree sharply. The Commission is working toward amendment of our rules of practice. We have had many extremely helpful inter-agency conferences. I have also had frank conversations with individual industry members. I assure you we are not idle and that we are well aware of the approaching July first deadline. I also assure you that any of you who wish to discuss any of the implications of this statute will find our doors invitingly open. **[The End]**

The Fair Packaging and Labeling Act of 1966

By ROBERT E. GILES

Mr. Giles Is General Counsel to the U. S. Department of Commerce.

It is noteworthy that in the basic skeleton of moral and social law which Moses conveyed to his people, together with the Ten Commandments, was the injunction that, "Ye shall do no unrighteousness in judgment, in meteyards, in weight, or in measure. Just scales, just weights * * * shall ye have. I am the Lord which brought you out of the Land of Egypt. Therefore shall ye observe all my statutes."

Labeling and packaging are indeed merely parts of our system of weights and measures in modern dress. Today the scales and the weights are only rarely seen by the purchaser. Instead, he picks up a prepackaged parcel, can, box, or other container, often judging them in a hurry on external appearances.[1]

THE FAIR PACKAGING AND LABELING ACT, Public Law 89-755, was signed into law by President Johnson on November 3, 1966. On that occasion, the President observed that the American housewife should not need a scale, a yardstick, or a slide rule when she shops; and the housewife should not have to worry which is bigger: "the full jumbo quart" or "the giant economy quart." President Johnson also expressed the belief that, "The great majority of American manufacturers will welcome this law. It protects the honest manufacturer against dishonest competitors. It encourages fair competition, competition based on quality, value, and price. It reflects our strong belief that American producers can meet—and want to meet—the test of truth."

[1] Statement by Senator Wiley of Wisconsin on the opening day of hearings on packaging and labeling practices by the Senate Subcommittee on Antitrust and Monopoly, June 28, 1961. See Senate Judiciary Committee Hearings pursuant to S. Res. 52, Part I, June 28, 29, and 30, 1961.

Development of Public Law 89-755

The legislation which became Public Law 89-755 with its signing by the President on November 3, 1966[2] had its Congressional beginning more than five years earlier, when Senator Hart of Michigan opened a series of subcommittee hearings on June 28, 1961. On that date, Senator Hart summarized the objective of the hearings in these words:

> The purpose of this inquiry is to determine whether the information concerning the products on sale is such that the consumer can make a reasonably intelligent choice between competing products in today's marketplace. Do the packages and labels aid in performing this essential economic function by giving necessary information, clearly stated? Are packages and labels designed so that the shoppers can reasonably obtain and understand necessary and significant information pertaining to quantity, quality, and value? Do there appear to be techniques or practices which confound or confuse the consumer? If so, how extensive are they?[3]

Between that day in June 1961, when Senator Hart posed his series of questions, and the day in October 1966, when the Congress gave its answers in the form of an approved bill[4] several volumes of testimony on the subject were developed by Congressional Committees. While some segments of private industry, and some companies, regarded the proposed legislation with less concern than others, I think it is correct to say that the dominant theme of industry testimony was that the proposed legislation on labeling requirements was largely unnecessary in view of the already existing regulatory authority vested in the Food and Drug Administration (FDA) and the Federal Trade Commission (FTC), and the proposal for regulating packaging was especially undesirable. It soon became clear that the strongest industry opposition centered on that part of the proposed legislation which would give the FDA and the FTC authority to issue mandatory regulations on packaging as distinct from labeling.

Notwithstanding industry opposition, the Senate Commerce Committee favorably reported S. 985 on May 25, 1966, and the measure was approved by the Senate on June 9, 1966, by a vote of 72-9. As originally approved by the Senate, S. 985 authorized the FTC and the Department of Health, Education and Welfare (HEW) to promulgate regulations on the weights or quantities in which a consumer

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[2] The effective date of the act, however, is July 1, 1967; see Sec. 13, P. L. 89-755.

[3] Hearings before Senate Subcommittee on Antitrust and Monopoly, June 28, 29, and 30, 1961, Part I, p. 2. Investigative hearings before this Senate Subcommittee were held in June, October, and December 1961, and in February, March and April 1962.

[4] 11 *U. S. Congressional News* '66, p. 5315; Conf. Report No. 2286, 89th Cong.

commodity could be distributed, in effect to regulate packages. However, this regulatory authority could not be exercised without giving the Secretary of Commerce the opportunity to develop a voluntary product standard, if he was so requested by an affected producer or distributor. And further, if a voluntary product standard was published by the Secretary of Commerce within the prescribed time, its provisions would be binding on the regulatory agencies. That is, their mandatory regulations, if any, could not vary from a voluntary standard published in accordance with the procedural requirements set forth in the bill. In this respect, S. 985 differed considerably from bills introduced earlier which contained no provision deferring to a voluntary product standard developed by industry under the Department of Commerce voluntary standards program.

The House Committee on Interstate and Foreign Commerce completed its work and favorably reported H. R. 15440 on September 23, 1966. The principal difference between the Senate-approved bill and the House Committee bill was the provision relating to regulation of weights or quantities in which a product would be distributed. The House Committee was not convinced that the case for such regulatory authority had been made, and it was not ready to recommend House approval of this provision of the Senate bill.

Instead, under the House Committee version, the Secretary of Commerce would be called upon to make determinations of "undue proliferation" of weights, measures, or quantities, where such was the case, and promptly undertake efforts with the affected industry to develop and implement voluntary product standards. If this was not accomplished within a period of a year, the Secretary would be required to report to Congress with his recommendations as to additional legislation to deal with the situation.

By a wide margin, the House approved the bill recommended by its Committee, amending S. 985 to substitute the language of H. R. 15440.

Soon thereafter, the Conference Committee reported agreement, with the Senate acquiescing to the House on the major points in issue.

The principal responsibilities prescribed by S. 985, as finally passed by Congress, may be summarized as follows:

HEW and FTC

The Secretary of HEW (with regard to food, drugs, devices, and cosmetics) and the FTC (for all other consumer commodities) are

directed to establish regulations to require the prominent display of meaningful and uniform information concerning the identity of the manufacturer, the net quantity of contents, and a statement of the net quantity of each "serving" when the term "serving" is used.

In addition, HEW and FTC are given *discretionary* authority to issue labeling regulations when necessary to prevent deception or to facilitate value comparisons, including standards governing size descriptions such as "small," "medium," or "large," statements of ingredients, "cents-off" sales, and the prohibition of nonfunctional slack-fill.

