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Food Drug Cosmetic Law JOURNAL

Foods, Drugs and Devices Panel Held at the Annual Meeting of the American Bar Association in Washington, D. C.

Product Liability—1973

. . . . . WILLIAM J. CONDON

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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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Food·Drug·Cosmetic Law Journal

Look What Consumerism Has Done Now

By HARVEY L. HENSEL

Mr. Hensel Is a Member of the Illinois Bar.

WHEN I WAS GIVEN THE OPPORTUNITY to participate in this program, I immediately thought of two possible subjects that I could discuss. Both subjects concern the effect of consumerism at the state and local level on two different types of food laws. The first subject I would like to discuss is the status of the weights and measures principle of allowing a variation in net weight when the variation is caused by a gain or loss of moisture. The second subject is the breakdown in uniformity of food laws caused by the passing of a large number of nonuniform open dating laws at the state and local levels.

While the subjects are not directly connected, there are some common undercurrents that may occur to you as the subjects are developed. Also, it is my hope that current reports on these subjects will help those present make a significant contribution to the final result in each case.

First, let us consider the status of the current controversy concerning the loss of moisture in food products as affecting the net weight of the product. It is a well-recognized fact that some package products do lose or gain moisture between the time that they are packaged at the manufacturing plant and the time they are sold at retail stores. Meat, poultry and flour are typical examples of products of this type. The Federal Food and Drug Administration (FDA) has

recognized this principle through regulations for over 30 years. The most recent statement of this principle by this agency is found in the regulations promulgated under the Fair Packaging and Labeling Act[1] which state:

> Reasonable variations caused by loss or gain of moisture during the course of good distribution practices or by unavoidable deviations in good manufacturing practice will be recognized.[2]

Current regulations issued under the Wholesome Meat Act,[3] and under the Poultry Products Inspection Act,[4] contain the identical language quoted above from the Fair Packaging and Labeling Act regulations. The Model State Packaging and Labeling Law and Regulations of the National Conference on Weights and Measures has also recognized the same principle for the last 20 years, although with a little different language. Section 12.1.2 of the model regulations states, in part, as follows:

> Variations from the declared weight or measure shall be permitted when caused by ordinary and customary exposure to conditions that normally occur in good distribution practice and that unavoidably result in the change of weight or measure, but only after the commodity is introduced into intrastate commerce.

Thus, we see that for many years, at both the FDA, the United States Department of Agriculture (USDA) and the state level, the principle of loss of weight due to loss of moisture has been recognized. It also should be noted that though the principle was recognized, no attempt had been made to spell out the allowable variation on a product-by-product or package-by-package basis. The variation has been informally allowed on a 1 or 2 per cent basis. While the failure to detail the allowable variation is understandable, in view of the many factors that should be taken into consideration, this failure may be the Achilles' heel in this story.

Recent Lawsuits Involving Moisture Loss

All of the foregoing is background for the beginning of the current aspect of this problem. In the fall of 1971, California decided that it would not recognize an allowance for loss of moisture and would insist upon a package of meat, for example, being at full weight when it was displayed for sale at retail. For some unknown reason, California decided to press against Rath Packing Company in an attempt to support their interpretation of the law. After insisting on

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[1] 15 U. S. C. §§ 1451-61 (1970).
[2] 21 C. F. R. § 1.8b(q) (1973).
[3] 81 Stat. 584 (codified in scattered sections of 19, 21 U. S. C.); see 9 C. F. R. § 317.2(h)(2) (1973).
[4] 21 U. S. C. §§ 451-70 (1970); see 9 C. F. R. § 381-121(c)(6) (1973).

many occasions that Rath put its bacon off-sale for l eing short-weight, two consumer-oriented suits were filed against Rath in Riverside County and Los Angeles County. Both suits allege l false advertising for each short-weight package of bacon.

Damages of $2500.00 times each short-weight package of bacon were asked. This amounted to $2,900,000 in Los Angeles and $800,-000.00 in Riverside. Anyone with any experience with short-weight cases quickly realizes these are not the normal *ad damnums* in this type of case. Rath first attempted to get both cases consolidated and transferred into a federal district court but failed. Rath then filed original actions in a federal district court against the Director of Weights and Measures of Los Angeles and Riverside Counties, alleging that the Wholesome Meat Act preempted the State of California from imposing labeling requirements that were "in addition to or different than those imposed by the Federal Act and Regulations." As indicated above, the federal regulations permitted reasonable loss or gain of moisture during good distribution practices.[5] While the federal case was pending, actions continued at the state level in both Los Angeles and Riverside.

Court Held Federal Regulations Too Vague

In November, 1972, the trial occurred in the federal district court case. On April 3, 1973, the U. S. District Court for the Central District of California handed down its decision.[6] The decision can best be described by saying it contains something for everybody. The court held that:

> (1) The Meat Inspection Act, as amended by the Wholesome Meat Act, requires an accurate statement of the quantity of contents, subject to the authority of the Secretary to prescribe for reasonable variations by regulations, in all points in the distribution system until purchased by the consumer.[7] (While this point recognized the principle of the effect of loss of moisture on loss of weight, it eliminated one of Rath's arguments that the only time the package had to be at full weight was at the time it was packaged.)
>
> (2) The federal preemption section of the Wholesome Meat Act clearly limits the state from imposing "marking, labeling, packaging or ingredient requirements in addition to, or different than, those

[5] See text accompanying note 2 *supra*.

[6] *Rath Packing Co. v. Becker*, 357 F. Supp. 529 (C. D. Cal. 1973).

[7] *See id.* 533-34.

made under this chapter. . . .[8] Furthermore, actions by the state concerning net weight requirements must be consistent with the federal law.