Secretary of Commerce

If the Secretary of Commerce determines there is undue proliferation of the weights, measures, or quantities in which a consumer commodity is being distributed, which impairs the ability of consumers to make value comparisons, he must request industry to participate in developing a voluntary product standard. If, after one year from such request, a standard has not been published, or, if published, is not being observed, the Secretary of Commerce is required to report promptly to Congress with his legislative recommendations to deal with the situation.

Up to this point, I have attempted to give a capsule resume of the legislative development of the Fair Packaging and Labeling Act. I believe some appreciation of the context in which a proposal before Congress evolves and ultimately becomes law is helpful in understanding how that law is apt to be administered. Further, I think it is relevant to an understanding of the present and the future to know that President Johnson strongly supported enactment of "effective legislation" dealing with packaging and labeling practices,[5] as did President Kennedy before him.[6] Two Secretaries of Commerce,[7] as

[5] Message from the President transmitting The American Consumer, February 5, 1964, 88th Cong., 2d Sess., H. R. Document No. 220; President's Economic Report to Congress, January 28, 1965, p. 19; Message from the President transmitting State of the Union Message, January 12, 1966, 89th Cong., 2d Sess., H. R. Document No. 321; Message from the President transmitting Proposed Programs and Legislation to Further Protect the Consumer's Interest, March 21, 1966, 89th Cong., 2d Sess., H. R. Document No. 413.

[6] Message from the President on Consumer's Protection and Interest Program, March 15, 1962, 87th Cong., 2d Sess., H. R. Document No. 364.

[7] Secretary of Commerce Luther H. Hodges, March 6, 1963, Hearings, Packaging and Labeling Legislation, Subcommittee on Antitrust and Monopoly, Senate Committee on the Judiciary, pursuant to S. Res. 56, on S. 387, 88th Cong., 1st Sess., pp. 26-33; Secretary of Commerce John T. Connor, April 30, 1965, Hearings, Fair Packaging and Labeling, Senate Com-

(Continued on following page.)

well as other officials of the Executive Branch, testified before Congress in support of legislation on this subject. Certainly, it is relevant to keep in mind that President Johnson has emphasized that it is his wish and his intention that Public Law 89-755 shall be administered effectively and efficiently, in the public interest.[8]

Finally, I believe it may be important not to forget that the Senate was convinced that a provision giving HEW and FTC regulatory authority over packaging as well as labeling practices should have been enacted in 1966. The acquiescence of the Senate to the House on S. 985 means that the voluntary standards approach with respect to packaging practices will have an opportunity to demonstrate that it can be effective.

Perhaps the legislative history should also be read as telling us that if this opportunity is not put to effective use, the opportunity may not always be with us. In making this observation, I do not mean to suggest that industry *must* develop "voluntary standards" on this or that, otherwise industry *will* be faced with mandatory regulations on this and that. Rather, I am saying that industry would do well to examine very carefully the complaints in this area which have come to light, or which may develop. Industry should be able to show to the public and to public officials either that there is no merit to a particular complaint, or—if there is merit—that the industry is moving promptly and properly to correct the matter.

Responsibility of the Department of Commerce

Let us now examine the specific responsibilities which Public Law 89-755 places on the Department of Commerce. I shall endeavor to explain what the statute says in this respect, and indicate insofar as I can how the Department is likely to administer its responsibilities under this law.

The principal responsibilities of the Secretary of Commerce are set forth in Sections 5(d) and 5(e) of the Act, and since these are relatively short, I think it would be useful to quote them verbatim:

(d) Whenever the Secretary of Commerce determines that there is undue proliferation of the weights, measures, or quantities in which any consumer com-

(Footnote 7 continued.)
mittee on Commerce, on S. 985, 89th Cong., 1st Sess., pp. 223-34; Secretary Connor, July 26, 27, September 8, Hearings, Fair Packaging and Labeling, House Committee on Interstate and Foreign Commerce, on H. R. 15440, S. 985, 89th Cong., 2d Sess., pp. 31-38, 93-172, 974-75.

[8] President's Remarks at the Signing Ceremony for P. L. 89-755, *Federal Register, Weekly Compilation of Presidential Documents,* Vol. 2, No. 44, Nov. 7, 1966, p. 1599.

modity or reasonably comparable consumer commodities are being distributed in packages for sale at retail and such undue proliferation impairs the reasonable ability of consumers to make value comparisons with respect to such consumer commodity or commodities, he shall request manufacturers, packers, and distributors of the commodity or commodities to participate in the development of a voluntary product standard for such commodity or commodities under the procedures for the development of voluntary products standards established by the Secretary * * * *. Such procedures shall provide adequate manufacturer, packer, distributor, and consumer representation.

(e) If (1) after one year after the date on which the Secretary of Commerce first makes the request of manufacturers, packers, and distributors to participate in the development of a voluntary product standard as provided in subsection (d) of this section, he determines that such a standard will not be published pursuant to the provisions of such subsection (d), or (2) if such a standard is published and the Secretary of Commerce determines that it has not been observed, he shall promptly report such determination to the Congress with a statement of the efforts that have been made under the voluntary standards program and his recommendation as to whether Congress should enact legislation providing regulatory authority to deal with the situation in question.

The Department of Commerce does not have the responsibility or the authority under this Act to issue any regulation governing the packaging or labeling practices of private industry.

The Department *does* have the responsibility and the authority to—

(1) *Determine* whether there is undue proliferation of the weights, measures, or quantities in which any consumer commodity is being distributed in packages for retail sale, which impairs the reasonable ability of consumers to make value comparisons.

(2) *Request* manufacturers, packers, and distributors, where a determination of undue proliferation has been made, to participate in the development of a voluntary product standard under the procedures governing the Department's voluntary standards program.

(3) *Report* to Congress, with a recommendation as to whether legislation providing regulatory authority should be enacted, if after one year from the date private industry has been requested to participate in the development of a voluntary product standard, it is determined that such a standard will not be published or, if published, not observed.

What Is Meant by the Term, "Undue Proliferation?"

Since a finding of "undue proliferation" is necessary to set in motion the statutory process outlined above, the meaning of this term will be of obvious interest to any affected business firm. The statute

does not furnish us a detailed, definitive explanation. The statute does, however, set out some helpful guideposts which point us in the right direction.

At the very least, the condition of "undue proliferation" must be one which "impairs the reasonable ability of consumers to make value comparisons" with respect to consumer commodities. Thus, what is required is more than mere numbers which may offend an administrator's sense of compact orderliness. Such numbers must also produce a deleterious effect for the consumer by impairing his ability to make a judgment in the marketplace.

Then, it may be asked, how does one go about determining whether the ability of the consumer to make value comparisons between comparable consumer commodities is impaired? Is it not apparent that this determination will necessarily involve a considerable degree of administrative discretion and judgment?