(3) Section 317.2(h)(2)[9] of the federal regulations issued by the Secretary of Agriculture was void for vagueness because while it recognized the principle of reasonable variation, it did not spell out, with any certainty, how this principle was to be applied.[10]

(4) Section 12211 of the California Business and Professions Code, and title 4, chapter 8, subchapter 2, article 5 of the California Administrative Code are inconsistent with the Wholesome Meat Act because they provide for the averaging of the net weight of the packages being sampled, while the federal act provides for an accurate statement of net weight.[11]

(5) The U. S. Secretary of Agriculture has sole authority to speak, by proper regulations, on what reasonable net weight variances may be allowed on federally inspected products.[12]

(6) The defendants were restrained from applying state law provisions to federally inspected meat products. This injunction also applied to the Director of Agriculture of the State of California who had intervened in the case.[13]

In summary, the Court held that the federal regulations applied but they were void because they were too vague. Appeals have been filed by all parties to the action.

Since the time of the decision, the State of California has adopted a new emergency regulation requiring that every package of meat be full weight at retail. Rath then went into court to have the emergency regulation declared void as being in conflict with the court decision. The court, however, denied Rath's motion. This means that the State of California can continue to enforce emergency regulations until the Secretary of Agriculture adopts effective new regulations on net weight or until the injunction requested by Rath is expanded on a cross appeal of the federal district court decision.

In addition to the above litigation involving meat products, suits have been filed by flour companies in both Los Angeles and New York. The Los Angeles flour case is before the same federal district court judge that decided the Rath case. While the principle involved is the same, i.e., the right to have a variation in net weight due to a

[8] *Id.* 532-33.
[9] 9 U. S. C. § 317.2(h)(2) (1973).
[10] *Id.* at 534.
[11] *Id.* at 533-34.
[12] *Id.* at 534.
[13] *Id.* at 535.

loss or gain of moisture, the legal argument is somewhat different. In addition to federal preemption, the flour companies are basing their argument on the due process clause of the 14th Amendment and the imposition of an unreasonable burden on interstate commerce.[14]

Move to Eliminate Recognition of Moisture Loss Principle

There have been two more developments which have occurred in connection with this principle. At the July, 1972 National Weights and Measures Conference, the California delegates made a strong plea to have section 12.1.2 of the Model State Packaging and Labeling Regulations deleted in order to eliminate recognition of the principle of variation in net weight due to loss of moisture. The Conference Laws and Regulations Committee recommended that no action be taken in July, 1972 but that the matter be further studied. In 1973, the Laws and Regulations Committee's report again indicated that they felt that no action should be taken at this time because of other pending developments. The Conference accepted this recommendation in its meeting in Minneapolis in July of this year. This issue is, however, still very much alive among State Weights and Measures Directors.

In another important development, there has been a strong indication that the USDA is about to issue new net weight regulations and that the new regulations will not recognize the principle of variation in net weight due to loss of moisture. Thus, we see that the consumer-oriented lawsuits brought by the State of California against Rath[15] may have the effect of changing the federal regulations governing meat products. In addition, a change by the USDA may influence the FDA's position in this matter. This also illustrates one of the dangers of arguing for federal preemption in a given situation. If the federal rule is unsatisfactorily changed you are not in a very good position.

One more development should be brought to your attention. The Bureau of Standards is working on a precise detailed product-by-product regulation for determining net weight. This regulation may or may not adopt the moisture variation principle. It is anticipated that after this regulation is in final form (and this will take a great deal of time) it will be adopted by the USDA, the FDA and the states. It is obviously important to carefully watch this development.

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[14] For a more detailed report on this aspect of the subject, see Address by George Burditt, National Conference of Weights and Measures, 1973.

[15] See text accompanying notes 5-13 *supra*.

In summary, we have an existing long-standing legal principle, based on a law of nature, being challenged by consumer expectation (that is, the expectation that whenever a product is purchased, the full listed weight will be present). It would appear that the opponents are well matched and the legal outcome is uncertain. All parties should remember, however, that if the law is changed, packages must be overfilled at the time of packaging, thus increasing the cost at retail.

Next, I would like to give you a status report on what is the most serious situation the food industry has ever faced in the area of nonuniform food labeling laws.

Nonuniform Food Labeling Laws

Problems with uniformity are not new in the food industry, but they have been generally restricted to one industry or state. The Michigan Comminuted Meat Law is one well-known example. This problem was recently resolved in the case of *Armour & Co. v. Ball*.[16]

One of the few general nonuniformity problems occurred about 10 years ago when various states started to issue nonuniform regulations regarding the type size for the net weight statement.

A strong united industry effort under the general guidance of a newly formed committee called the Industry Committee on Packaging and Labeling brought back uniformity. The method used was (1) agreement on a model regulation and (2) cooperation with the National Conference of Weights and Measures to insure that all states had the same requirements. The later passage of the Fair Packaging and Labeling Act basically codified the uniformity which had already been achieved.

Unfortunately, we now have another example of a general nonuniform requirement which is in the process of sweeping the country by city and county ordinances, as well as by state laws and regulations. The subject is open dating.

"Open Dating" of Foods

The principle of "open dating" evolved from the use by manufacturers of code dating. The purpose of code dating was to give retailers information regarding the age of products so that products could be properly rotated on the retailers' shelves. The consumers' request has been very simple—if the retailer is entitled to information regarding the freshness of a product so are the consumers. Therefore, print the information so consumers can read it.

[16] 468 F. 2d 76 (6th Cir. 1972).

From industry's standpoint, the problem is not simple. Open dating laws involve some type of a guarantee of freshness for a specified period of time. While the manufacturer places the date on the product, the handling of the product by the carrier and the retailer determines the final condition of the product.

As pressure increased for open dating laws, two approaches were taken by industry to try to keep such laws uniform.

The original approach was basically a stall for time. The lawmakers were told that retailers were trying open dating on a voluntary basis and government bodies were studying the results. The legislators were therefore urged to take no action until results of these studies were available. While this approach was successful in buying some time, the studies are for the most part now completed and there is nothing in the studies that provides a strong counterweight to the consumer's desire for the additional information on the label. Actually, the studies seem to show that open dating enables the retailer to do a better job in stock rotation, and in that way, the consumer benefits. In addition, the studies showed the consumer has a more favorable attitude toward products with open dates, even though these consumers do not change stores or brands to insure purchase of foods so dated.

The second approach to achieve uniformity has been the type size-net weight approach: develop a model and then sell it to the political bodies who want an open dating regulation. Up to now, this approach has not worked for the simple reason that industry has not been able to agree on a model bill. Many hours have been spent on the subject in meetings sponsored by the Industry Committee on Packaging and Labeling. However, the original feeling that open dating is unnecessary plus differences in views on type of date, explanation of date, and foods covered have prevented a model from being developed. Three recent developments may breathe new life into this approach. One is the gradual realization that open dating is here and like it or not, something must be done to achieve uniformity. Another is the development of a model regulation by the National Weights and Measures Conference at its meeting last month in Minneapolis. Finally, the USDA's current proposal on open dating may also assist in the development of a model.

Even the final development of a model, however, will not make uniformity out of our present nonuniform situation. Let us take a detailed look at our present status in open dating laws.

Present Status of Open Dating Laws

There are now six open dating laws covering all "perishable foods." Three of these laws have been promulgated by states, two by cities, and one by a county. There is one open dating law covering all foods (Massachusetts) and one open dating law covering all bakery goods (Rhode Island). In addition, there are eight laws requiring open dating on dairy products. This makes a total of sixteen open dating laws. This number is increasing every month. During the current legislative session, 84 open dating bills have been introduced in twenty-three states. None of the open dating laws are identical. They vary as to products covered, type of date required and manner of disclosure.

The time is rapidly approaching, if not already here, when interstate food manufacturers will need separate packaging lines to comply with the open dating laws of various jurisdictions. This is an inefficiency that seems highly undesirable in these times of very high food prices.

Industry representatives dealing with this problem are coming to the conclusion that stronger methods are going to be necessary to get us back to uniformity in the area of open dating.

Suggestions to Increase Uniformity in Open Dating Laws

One possibility would be for the FDA to act in this area by regulation. This could be done in terms of a voluntary open dating regulation somewhat similar to regulations on nutritional labeling.

I realize that some people might question the FDA's statutory basis for this action. However, I think it is clear that the FDA could take the same position as the USDA; namely, that a date without an explanation is misleading. From this, it might follow that, in order to avoid consumer confusion, a procedure to regulate the use of dates could be established.

There would also be some question as to the preemption effect of such a regulation. There would be no doubt, however, that a model would emerge which most states and local governments would follow in drafting their own legislation.

It does not seem likely at the moment that the FDA will propose such a regulation. However, a petition to the FDA by any interested organization would probably be published by the FDA. This would start the process of a regulation being issued by the FDA.

The other approach being seriously considered is to request Congress to amend the Food and Drug Law to clearly provide for open dating regulations and some type of federal preemption. The problems presented by such an approach are:

1. Would Congress pass such a bill?

2. How long would it take to get the bill through Congress? (This is important because the Massachusetts open dating regulation covering all foods becomes effective January 1, 1974.)

3. Would Congress include in the bill an effective federal preemption clause?

4. Should the bill request federal preemption for all food labeling laws and not just open dating?

5. Would states like Massachusetts refuse to follow the federal preemption clause of a new law as Michigan did in the case of the preemption clause of the Wholesome Meat Act?

Regardless of the risks in this procedure, these may be risks that must be taken in order to provide industry a solid legal basis for uniformity.

There is one current fact of life that may increase the chance of Congress being willing to pass a strong preemption provision in connection with food laws. The current high price of food presents a strong positive reason for Congress to pass legislation that will increase the productivity of the food industry, and therefore lower prices.

Legal Battles Will Ensue

The legal battles concerning open dating are just beginning. A Rhode Island court has enjoined the enforcement of the Rhode Island Open Dating Law which would have required the date of baking on all packaged baked goods sold in the state. Plans are being made for a suit to be filed in Massachusetts to test the legality of their open dating regulation that applies to all foods. A hearing will be held in Minnesota during the latter part of this month on proposed Minnesota open dating regulations. The main issue to be determined is whether the Minnesota open dating law will apply to all foods or only to those foods with a 90-day or less shelf life.

One final comment on open dating. Most of the present open dating laws do not require an explanation on the package as to what the date means. It seems to me that this type of date is confusing to the consumer and legally misleading. I believe that the requirement of such a phrase on the package will be the trend for the future even though it increases the possibility for serious nonuniform law problems.

In both the areas of net weight laws and food labeling laws, the force of consumerism is bringing about changes. It will be our job as food lawyers to assist in the molding of the inevitable changes to create the maximum benefit to consumers with minimum added costs for food products. **[The End]**

Food Labeling

By WALTER E. BYERLEY

Mr. Byerley Is a Member of the Texas and District of Columbia Bars.

WHAT I AM GOING TO DISCUSS is what, for want of a better term, I will call "The Philosophies of Food Labeling."

I trust you noted that I referred to "Philosophies"—plural—rather than the singular. All of you, upon a moment's reflection, will acknowledge that there is not, at present, unity in philosophy among consumers, the Food and Drug Administration (FDA) and industry. Indeed, there is not even unity within each of these discrete groups. All of you have probably had the frustrating experience of getting different answers from different people at FDA, and most of you, I am sure, have sat in conferences with clients, wherein the product technologist and the marketing manager had totally different philosophies about how a food should be labeled.