It may be possible for the Department in time to develop and publish some administrative guidelines concerning the determination of undue proliferation. In any event, however, it seems likely that each situation in which the issue is presented will have to be decided largely on a case-by-case basis.

Although the Act is not legally effective until July 1, 1967, the Department, of course, has already given much attention as to how and by whom the program will be administered in the Department. The Secretary has already decided that responsibilities under the Act will be delegated to the Assistant Secretary for Science and Technology, who, in turn, will look to the National Bureau of Standards to work with private industry in developing voluntary product standards. This will not be a new function for the Department•or for the Bureau of Standards. A Department of Commerce voluntary standards program was initiated in 1921 by President Herbert Hoover, who was then Secretary of Commerce.

During the coming weeks, Department officials will be meeting with industry representatives to inform them of our proposed plans for the administration of our responsibilities under the Act, and to seek the comments and suggestions of industry. In this connection, it is important to keep in mind that the statute and legislative history clearly indicate that the Department will follow published procedures in working with industry on the development of voluntary standards. The Department has had for many years published procedures applicable to its voluntary standards program. These were brought up

to date with a revision issued in December 1965,[9] and will be followed in carrying out our responsibilities under the Fair Packaging and Labeling Act of 1966.

Section 2 of the Act consists of a declaration of Congressional policy. I believe it would be useful for any attorney who is advising clients on this subject, whether the clients be private businessmen or government officials, to have this policy statement in mind. It reads as follows—

> Informed consumers are essential to the fair and efficient functioning of a free market economy. Packages and their labels should enable consumers to obtain accurate information as to the quantity of the contents and should facilitate value comparisons. Therefore, it is hereby declared to be the policy of the Congress to assist consumers and manufacturers in reaching these goals in the marketing of consumer goods.

I am confident that in carrying out its responsibilities under this Act the Department of Commerce will in fact make every effort to assist manufacturers, no less than consumers, and to assist consumers, no less than manufacturers, in achieving the goals which Congress has set for us. **[The End]**

TOLERANCES ESTABLISHED FOR DDT RESIDUES IN MILK AND MILK PRODUCTS

Effective March 15, the Food and Drug Administration has established tolerances for DDT residues in milk and milk products at levels recommended by a scientific advisory committee. These tolerances permit DDT residues of up to 0.05 parts per million in whole milk and 1.25 parts per million on a milk-fat basis in manufactured dairy products. These maximum residue levels apply to DDT, its chemical degradation products DDD and DDE, or any combination of the three.

The approval of tolerances does not alter existing recommendations that the pesticide is not to be used in or around dairy barns or on forage crops intended for dairy animals. Rather, the action acknowledges that small amounts of DDT continue to be found in milk despite the strictest precautions. FDA admits the importance of the continuing use of DDT and sees the acceptance of tolerances as a practical accommodation to an unavoidable situation.

The establishment of finite tolerances for DDT residues does not constitute approval of additional uses of the insecticide. Furthermore, before the request for higher residue levels for combinations of DDT and its degradation products can be met, the FDA committee will need further evidence of the safety of such combinations.

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[9] *Federal Register*, Vol. 30, No. 238; Title 15, Subtitle A, Part 10.

Guidance and Enforcement

By PAUL RAND DIXON

This Article, Reprinted from *The Business Lawyer* (November 1966, p. 159) with the Permission of the Publisher and of the Author, Was Presented at the Division of Food, Drug and Cosmetic Law of the Annual Meeting of the American Bar Association in Montreal on August 10, 1966. Mr. Dixon Is Chairman of the Federal Trade Commission. The Following Articles in This Issue Were Also Presented at This Meeting.

IN THE WELCOME LETTER I RECEIVED from your chairman, he said you wanted to be brought up to date on what the Federal Trade Commission's (FTC) plans are for doing its job. He said you would want to know how FTC is carrying out its dual mission of guidance and backstopping such guidance with formal actions looking to cease-and-desist orders. He then added that here might be an opportunity to point out how members of the bar could be of greater assistance to the Commission in carrying out its duties to correct false and misleading advertising that might cause injury to health or personal safety of the public, particularly low income families and the elderly. The going gets a little thick when a law enforcement official tries to point out persuasively how lawyers can make the cop's job easier. There might even be among you some who would be more interested in how to make it tougher. Certainly that would be popular with some of your clients.

Be that as it may, I do welcome this chance to tell you what we at the FTC are planning and doing. I also am pleased that your meeting here in Montreal has enabled our Canadian friends to participate in the discussions. In fact, one of the major thoughts I want to leave with you is as significant for Canadian ears as it is for your own. It is simply this:

The world is witness to the grimmest of conflicts between those nations who believe in political and economic freedom for the individual, within laws of his own making, and those Godless nations

whose dictators believe that to enslave the minds and efforts of their people is essential to their survival. The chips are down. Therefore, we who believe in free enterprise cannot tolerate unfair methods of competition and deception—greed and chicanery—or freedom invites us into a jungle. The predictions of our Communist foes that freedom carries the seeds of its own destruction and that capitalism is doomed would be fulfilled. They trumpet this as inevitable. And they couldn't be more wrong. The fact is that free men are quite capable of maintaining the morality essential to vigorous and healthy competition in business, and they are maintaining it—not under the whip of an all-powerful state but by self restraint and the guidance of good laws which, I believe, are being intelligently administered. In the world-wide struggle, the validity of our free enterprise system is under fire. Never has it been more important to maintain its integrity.

What is not fully appreciated is the role of government in maintaining fair competition and preventing deceptive practices. It is a far smaller role than is generally assumed. With our propensity for magnifying the dramatic, for emphasizing the cops-and-robbers aspect of law enforcement with the whip of legality being laid across the backs of wrong-doers, we are inclined to minimize the fact that business ethics provide a far greater deterrent to law violation than does the threat of adversary action by the government. Happily, it is true that patently false advertising is ever more conspicuous because of its rarity. The atrocious claims made a half century ago for a host of products would be laughable now if they would be disseminated by the news and broadcast media. But advertising acceptance standards have risen to the point that except in the rarest instances such hucksterism is shut off at the source of dissemination. The news and broadcast media simply won't accept it. Reinforcing their own ethical standards is the knowledge that their reputable advertisers have no relish for having their ads printed or broadcast alongside advertising which is patently false or misleading. Media have their reputations to maintain, and most of them do so even at the sacrifice of temporary but alluring profits. They would rather keep faith with their legitimate advertisers, with their readers, and with their listeners.

Now, lest this picture be filled with too much sunshine and light, it must be pointed out the old forms of chicanery have been tailored to modern sophistication. Instead of gobbling at credulity, they nibble at it slyly. For example, instead of claiming miracle health cures from palliatives such as those that were concocted from alcohol or

narcotics, the technique has switched to claiming wider efficacy for useful proprietary drugs than they possess. Half-truths have been substituted for lies, and deception is achieved by omission of facts rather than by bald misstatement of them. Needless to say, this form of false advertising poses no small problem for the media unequipped to make adequate investigation of the claims. They can't run a newspaper, magazine or broadcast station and conduct tests of products at the same time. Indeed, the problem of scientific testing of products and claims for them presents even the government with a most difficult problem. For example, the FTC has a staff of only 10 physicians and general scientists to provide technical advice and assistance in evaluating claims for all products, including claims made for every health product sold or advertised in interstate commerce in the United States. To be sure, we work closely with the Food and Drug Administration (FDA), but the task is still overwhelming.

This staff of physicians and scientists supports the work of some 20 attorneys in our Division of Food and Drug Advertising, which has responsibility for the legal aspect of matters directly affecting health. This includes advertising and some other practices in connection with the sale not only of drugs but other health-related products, such as foods, therapeutic devices, cosmetics, health books and others. The attorneys and the physicians and scientists work closely in the planning, development and prosecution of all of FTC's cases involving misleading advertising of foods and drugs. Grist for their mill comes from several sources: principally letters of complaint from consumers, the Commission's own monitoring of advertising, and from information provided by Better Business Bureaus and local law enforcement agencies.

Of course, the matters are impressed with different degrees of seriousness and urgency, and we are confronted with the problem of how to use our small staff most effectively. Factors considered in deciding which cases to tackle are: first, the impact, direct and indirect, upon public health represented by the questionable practice; second, the economic aspects such as the volume of sale, prevalence of the practice and the trading area encompassed; third, consideration of how much of our manpower and other resources would be required, keeping in mind the availability of needed evidence—clinical testing, for example, not only drains off substantial manpower but prolongs delay in protecting consumers; and fourth, the coordination of any proceeding with the activities of the FDA. Of course, there are other factors, too.

These considerations are directed to a subject industry and contemplate the advertising of all over-the-counter drugs offered for a single purpose and use. Indeed, more than one might be joined in the same project if they are closely related. There are advantages to the across-the-board approach. It favors the individual marketer from a competitive standpoint in that action against his competitors may be taken simultaneously and equitably, as opposed to case-by-case litigation. Also, the evidence needed to determine the truth or falsity of advertising for a drug product may be developed for an entire industry at not much more cost than that needed for consideration of the product of a single manufacturer. Furthermore, the FTC is able to achieve a more effective solution to deception in advertising if it has all the relevant facts pertinent to the various products of a specific type than it could gain from a case involving only one of the products. This broad approach not only makes for more efficient use of manpower but frequently makes possible a faster solution to industrywide problems than does the case-by-case approach.

There is another advantage—perhaps the most important of all. With enough facts at hand, particularly having learned how widespread the improper advertising of a product has become, the Commission can make a better judgment of what remedy would best protect the public interest. We have learned that the "whipping boy" technique has severe limitations, the principal one being that too often equally culpable competitors are not at all dismayed to see the whipping boy slowly tied up by a formal cease-and-desist order while they continue to profit by the same illegality. If they interpret government's action as "handwriting on the wall" for their own sins, they are very slow readers.

I don't know how many of you appreciate it fully, but the FTC has faced up to the realities of its law enforcement job to an extent unprecedented in its 51 years of existence. By this, I do not mean to imply the early days were fruitless. Emphatically not. The Commission's work then, substantiated by action of the courts, built up the body of case law that has pretty well delineated the edges of legality in the trade practice field. To be sure, further delineation will be necessary in a dynamic economy where new ideas and schemes are being developed—as indeed they should be. Nevertheless, enough guideposts were erected during the first half century so that any properly cautious businessman can be virtually sure of when he's on safe ground and when he's asking for trouble. The line may not be

precise under all conditions, but it is clear enough so that the FTC can give more attention to other realities of law enforcement.

The most pressing problem is how to cope with the magnitude of the trade regulation job. The very volume of American business would utterly and hopelessly inundate any simple cops-and-robbers effort by the FTC. Common sense dictated that the Commission take fullest advantage of the willingness, I might even say enthusiasm, of most businessmen to keep their industries' practices clean. They have no relish for dirty competition. Aware of this, the Commission is making an effort, unprecedented in scope, to provide business with the services it needs for more effective self-policing. The best of intent requires a modus operandi.

To cope with the volume of enforcement work, the Commission has been making far greater use of voluntary procedures for stopping unlawful practices. In the twelve months ending July 1, we can report that the industry guidance program set an all-time high for effectiveness. This was achieved by a combination of procedures, each designed to accomplish an objective with minimum recourse to formal adversary proceedings. Each offered businessmen the opportunity to avoid or to correct law violations without time-consuming and costly litigation. The important thing from the standpoint of the public interest and consumer protection was to prevent the illegality from happening in the first place, or, if it already was occurring, to halt it on as broad, as equitable, and as fast a basis as possible. These objectives have been paramount even though their pursuit has deprived the FTC of the statistical record of formal complaints and orders by which its performance used to be judged. Heavy traffic moves much faster if the drivers are informed of the rules of the road and the road is properly marked, than if a frantic cop tries to move it along by passing out tickets.

This is not to say that tickets are not necessary when the occasion warrants. Information and persuasion can fall on defiant ears. And the only way to deal with the willful violator of the law is to bring fast formal action against him. To fail to do so would be to break faith with those who have brought their practices into compliance with the law voluntarily.

Our industrywide approach to law violations finds its justification in the fact that so many have been engendered and nourished by competitive pressures. One firm will dream up an advertising pitch that is as successful as it is illegal, and competing firms are disinclined

to stand around wringing their hands as their share of the business dwindles. So what do they do? They decide to fight fire with fire—reluctantly perhaps, but the result is the same. All too soon, the credibility of the industry's advertising diminishes, and its advertising dollars become devalued. And, of course, consumers are victimized during the process.

Consider now how the Commission's recently developed procedures could have forestalled such a situation. Assuming that the first violator had initiated his advertising campaign in ignorance of its illegality, he could have saved himself and his industry a great deal of trouble by consulting a smart lawyer who would have advised him to keep his skirts clean by obtaining an advisory opinion from the FTC. In the very unlikely event that such an opinion would ever have to be modified, he would be given ample opportunity to adjust to the changed requirements. He also could be confident that the Commission does not disclose the identity of persons or firms requesting opinions. It does, however, issue a press release giving the essence of the opinions for the guidance of others.