Nonetheless, I think there are a few areas where most of the philosophies of food labeling converge. I submit that all persons desire that a food label should at least be:

TRUTHFUL
INFORMATIVE
UNAMBIGUOUS

The rub comes, of course, in defining these terms. One man's truth is another man's lie. The information your client wants to convey may not be the information Jim Turner or Ralph Nader thinks is absolutely necessary. Moreover, a statement which seems to its author totally unambiguous can be, and usually will be, misunderstood by large numbers of people.

"Consumerists"

By whose definition, then, shall we create our truthful, informative, and unambiguous label? Jim Turner says it shall be his. He thinks

that he knows what information consumers want to see on a label—and, moreover, he thinks he is capable of couching that information in language that unambiguously presents the truth, the whole truth, and nothing but the truth. You and I know that it is totally impossible to put together two words of the English language in such a way that they cannot possibly be misunderstood, but the Naders, Turners, and Choates do not know this. They, therefore, freely give advice to the industry on how to label foods. The fact that this advice is usually gratuitous calls to mind the ancient legal maxim that "Free advice is worth exactly what you paid for it."

Moreover, I think it is important to keep in mind that those persons designated "vocal consumer spokesmen" are certainly vocal, but are equally certainly *not* spokesmen for all consumers. Indeed, I know of no one person, or even small group of persons, who can claim to be spokesmen for all consumers. Each of these vocalists enters upon his crusade with a lifetime of biases and prejudices—and, frequently, a very limited knowledge of food production, food marketing, food law, and food regulations. He is, in final analysis, a spokesman only for his own viewpoint, or, at best, the viewpoint of the few disciples he has been able to gather around him.

I, therefore, do not believe it is entirely feasible, or wise, to take without qualification the advice of the "consumerists." Shall you follow FDA's advice? It, too, gives plentiful—and gratuitous—indications of its philosophy. The two most notable recent examples are the *Federal Register* publications of January 19 and March 14, 1973, both entitled, simply, "Food Labeling." I might add that the title is the only thing about these regulations that *is* simple.

These documents are an amazing amalgamation of concessions to the so-called "consumer movement," unwarranted extensions of the law, and logic run wild. Moreover, each section is totally unworkable for some segment of industry. Under ordinary circumstances, I would say that these regulations richly deserve to be ignored by the food industry. Unfortunately, present circumstances are not ordinary. I'll return to this theme later.

Food Labeling Controversy

The multitude of regulations on food labeling which we have seen in recent months, if followed to the letter, will result in a surfeit of information to the consumer. I anticipate that only about one consumer in fifty will even read all of the information on the labels,

and, of those who do read it, only one in a thousand will have the knowledge requisite to understand it. For the rest of the consumers —"that vast multitude which includes the ignorant, the unthinking, and the credulous" as the Supreme Court put it—the time and money spent in devising and printing new labels, and sometimes revising food composition so as to have a better label, is time and money wasted.

Following FDA's advice, then, is difficult and wasteful. Should industry make its own decisions on food labeling? This, of course, has been the historical pattern. Each company devised its own labels, always ensuring that the basic requirements of the law—common or usual name, contents, and ingredient statement where necessary—were met. The result, of course, was a rich array—some would say a bewildering array—of labels.

In fact, it was this wide variation in the method of presenting information that led FDA to adopt, and promulgate, the concept of the "information panel" with its rigid requirements of location and format. Although I believe, as do many others, that this requirement is an unlawful extension of FDA's authority, nonetheless, it is a regulation that is on the books, and your client can ignore it only at his own risk. The same is true, of course, for nutritional labeling, common or usual names for nonstandardized foods, nutritional quality guidelines, declaration of imitations, and the host of other newly revealed requirements.

It is not safe, therefore, simply to follow the industry philosophy. Where, then, does that leave us?

The easy answer, and the safe answer, and the answer that most segments of the food industry seem to be choosing, is to follow the FDA philosophy, despite its obvious shortcomings. The reasons for choosing this approach are many.

In the first place, of course, this is the path of least resistance. Most of your clients, and most of mine, will obey the FDA regulations in order to avoid the possibility of legal sanctions, even when those regulations are unlawful substantively and procedurally.

In the second place, our clients are running scared in this era of the consumer. No one wants to be the subject of a newspaper article by Morton Mintz, or a press release from Choate or Turner.

And third, of course, is the fact that it costs money—sometimes big money—to fight the FDA in court where FDA's batting average has always been, and remains, very high.

We, as lawyers, cannot force our clients to stand up for their legal rights. We can only tell them what those rights are and how they are being abridged and let them make the decision.

I fear, however, that many of us are not telling it like it is to our clients. Only one brother lawyer—in Chicago—has joined me in speaking out, in every forum available to us, against what we consider to be the unconstitutional activities of FDA. Yet, each of you in this room, upon admission to the bar, took an oath to uphold and support the Constitution and laws of the United States. We do not fulfill that oath by allowing the FDA or any other governmental agency to take unwarranted liberties with the law.

The FDA Philosophy

Let us examine for a moment the FDA philosophy. It has its roots in a statement made by the general counsel of FDA some eight months ago. I will not quote the statement verbatim, because of its length, but, paraphrased, it boils down to this: "We do not view the Federal Food, Drug, and Cosmetic Act as a charter, which allows FDA to do only those things expressly permitted; we view the Act as a Constitution, which allows us to do anything not expressly prohibited." That is a very dangerous statement. It is contrary to the entire thrust of almost 200 years of history. This country was founded upon the notion that the Federal Government's powers were strictly limited to those granted by the Constitution. The Ninth and Tenth Amendments make this very clear. Let me read to you the Tenth Amendment:

"The powers not delegated to the United States by the Constitution, nor prohibited by it to the States, are reserved to the States respectively, or to the people."

In those words you find a negation of the concept that a governmental agency has the power to take any action not expressly prohibited by its statutory birthright. Such a negation is void, however, unless someone, somewhere, has the intestinal fortitude to make it the basis of a court action.