Assuming now that no advisory opinion was sought and that the illegal gimmick got a toehold in the industry: As soon as the problem came to FTC's attention, it would apply the yardsticks mentioned earlier to determine the priority of the effort FTC could expend upon it. Hopefully, the situation could be quickly remedied by obtaining informal assurances that the illegality would be discontinued. But if these assurances could not be obtained, the FTC would bring formal action, grouping the complaints to the greatest extent feasible.

However, it frequently happens that the illegality spreads beyond a manageable toehold, and for the FTC to crack down on it with formal action would put too great a strain on the Commission's resources. Here again our new guidance procedures are performing a most useful role. By the issuance of industry guides, which can be directed either at problems besetting a particular industry, such as the advertising and labeling of automobile tires, or which can cut across industry lines, such as the guides on fictitious pricing, the FTC can eliminate the important element of uncertainty as to what it believes is illegal. The very spotlighting of improper practices serves as a great deterrent. With uncertainty removed, reputable firms will give up illegal practices, thereby greatly reducing the target at which FTC's formal actions need be aimed. The hold-outs

against the Commission's Guides have little relish for the more conspicuous situation in which they find themselves.

The defiant few have even less relish for our Trade Regulation Rules, for these are promulgated only after due notice in the *Federal Register* and formal hearings, and may he relied upon by the Commission in subsequent litigation to resolve issues on which the rules are relevant. By reducing the FTC's burden of proof, Trade Regulation Rules are taken seriously indeed by those who might otherwise toy with the idea of engaging in the illegality. They cut down the golden hours of dodging and delay.

To the foregoing arsenal of guidance procedures must be added our Trade Practice Conference Rules, with which you are undoubtedly familiar. Here again, clarification of the laws' requirements as applied to the practices in a particular industry helps the industry to police itself, with the Commission in a ready backstop position. Promulgated as they are, after public hearings to which all known members of the industry are invited, they remove the alibis of ignorance and uncertainty and turn a spotlight on willful violations.

There also has been a sharp step-up in the FTC's compliance program for the Guides and Rules we have issued. It was never intended that such guidance be merely hung out on a line to dry.

For example, during the past fiscal year, more than 1,300 interpretations of rules and guides were given businessmen seeking advice on the application of particular provisions to their business practices. At the same time, compliance surveys were under way for trade practice rules for the household furniture industry and the luggage and related products industry and the Guides against debt collection deception. Similar surveys have commenced to assure compliance with Guides Against Deceptive Advertising of Guarantees as applicable to dishwashers, washing machines, clothes driers, high intensity lamps, roofing materials and hi-fi components. The number of rule and guide violations disposed of on the basis of assurances that the practices in question had been discontinued increased by almost 30 percent over a year ago.

All of this work serves to narrow the Commission's principal target—willful violators of the trade practice laws—down to manageable size. And the more help we can get from any source, the better, for who does the most effective job is less important than that the job be done. Credit lines are something that I suppose are a necessary evil, but they are indefensible if the pursuit of them in-

terferes with the task at hand. And in this conviction I am not alone at the Commission; most of us feel the same way.

For example, we at the Commission would like to see the 50 states of our Union take potential business away from us by enacting more effective laws to prevent consumer deception and unfair competitive practices. By stopping such practices before they grow into problems of interstate proportions the need for federal action will be minimized, and the people most directly affected will have a telling voice in deciding what constitutes unfairness and deception. The more effective the states can be in nipping illegal schemes in the bud, the more energy the FTC can devote to dealing quickly and effectively with problems of regional or national significance. Moreover, the need to take action against deceptive practices by local businessmen has become even more apparent in the low-income markets where those least able to afford it are being gypped.

Believe me, your FTC has no aspirations to become the preeminent defender of our free enterprise system. Only businessmen themselves can fill that role. Ours is simply the obligation to help them abide by the law to the limit of our ability.

And to you members of the bar, I would leave this thought: yours is the same obligation. **[The End]**

CONTENTS OF CHILDREN'S ASPIRIN CONTAINERS RESTRICTED

As a result of the FDA-sponsored Conference on the Accidental Ingestion of Salicylate Products by Children, it has been ruled that no more than 36 tablets of children's aspirin (1¼ grain) will be shipped in retail containers after June 1, 1967.

The conferees further agreed that children's aspirin should continue as 1¼ grain in size, that the flavoring of children's aspirin should be continued while that of adult's aspirin should be discontinued, and that the use of the present bottle size to contain the fewer pills should be permitted. The labels on all aspirin containers should bear a warning, while advertising on the label should not emphasize flavor to the neglect of such warning. The need for an ideal safety closure for all drug containers was also discussed.

The FDA has amended its policy statement concerning the labeling of drugs containing salicylates and the regulations regarding warnings on over-the-counter drugs to conform to these conclusions and recommendations. Reg. Secs. 3.509, 131.9, 131.10 and 131.15; 31 *Federal Register* 3440—3441, CCH Food Drug Cosmetic Law Reports, ¶ 4509, 71,709, 71,710 and 71,766.

The Canadian Viewpoint

By R. A. CHAPMAN

The Following Article Is Reprinted from *The Business Lawyer* (November 1966, p. 165) with the Permission of the Publisher and of the Author. Mr. Chapman Is Director-General, Canadian Food and Drug Directorate.

BECAUSE OF THE VERY MANY SIMILARITIES existing in our respective food and drug industries I would like to outline for you, briefly, a few of the problems encountered during my relatively short sojourn as Director-General, Food and Drugs. Incidentally, that title is even more recent than my appointment—it was changed from Director to Director-General within the last few months. I don't think it would be possible to be associated with the Food, Drug and Cosmetic industries in view of the tremendous technological changes which are taking place—as well as an increasing awareness by the public of these advances—and the increasing demands from this same public for higher quality, tighter controls and lower prices (all in the same package, of course) without at the same time encountering a few problems. Our problems do not seem to have received quite as much publicity as some of those in Washington. But what are the problem areas in Canada? Well, drugs seem to be giving us more difficulties than foods. As you are no doubt well aware, the Patent Act in Canada provides for the issuance of a license for a patent or invention intended for or capable of being used for the preparation or production of a medicine, unless the Commissioner of Patents "sees good reason to the contrary." Recently there have been a number of applications by smaller pharmaceutical firms for compulsory licenses to manufacture some of the more potent drugs. In some instances such licenses have been granted. This situation has resulted in considerable concern among Canadian pharmaceutical firms. A little over a year ago this situation was aired in the House of Commons with the result that a special ad hoc committee was appointed to review the whole subject "involving patent licensing arrangements with respect to drugs." The report of this Committee,

which was chaired by Dr. Irwin Hilliard, Physician-in-Chief, Toronto Western Hospital, has now been tabled in the House of Commons. One of the important observations of this Committee read as follows: "Very special legislation is necessary, not only because recent scientific and medical advances have made drugs so much more powerful and dangerous, but also because the public at large is completely unable to realize some of the dangers inherent in the misuse of some of these products." The most important recommendations of this Committee can be summarized as follows:

1. In regard to compulsory licensing, a license should not be granted unless a favorable report had been furnished by the Food and Drug Directorate to the Commissioner of Patents "on the competency of the applicant for such license to manufacture or produce the substance." Arrangements have been made to furnish such information, but there is no legal requirement at the present time that the Commissioner of Patents act on such a report.