Food labeling, of course, does not seem to be the most compelling vehicle for raising constitutional issues. And yet some very important constitutional issues have been raised by rather mundane circumstances. Had it not been for a small chicken grower in New York, the National Recovery Act (NRA) might have continued unabated. The desire of a child to go to a certain school; the tired feet of a bus

passenger—these have been the genesis of great Constitutional decisions. Why not the label on a package of food?

My topic—food labeling—has led us into a discussion of philosophy, and from there to a discussion of constitutionality. I offer no answer to the question I posed as to whose philosophy you should follow. I do, however, state—as strongly as I can—that unless we stop the FDA from the promulgation of unlawful regulations, the question will be moot—for our clients will have no choice but to follow FDA philosophy, which, in turn, will soon become only a reflection of the Turner-Nader-Choate philosophy. Do you really want that? **[The End]**

FDA PROPOSES GUIDELINES FOR LABELING DRUGS THAT ARE REFORMULATED

Numerous questions have arisen, according to the Food and Drug Administration, concerning the circumstances under which changes in the formulation and/or labeling of a drug product would cause the proprietary or trade name to be considered misleading under the misbranding provisions of the Federal Food, Drug and Cosmetic Act. In order to clarify the misbranding provisions of the Act, the FDA has proposed an amendment to 21 CFR 1.101. The policy stated in the proposed amendment is that excision of a brand name is required only where nothing short of excision would eliminate the possibility of deception and that retention of a brand name is permissible where either permanent qualification of the name or prominent public disclosure of the change in the product for a significant period of time would be sufficient to inform the public of the change in the product or its use.

For purposes of determining the distinction, the FDA defined three types of changes made in drug products: first, those that do not significantly change the use or expected composition of the drug; second, those that significantly change the use or expected composition of the drug and require prominent public notice of the change; third, those that so fundamentally alter the nature or use of the drug that its brand name must be qualified or changed.

Comments on the proposal may be filed with the FDA until May 28, 1974.

CCH Food Drug Cosmetic Law Reporter

After the Glorious Revolution: Thoughts for Food and Drug Lawyers on the New Regime

By JOEL E. HOFFMAN

Mr. Hoffman Is a Member of the New York and District of Columbia Bars.

THE FOUR DECISIONS handed down by the Supreme Court on June 18, 1973 in the *Hynson, Bentex, CIBA*, and *USV* cases[1] have brought us to a new era in government regulation of foods, drugs, devices and cosmetics. The 1938 Act[2] has been revitalized in ways that many would have thought were impossible, and the Food and Drug Administration has been given a mandate of unprecedented scope.

Yet, with power always comes responsibility. Lawyers recognize that the power to regulate in the public interest carries with it an obligation to observe both procedural and substantive fairness in the exercise of that power. Procedural fairness means giving each affected interest an adequate opportunity to be heard. Substantive fairness means preserving and accommodating all legitimate values to the maximum extent possible. A lawyer's position, active in the organized Bar in a field so heavily affected with a public interest as food and drug law, is to work for the maintenance of these standards, by

[1] *Weinberger v. Hynson, Westcott & Dunning, Inc.*, 93 S. Ct. 2469 (1973); *Weinberger v. Bentex Pharmaceuticals, Inc.*, 93 S. Ct. 2488 (1973); *CIBA Corp. v. Weinberger*, 93 S. Ct. 2495 (1973); *USV Pharmaceutical Corp. v. Weinberger*, 93 S. Ct. 2498 (1973).

[2] Federal Food, Drug, and Cosmetic Act, 52 Stat. 1040 (1938), *as amended*, 21 U.S.C. §§ 301-92 (1970).

vigilantly scrutinizing the Agency's regulatory programs and by pressing for corrective action when these standards are not met.

On the procedural side, the minimum elements of fairness in governmental processes are those set up by the courts to implement the due process clause of the Constitution, and those set up by Congress both in the Administrative Procedure Act[3] and in particular regulatory statutes. This is an area where the organized Bar has long been active.

Proposals for Improvement in Rulemaking Procedures

In 1969, a Joint ABA Committee representing both this Committee of the Corporation Law Section and the Section of Administrative Law presented the Food and Drug Administration with a series of seven proposals for improvement in its rulemaking procedures.[4] The proposals dealt with prehearing discovery; proper use of the prehearing conference; canned testimony; production of prior statements by witnesses; separation of functions; one-sided communications; and unnecessary limits on the scope of cross-examination.

The merits of some of these proposals, at least, were acknowledged by Commissioner Edwards,[5] but little, if anything, was done to implement them.

One of the reasons given by Commissioner Edwards for delaying a thorough examination and revision of the Agency's rulemaking procedures, as requested by the ABA Committee, was the pendency of a review of those procedures by the Administrative Conference of the United States. The Administrative Conference study was completed in December, 1971,[6] and at that time, the Conference adopted its own series of nine recommendations to the FDA.[7] These were "directed toward (1) encouraging the increased use of written testimony, (2) seeking to improve the delineation of factual areas of controversy in

[3] 5 U.S.C. §§ 551-59 (1970).

[4] 7 Sect. of Ad. L., American Bar Ass'n, Ann. Comm. Rep. 107-08 (1970). The recommendations were described by the Chairman of the Joint Committee in *Pendergast, The Nature of Section 701 Hearings and Suggestions for Improving the Procedures for the Conduct of Such Hearings,* 24 F. D. Cosm. L. J. 527 (1969).

[5] Letter from Charles C. Edwards, M.D., to Charles W. Whitmore, M.D., Chairman, Food and Drug Committee, Section of Administrative Law, American Bar Association, Aug. 6, 1970.

[6] The study is published in Hamilton, *Rulemaking on a Record by the Food and Drug Administration,* 50 Tex. L. Rev. 1132 (1972).