2. A similar proposal was made in regard to voluntary arrangements but in this case the person entering into the voluntary arrangement should furnish such information to the Directorate, and

3. That the definition of a new drug be amended to include a drug not currently in new drug status if it is to be manufactured or produced by a method or process that is substantially different from the method or process currently being used in Canada; or if with prolonged use, new or more serious or more frequent side effects develop.

As you can appreciate, there are a number of legal considerations involved in these recommendations and while collaborative arrangements have been worked out with the Commissioner of Patents, any possible changes in legislation are still under consideration.

Another area pertaining to drugs that has been causing concern relates to what we call "preclinical submissions." These correspond in general to investigational new drug applications in the United States. In Canada, our regulations require that the preclinical submission must be in a satisfactory form and content and such an indication must be received by the person making the submission before proceeding with clinical trials. A Special Committee of the House of Commons recommended in late 1964 that this matter be "reviewed in one year." Such a study has been carried out by an

ad hoc group under the chairmanship of Dr. Eldon Boyd, Professor of Pharmacology, Queen's University, Kingston, Ontario. Both these reports will be considered by the Canadian Drug Advisory Committee when it meets in Ottawa early in September. I might add for your information that the Canadian Drug Advisory Committee was established by Order in Council to advise the Department of National Health and Welfare on all matters respecting drugs and consists of members nominated by the following organizations:

The Royal College of Physicians and Surgeons of Canada,

The Canadian Medical Association,

The Canadian Pharmaceutical Association,

The Pharmaceutical Manufacturers Association of Canada,

The Proprietary Association of Canada, and

The Pharmacological Society of Canada.

In the food field, matters have been relatively quiet. The food additive regulations adopted in September, 1964, appear to be working reasonably well and there have not been any of the dire consequences to the food industry that were predicted by some individuals when these regulations were proposed.

Current Developments in the International Field

I should like to conclude with a few comments on current developments in the international field. I believe most of you are aware of the activities of the Joint Food and Agriculture Organization/World Health Organization (FAO/WHO) Codex Alimentarius Commission and its efforts to develop uniform food standards which it is hoped will have international acceptance. In my opinion, remarkable progress has been made in this program since 1962. As you may be aware, Canada has been assigned responsibility for food labelling. A second meeting of the Codex Committee on Food Labelling was held in Ottawa from July 25-29, 1966. Representatives were present from eleven countries and three international organizations. I am pleased to report that we were successful in developing a general standard for food labelling for pre-packaged foods. The items considered included the name of the food; list of ingredients; net contents; name and address of the person responsible for the food; country of origin; grade designations; size, location and presentation of mandatory information; language to be employed and labelling requirements for special foods such as those which had been irradiated. I was very pleased with the extent of agreement which we were able

to reach. This standard for food labelling will now go to national governments for comments.

It is my opinion that we need an organization similar to the Codex Alimentarius Commission in the drug field. Drugs of all types are entering in increasing amounts into international trade. More national governments are developing specific requirements for manufacturing facilities and quality control procedures. In order to determine whether or not these requirements are being met, drug inspectors from the importing countries should visit plants and review control procedures in countries from which the drugs are exported; in some cases, this is being done. In the first place, this is a very costly arrangement, and if allowed to continue and expand could result in drug inspectors from practically all countries travelling to exporting countries to ensure compliance with national regulations. This would, of course, be an impossible situation. Already some exporting countries are taking a very dim view of such "foreign inspectors"—and I put those words in quotes—wanting to examine every detail of their drug manufacturing facilities. WHO would appear to be the logical body to coordinate such a project, and I understand that consideration has recently been given to this problem.

[The End]

POLICY STATEMENT ISSUED CONCERNING ANIMAL FEEDS CONTAMINATED WITH SALMONELLA

The Food and Drug Administration has adopted a regulation stating that articles used in animal feeds fall within the definition of "food" in section 201 (f) of the Federal Food, Drug and Cosmetic Act. Further, feeds contaminated with salmonella, when encountered in interstate commerce, will be considered adulterated within the meaning of section 402 (a) of the act.

It has been shown that salmonella, a bacteria pathogenic to man and animals, may be carried in animal feeds and transmitted to the animal product. Contamination can occur through inadequate heat treatment during processing or through improper storage or handling subsequent to processing.

Feeds which may become contaminated include bone meal, blood meal, crab meal, feather meal, fish meal, fish solubles, meat scraps, poultry meat meal, tankage, or similar animal byproducts or mixtures. Reg. Sec. 3.58, 32 *Federal Register* 4059.

Trends in Drug Legislation Under the Food and Drugs Act in Canada

By R. E. CURRAN, Q.C.

The Following Article Was Reprinted from *The Business Lawyer* (November 1966, p. 168) with the Permission of the Publisher and of the Author. Mr. Curran Is Counselor-at-law in Canada.

TO AN AUDIENCE COMPOSED ESSENTIALLY OF AMERICAN LAWYERS concerned with food and drug legislation, I thought it might be of some interest to say a few words respecting the Canadian Food and Drugs Act and to indicate certain trends which our legislation reflects on the basis of recent experience.

Before dealing with the present legislation, it may be useful to put into some perspective the beginning and development of our law.

History of Food and Drug Legislation in Canada

The first food and drug legislation in Canada was enacted some ninety years ago. It was based on a corresponding statute of the United Kingdom passed in 1872. The United Kingdom statute, which replaced the first United Kingdom Act of 1860, for the first time included drugs along with foods and sought to control their adulteration in the interests of the consuming public.

The Canadian legislation was similar in purpose but had a rather curious legislative introduction. For some time past there had been publicity given to the increase of the consumption of alcohol with the corresponding evil of drunkenness. The proponents for alcohol urged that the problems stemmed from bad liquor rather than excessive consumption. It was urged that the remedy lay in stricter control of compounders of spirits and the imposition of appropriate license duties to be paid by such persons. There was accordingly introduced in Parliament "An Act to Impose Licence Duties on Compounders of Spirits, to Amend the Inland Revenue Act and to Prevent the Adulteration of Food, Drink and Drugs." While in the statute emphasis was given to the compounding of spirits and duties thereon, it nevertheless did include provisions with respect to adulteration which formed a commencement point for our present law.

I should perhaps point out that our Food and Drugs Act has always been viewed as criminal law. Under the Canadian constitution, criminal law is a federal responsibility. The Food and Drugs Act as criminal law, therefore, has application throughout Canada and does not rest upon any interprovincial movement of articles which are subject to it. This has advantages in terms of universality of application, but it also imposes some limitation in that the legislation and the regulations must be directly related to criminal law and cannot be merely regulatory in scope unless so related.

We have not, however, found these limitations to hamper or impede in any way the purpose of the law in protecting the public from hazards to health or from fraud, both of which were crimes at common law.

Our early law, however, has undergone a complete metamorphosis before emerging in its present form. It saw successive revisions, innovations and differences of control, but all within the confines of the criminal law. One of the major innovations was the inclusion of the principle of delegated legislation by regulation of the Governor in Council. This particular aspect which found a place in a revision of the Food and Drugs Act in the 1890's probably has been the greatest single factor in providing needed flexibility in a field so constantly changing as to permit our law to keep in step with the march of science and medicine.

Although drugs have always been included in our legislation, this, until recent times, was largely lip service because the science of chemotherapy was truly in its infancy in comparison with present advances.

I think it fair to say that throughout the developing years the major emphasis was given to food adulteration, including misbranding. This is not to say that the importance of drugs was ignored but this importance was very definitely overshadowed by food for the simple reason that drug development had not then taken on the impetus it received after the end of the Second World War.

I hope that we may not appear too complacent in suggesting that the side of our legislation which pertains to food has settled into an orderly pattern of development. It perhaps is safe to say that as of now we do not predict any revolution or dramatic changes in the food industry that cannot be controlled by existing regulations and procedures or otherwise dealt with in accordance with the normal pattern respecting the development of regulations.

The Food and Drug Directorate of Canada have been conscious of the desire of industry to improve food products in the interests

of the consuming public. Through the initiative and inventiveness of that industry, the Canadian public have available to them a variety of food products which is perhaps second only to the variety available to the American public. I think the manufacturers would by and large pay tribute to the co-operation which they have invariably received from the administration and to its deliberate avoidance of unnecessary legislative roadblocks.

Development in Drug Procedures

During and since the Second World War, the drug industry has become one of growing importance. To a very great extent, our legislative pattern reflects trends, as well as practices, in other major countries. We have not hesitated to engage in what may be a form of neighborly borrowing and some of our procedures, as well as regulations, reflect the pattern of the United States. A practical illustration of this lies in our first New Drug Regulations which were enacted at the end of the Second World War. These regulations were substantially based on the new drug procedures which had been established before the War in the United States.

To a considerable extent, the establishment of special regulations regarding the sale and distribution of new drugs focused attention on the importance of drug development. To many, drug development seemed to indicate high profits to the drug industry and with insufficient recognition of the benefits which the public derived from new drugs. There was, however, a growing awareness on the part of responsible authorities that science in seeking to close the horizons of ignorance, encountered risk in the rapid development of new and potent drugs. It would be wrong to say there was public apathy regarding these risks, but anything smacking of bureaucratic interference that appeared to slow down the wheels of drug progress was not popularly regarded.

Many today point to Thalidomide as the beginning of public awareness regarding the distribution of new drugs. It would indeed be unfortunate if public awareness of the importance of drug development had to be related to tragedy. There is no question, however, since the Thalidomide tragedy of 1962, there has been an accelerated awareness of drugs, their risks, and their benefits if they are to be effective for their purpose.

This brings me to a few illustrations which our present legislation reflects. Some of these had been under consideration for many years but undoubtedly the climate of 1962 was favorable to the en-

actment of special regulations which would not have been easily passed before that time.

Among the matters which had been under consideration were our regulations respecting manufacturing facilities and controls. Prior to their enactment, the emphasis had been given to the end product, its potency, purity and the claims made for it. Apart from insanitation, the legislation had not positively dealt with the suitability of conditions of manufacture or premises. In 1963 we introduced what I like to refer to as our good housekeeping regulations which for the first time laid down positive requirements covering all drug manufacturers in Canada. These regulations provide that no manufacturer may sell a drug unless the conditions of manufacture are suitable having regard to the nature and purpose of the drug. The regulations then specify what is meant by suitability and here they reach into the heart of the drug manufacturing industry. They prescribe conditions for the premises, their construction, the quality control systems and procedures, the competency of supervisory staff, the maintenance of records of the tests used for checking the bulk drug and finished dosage form as well as measures taken to ensure the recall of a lot or batch of drugs from the market. They also provide that a drug manufacturer outside of Canada enjoys no special preference but must meet the same conditions insofar as suitability of manufacture is concerned as if the drug had been manufactured in this country. Unless this evidence is positively furnished, the drug can be denied admission to Canada until such time as the Director General is satisfied that the drug meets the requirements of the regulations.

While 1963 marked the introduction of general regulations regarding suitability of manufacture applicable to all drugs, there had been in operation for many years special requirements respecting certain classes of drugs. Following the development of the biologicals, the regulations provided for a form of licensing of certain specified products. Such products could only be brought into Canada or sold in Canada if manufactured by a person to whom a license had been given and the license was designed really to insure adequacy of manufacture, including controls and other matters to establish that the drug would not be unsafe for use.

The specific licensing provisions regarding certain enumerated classes of drugs have been continued but over and above these special regulations, all drugs in Canada are subject to the requirements of good housekeeping.

Following the global attention on Thalidomide, the Minister of National Health and Welfare asked the Royal College of Physicians and Surgeons of Canada to set up a special expert committee "to examine critically and objectively our present procedures for dealing with new drugs, the requirements of the regulations and any other matters that in the opinion of the committee are relevant to the issue."

This committee went exhaustively into the question of new drug procedure and controls. It sought information in the United States, it interviewed manufacturers, research scientists and others concerned with drug development.

The committee in due course made its report to the Minister in which it recommended certain changes in our new drug procedures. Contemporaneous with the committee's investigation, there was also legislation introduced in the United States much for the same purpose.

Among the committee's recommendations was the concept of filing a satisfactory submission designated as a preclinical submission prior to the distribution of the drug for clinical investigation.