[7] Recommendation No. 29, Ad. Conf. of the U.S., 1971-72 Rep. 66 (1972).

advance of the hearing, (3) providing for greater access to information about the Agency's case in advance of the hearing, and (4) altering the Agency's approach toward one-sided contacts and separation of functions."[8] The Administrative Conference also urged the FDA to facilitate participation in hearings by consumer groups not represented by counsel; to strengthen the authority of the Administrative Law Judge conducting the hearings; to eliminate unnecessary restrictions on the scope of cross-examination; and to reconsider the Agency's traditional tendency to deny hearings altogether even where arguably material facts are in dispute.

The Administrative Conference enjoys great prestige, and its recommendations, although not binding, are intended to heavily influence the agencies on which it reports. In this case, however, the Conference's proposals to the FDA have, by and large, joined those of the Bar Association in sinking without a trace.

Hynson Decision

The recent Supreme Court decisions make it imperative for the FDA to confront these procedural problems *now*, along with still others which emerge from the implications of Mr. Justice Douglas' opinions. For example, the *Hynson* decision made clear that where Congress has granted a right to a hearing, the FDA can refuse to hold a hearing only "when it appears conclusively from the applicant's 'pleadings' that it cannot succeed,"[9] and that a conclusion to that effect cannot be rested upon an "exercise of discretion or subjective judgment."[10] In its argument before the Supreme Court, the Agency suggested that its failure to grant even a single hearing thus far in the Drug Efficacy Study Implementation program was simply the result of its having taken up the easiest cases first.[11] The FDA's track record in disposing of hearing requests under other provisions of the statute,[12] however, suggests that if *Hynson* is to be complied with, a new approach to this problem is required.

To take another example of newly unfolding problems, the *Hynson* and *Bentex* opinions clearly sanction administrative proceedings regulating drugs by classes as an alternative to giving a separate

[8] *Id.*

[9] *Weinberger v. Hynson, Westcott & Dunning, Inc.*, 93 S. Ct. 2469, 2479 (1973) (footnote omitted).

[10] *Id.* at 2479 n. 17.

[11] Consolidated Reply Brief for the Federal Parties at 31-33, *Weinberger v. Hynson, Westcott & Dunning, Inc.*, 93 S. Ct. 2469 (1973).

[12] *See* Hamilton, note 22 *supra*, at 1183-89.

hearing to each person subject to regulation.[13] The opinions leave unanswered, however, the question whether such proceedings amount to class adjudication or to rulemaking. There are procedural requirements in adjudication which do not apply in rulemaking, even "rulemaking on the record" (such as under Section 701(e) of the 1938 Act),[14] which must be conducted pursuant to sections 7 and 8 of the Administrative Procedure Act,[15] which lays down the procedures for formal adjudication.[16]

Nor would the burden of providing procedural fairness in these class regulatory proceedings be met merely by characterizing them (assuming the law would permit it) as "informal" rulemaking not subject to the on-the-record provisions of sections 7 and 8 of the Administrative Procedure Act. Even where those sections are inapplicable, so that the Agency is free to proceed under the notice-and-comment rulemaking provisions of section 4 of the Administrative Procedure Act,[17] a more penetrating procedure may be necessary, first, to bring the Agency sufficient information for it to carry out effectively the provisions of its substantive statute, and second, to permit a reviewing court to conduct the kind of judicial review contemplated by Congress. This developing principle may be discerned from a series of recent District of Columbia Circuit Court of Appeals decisions involving agencies as disparate as the Federal Power Commission,[18] the Civil Aeronautics Board,[19] and the Environmental Protection Agency.[20] What is required, as the Court of Appeals noted in the latest of these cases, is "an examination of the purposes and provisions of the substantive statute being administered"—that is, "an analysis of the regulatory scheme envisioned by Congress . . . and a determination of what is necessary to effectuate the policies of this regulatory statute."[21] The Court of Appeals presumably contemplated

[13] *Weinberger v. Hynson, Westcott & Dunning, Inc.*, 93 S. Ct. 2469, 2480-81 (1973); *Weinberger v. Bentex Pharmaceuticals, Inc.*, 93 S. Ct. 2488, 2492, 2494 (1973).

[14] Federal Food, Drug, and Cosmetic Act § 701(e), *as amended*, 21 U.S.C. § 371(e) (1970).

[15] 5 U.S.C. §§ 556-57 (1970).

[16] *See* Administrative Procedure Act § 5, 5 U.S.C. § 554 (1970).

[17] 5 U.S.C. § 553 (1970).

[18] *Chicago v. FPC*, 458 F. 2d 731 (D.C. Cir. 1971), *cert. denied*, 405 U.S. 1074 (1972); *Mobil Oil Corp. v. FPC*, No. 72-1471 (D.C. Cir., July 11, 1973). *Cf. Phillips Petroleum Co. v. FPC*, 475 F. 2d 842 (10th Cir. 1973), *petition for cert. filed sub nom. Chevron Oil Co. v. FPC*, 42 U.S.L.W. 3063 (U.S. July 10, 1973).

[19] *American Airlines, Inc. v. CAB*, 359 F. 2d 624 (D.C. Cir. 1966) (en banc).

[20] *Kennecott Copper Corp. v. EPA*, 462 F. 2d 846 (D.C. Cir. 1972); *International Harvester Co. v. Ruckelshaus*, 478 F. 2d 615 (D.C. Cir. 1973); *Portland Cement Ass'n v. Ruckelshaus*, No. 73-1073 (D.C. Cir., June 29, 1973).

[21] *Mobil Oil Corp. v. FPC*, No. 72-1471 (D. C. Cir., July 11, 1973), slip op. at 30.

this sort of analysis in a recent Federal Trade Commission (FTC) Trade Regulation Rules decision, where the Federal Trade Commission's power to issue substantive rules was upheld, but the case was remanded to the district court for consideration of whether the Agency's rulemaking procedures were adequate, given the nature of the particular rule in question.[22]

Expert Advisory Committees

One way that has been suggested for avoiding all these difficult problems is to increase the FDA's reliance upon outside expert advisory committees. The theory seems to be that, when scientists get together unencumbered by lawyers' formalisms, it will be easier to discover the truth, and that the Agency thereafter need concern itself only with abstract policy issues to be resolved through still other mechanisms which will exclude traditional forms of administrative hearings. A recent forceful and articulate exposition of this proposal calls the process "publicly exposed peer review,"[23] and there are signs that the FDA is inclined to move in that direction.[24]

It might well be argued that the characteristics of administrative hearings which the authors of such proposals deem undesirable are, in fact, important contributors to the evenhanded application of law and to reasoned decision making.[25] Even more fundamentally, however, reliance upon the outside expert advisory committee can easily become a kind of "cop-out," enabling Agency officials to ward off criticism of their policies by disclaiming responsibility for at least the factual components of their decisions. We have seen the foreshadowings of this sort of abdication in the FDA's constant invocation of the prestige of the National Academy of Sciences-National Research Council (NAS-NRC) when called upon to litigate the propriety of its Drug Efficacy Study evaluations, although in one such case the District of Columbia Court of Appeals condemned the NAS-NRC

[22] *National Petroleum Refiners Ass'n v. FTC*, No. 72-1446 (D. C. Cir., June 27, 1973).

[23] Hall, *A "... Diet Wholesome, but not Excessive"—Trends, Challenges, and Some Reflections on Hearing Procedures*, 28 F. D. Cosm. L. J. 473, 484 (1973).

[24] *See* Hutt, *Safety Regulations in the Real World*, 28 F. D. Cosm. L. J. 460, 470-71 (1973); FDC Rep., July 2, 1973, at 11, 12 (quoting FDA Gen. Counsel Hutt); *id.*, July 30, 1973, at 17 (quoting FDA Comm'r Schmidt).

[25] *See Greater Boston Television Corp. v. FCC*, 444 F. 2d 841, 850-53 (D. C. Cir. 1970), *cert. denied*, 403 U. S. 923 (1971); *Environmental Defense Fund, Inc. v. Ruckelshaus*, 439 F. 2d 584, 595 (D. C. Cir. 1971).

panel report as "cryptic and conclusory, without any statement of supporting facts."[26]

De facto delegation of governmental powers to private outside experts raises profound questions of public policy. We have always been suspicious of private government in this country, because of the difficulties in holding private government accountable to the people through democratic processes.[27] This distrust is reflected in the recently enacted Federal Advisory Committee Act,[28] which expresses a Congressional policy to discourage governmental reliance upon outside advisory committees, and which requires such committees to operate much more publicly than has been the practice in the past. There is reason to doubt that the agencies of the federal government, including the FDA, have yet begun to pay serious attention to the provisions of this important statute.

In the end, moreover, reliance upon outside advisory committees to avoid the problems of the administrative process may only bring us back full circle to the point where we began. As private groups begin to take on quasi-governmental functions, courts have traditionally required them to abide by the requirements of procedural due process.[29] The recent controversies over the keeping of minutes by the Over-the-Counter (OTC) Review panels are a good example of this tendency.[30] Expert advisory committees may thus ultimately find themselves obligated to provide much the same procedural guarantees of reasoned decision making as the governmental officers they were intended partially to displace.

Viewpoints Represented on Committees

Finally, and related to the basic question of public accountability, is the matter of whose viewpoints will be represented on these outside advisory committees. One of the most frequent criticisms of the NAS-NRC Drug Efficacy Study panels was that they appeared to represent almost exclusively the academic side of the medical profession, with little, if any, participation by the pragmatically-oriented practicing

[26] *USV Pharmaceutical Corp. v. Secretary of HEW*, 466 F. 2d 455, 461 (D. C. Cir. 1972).

[27] *Cf. Fashion Originators' Guild of America, Inc. v. FTC*, 312 U. S. 457 (1941); *A. L. A. Schechter Poultry Corp. v. United States*, 295 U. S. 495 (1935).

[28] Pub. L. No. 92-463 (Oct. 6, 1972).

[29] *See, e.g., Silver v. New York Stock Exchange*, 373 U. S. 341 (1963).

[30] *See* FDC Reps., June 25, 1973, at T & G-1.

physician. Also needed on these advisory committees are spokesmen for the economic and social interests of consumers, as well as for the legitimate interests of the manufacturers whom we expect to continue to provide necessary or desirable pharmaceuticals, medical devices, food products, and cosmetics. Without such broad-based participation, there is a serious risk that outside advisory committees will fail in terms of providing substantive fairness, that is, insuring that all legitimate values are preserved and accommodated in regulatory programs.

Happily, there are signs that the FDA may no longer tend quite so strongly toward the "father knows best" posture of recent years. Procedurally, FDA General Counsel Hutt is reported to be emphasizing within the FDA the need to devise sound new procedures across the entire range of the Agency's responsibilities, so as to guarantee fundamental fairness to all concerned.[31] Consumer and industry representatives are beginning to be included on the OTC Review panels, reportedly with good results.[32]

Substantively, Commissioner Schmidt has recently been quoted as saying that "there is no prohibition; nor should there be any prohibition . . . to an MD using a drug for a condition other than that commonly accepted," and that "[t]here is a fine point between the regulation of drugs and the regulation of the MD using the drugs."[33] Again, the new special dietary food labeling regulations[34] explicitly recognize that, as stated in the preamble, "individuals have a right to obtain" safe ingredients or products believed by the FDA to be without value, "as long as they are truthfully labeled"[35]—a diametric reversal of the Agency's policy of only a few years ago.