The committee's report was considered by a special committee of Parliament and as a result new and much more detailed regulations were established. It was the recommendation of the committee that the new regulations and particularly those relating to preclinical requirements, should be reviewed within a reasonable period of a year or so in order that the regulations could reflect the best experience possible. While our regulations are substantially similar to those in the United States, there are some differences in approach if not in objective.

One of the differences is in the acceptance or otherwise of a preclinical submission. Under the Canadian law it is not sufficient merely to file a preclinical submission and then to proceed with clinical evaluation. Our law requires that the preclinical submission must be in a form and in content satisfactory to the Director.

In the review of the drug industry conducted by the Parliamentary Committee, proposals were made involving forms of licensing of the drug industry. It has been held under Canadian jurisprudence that the licensing of a trade, industry or profession as a condition of carrying on business would be beyond the competence of federal authorities. This essentially involves matters of property and civil rights which are solely within provincial competence.

In the proposals for licensing, some felt that this would provide a guarantee of the quality of a drug product. Others felt that it would insure adequacy of premises. Other proposals to the same end were on

the basis that this would provide needed information as to who was in the drug industry and what they were making for public sale.

In appearing before the Parliamentary Committee, I endeavored to deal with the constitutional points that licensing would raise and pointed out that if all that was really required was knowledge of drug manufacturers and their products, the same result could be achieved without raising a constitutional problem.

It was the view that the essential purpose to be achieved was knowledge of what manufacturers were in business in Canada or, if outside of Canada, were selling drugs to the Canadian public. Coupled with this would be information regarding the names of the products to be sold, their medicinal ingredients and the recommended single or daily dosage. It was felt that this result could be obtained by a form of notification, with supplementary information by a manufacturer regarding any new products developed. There has accordingly been enacted a regulation which will require by October 1, next, information from all manufacturers in Canada of their place of business, the names of drugs sold, the ingredients and their recommended single or daily dosage. The regulations, moreover, require changes in the manufacturer's list to be reported as in the original notification. This information is virtually the same as will be shown on the label and is not regarded as imposing any onerous duty or obligation on a manufacturer. It will provide valuable information to the Directorate, and special administrative procedures are being arranged which will provide for the classification of the information, the retrieval through mechanical devices of information on drugs in accordance with ingredients, purpose of use and other matters which the authorities should have in the interests of the consuming public.

Generic Name Drugs

Arising out of the representations to the Parliamentary Committee to which I have made reference, as well as other areas, is the question of drugs sold under non-proprietary names or, as they have come to be referred to, generic name drugs. There is probably a great deal of public misunderstanding with respect to the use of generic names. The acceptance of a name for a drug by a pharmacopoeia in itself expresses no standard of quality for the drug. Many feel, however, that if doctors would prescribe drugs by their generic names, the patient would receive an equal quality but cheaper drug. This misconception of the facts has not been fully appreciated by many of the inquiries on drug prices.

In an ideal situation, drugs other than specialties of a particular manufacturer would be sold under the non-proprietary name without identification and the emphasis of a manufacturer's brand name. It would be rather naive to expect such anonymity by manufacturers, and drugs have accordingly developed under a manufacturer's brand name, but with the law requiring that the non-proprietary name or—as designated in the regulations under the Food and Drugs Act—the "proper name" of the drug appear on the label in type at least half the size of the trade or brand name.

Conscientious practitioners who believe in the generic name principle may prescribe a drug by its non-proprietary name. It is very questionable whether the patient derives any financial advantage from such a prescription. If the physician does not prescribe the brand of a particular manufacturer to identify the drug which he intends his patient to have, the pharmacist must choose one of several brands, each presumably being more or less identical in terms of purity, potency and recommended dosage and competitive in price.

Manufacturers feel, perhaps rightly, that their particular brand is superior to others because of special quality control procedures that they have developed. In Canada, pharmacists are reluctant to make, if not prohibited from making, a substitution of drugs prescribed by a physician. The end result of all of this is that generic names have not achieved any great use in prescriptions and, of course, the efforts in this direction are substantially combatted by manufacturers' detail men who preach the superiority of their brand of a generic drug.

Because of the prominence that generic names from time to time receive in discussions of drug prices, I thought it might be of some general interest to touch briefly on this matter.

"Controlled Drugs"

A remaining area which is under present consideration involves what may for convenience be referred to as drugs meriting some very special form of control, with the offense of illicit possession being established.

At the present time under our legislation we have drugs which may freely be sold over the counter, we have a schedule of drugs the sale of which can only be made on prescription, we have drugs the manufacture of which involves a special license—I refer here to the biologicals and to certain other designated classes.

Some years ago we also added another class which we entitled "controlled drugs." These are the barbiturates and amphetamines. These drugs are subject to special licensing arrangements, the keeping of

records and other matters of control which substantially parallel our narcotic control provisions. Illicit possession of these drugs is not, however, an offense but trafficking or possession for trafficking is.

In 1963, there was introduced in the Food and Drug Act a further schedule of what may be described as prohibited drugs. Thalidomide prompted the making of this schedule. Only two drugs were placed on the schedule, one being Thalidomide and the other being lysergic acid diethylamide commonly known as LSD. Within a short space of time pressures developed to make LSD available for research purposes in approved mental institutions. Regulations were accordingly developed that would permit of small amounts of this drug being available for this purpose. At that time, there was no traffic in LSD and, in fact, it was relatively unknown except in very limited research studies in the field of psychiatry in specified institutions. It was thought sufficient at that time merely to prohibit its sale, subject, however, to the exemption that I have described, particularly since the manufacturer had indicated to the Department that it was no longer interested in developing the drug for marketing. In recent months, however, the illicit use and traffic in LSD has assumed somewhat alarming proportions. Unfortunately, it has found its way into campus life in certain universities in Canada and the United States. Our efforts to control this activity are hampered by the fact that possession is not an offense. We have under consideration, however, measures which will, we hope, rectify this situation.

Obviously no form of legislation can prevent all types of misuse and abuse. It is unlikely that we will ever be able to combat successfully by legislative process such esoteric practices as glue, gasoline or ether sniffing, any more than it has been possible to control the alcoholic who has a predilection for Jamaica ginger extract or vanilla extract. We feel that our efforts should be directed towards protection of the public in the field of legitimate drug use. As someone once said, it is difficult to legislate for common sense and I hope that we do not ever attempt to do so.

Meanwhile, we are perhaps optimistically looking forward to the development of the happy pill. This is not, I quote, "the pill," but rather one that will make one feel exactly as he would like to feel at all times, in whatever mood, but without side effects or adverse reactions. Until that Utopian day arrives, I think that we will need to keep in step with drug developments by regulatory devices that will protect the public to the extent possible and not in any way impede the march of science. **[The End]**

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