In these and other ways, the present administration of the FDA has evidenced an increasing sensitivity to the importance of providing both procedural and substantive fairness in its regulatory programs, as well as to the difficulty of this task. The thoughtfulness and perceptions displayed in FDA General Counsel Hutt's recent paper entitled "Safety Regulations in the Real World," delivered at a Forum of the National Academy of Sciences, is a particularly outstanding example.[36]

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[31] *Id.*, July 2, 1973, at 9, 11.
[32] *Id.*, April 9, 1973, at 7.
[33] *Id.*, July 30, 1973, at 22.
[34] 38 Fed. Reg. 20717 (1973).
[35] *Id.* at 20716.
[36] See note 24 *supra*.

Proposals to Amend Administrative Procedure Act

The organized Bar, however, also has a role to play. The recommendations of the American Bar Association (ABA) Joint Committee, and the Administrative Conference proposals, should be reviewed in the light of present circumstances and, where still valid, should be the focus of renewed activity. The ABA's twelve recommendations for amendment of the Administrative Procedure Act,[37] endorsed by our House of Delegates, contain much which is relevant to the work of the FDA, and all food and drug lawyers should participate in the efforts to obtain implementing legislation. At the Agency level, the FDA should be encouraged to implement those aspects of the twelve recommendations which are within its power under present law even though not required.[38] Furthermore, any forthcoming proposals for procedural rulemaking by the Agency or for reliance upon new advisory committees and panels should be carefully studied and, where appropriate, commented on by the Bar independently of the interests of particular clients.

Recent events in Washington have underscored how essential it is for lawyers to retain their independence, their objectivity, and their capacity for judgment. By continuing and increasing the efforts of the Bar to make these qualities available to the FDA as it moves into the new era opened by the Supreme Court decisions of June 18, lawyers will have well served the public interest. **[The End]**

REVOCATION OF DES RESIDUE TEST METHODS PROPOSED

The presently approved qualitative and quantitative methods for identification and measurement of diethylstilbestrol (DES) residues in the edible tissue of DES-treated animals would be revoked by proposed amendments issued by the Food and Drug Administration. Under the Federal Food, Drug and Cosmetic Act, a carcinogenic substance may be used in animals intended for use as food if no residue of the substance is found by test methods approved by the Secretary of Health, Education and Welfare. The test methods presently approved for detection of DES residues are not sufficiently sensitive, the FDA said, and are not considered by the FDA to be suitable methods by which DES use may qualify for an exemption from the anticancer clause of the Act. The data and information upon which the FDA based its conclusions may be viewed during business hours at the office of the FDA Hearing Clerk.

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[37] 24 Ad. L. Rev. 389 (1972).

[38] *Compare, e.g.,* ABA Recommendation No. 3, 24 Ad. L. Rev. at 393-94 and *Levine, Separation of Functions in FDA Administrative Proceedings,* 23 F. D. Cosm. L. J. 132 (1968), with *Hoffmann-LaRoche, Inc. v. Kleindienst,* 478 F. 2d 1 (3rd Cir. 1973).

Recalls Revisited

By RICHARD W. KASPERSON

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I HAVE PREVIOUSLY DISCUSSED the subject of product recalls from a corporate standpoint, with specific reference to a company's responsibilities to the public, to its stockholders and to the regulatory authorities. Most of my thoughts were included in an article in the June, 1972 issue of the *Food Drug Cosmetic Law Journal*.[1]

At that time, I was dubious about the meaning of the term recall. I still am.

When the recall procedure began about fifteen years ago, recalls were limited to situations where a hazard to health had been found to be present in a product and a procedure more expeditious than multiple seizure was necessary in order to assure prompt recovery of the product which had already gone through sales channels.

This limited use of recalls was recognized in a recent Congressional committee report, which said:

> Initially, recalls were requested only in situations of serious hazard to health. This was indicated by Mr. William W. Goodrich, FDA's General Counsel, who testified as follows about the origin of the recall: . . . there were some episodes of poisoning. We put out a public warning about them, and the next question was to the company: Are you going to get it off the market or shall we seize it? And from that beginning the recall system grew.[2]

In that same report, the Food and Drug Administration procedure manual is quoted as saying:

> Recall is the indicated action where there is a definite hazard to health or other serious problem requiring extensive removal of a faulty product from the market.[3]

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[1] Kasperson, *Food, Drug and Cosmetic Law Section Recall Panel*, F. D. Cosm. L. J. 349 (June, 1972).

[2] House Comm. on Government Operations, Recall Procedures of the Food and Drug Administration, H. R. Rep. No. 92-585, 92d Cong., 1st Sess. 3 (1971).

[3] *Id.* at 6.

Over the years, however, the concept of recall expanded. Again in that report, the Committee says:

> The growth of the recall program is amply illustrated by a comparison of the number of recalls for the years prior to June 30, 1964, with the recalls for fiscal year 1970. In the two-and-one-half-year period between January 1, 1962, and June 30, 1964, there were in all 243 recalls by large and small companies, or an average of about 97 per year. By contrast, in fiscal 1970, about 1,400 recalls were instituted by FDA. The recall has been the principal FDA enforcement tool for dealing with violations of the law.[4]

Procedures for Recall of Products

However, the FDA, on June 15, 1971, published in the *Federal Register*[5] a Statement of General Policy on Procedures for Recall of Products from Market. The statement emphasized the fact that the recalls are restricted to those circumstances where there exist "present threats to the safety of consumers"[6] or alternatively, "a potential threat to consumer safety and well-being, involve[s] product adulteration, cause[s] gross fraud or deception of consumers, or are materially misleading causing consumer injury or damage. . . ."[7] "Present threat" requires recall to the consumer level, whereas "potential threat" requires recall only to the retailer level.[8]

I have some question as to whether the FDA is following its own guidelines. For instance, the *FDA Weekly Recall Report* for January 18 through 24, 1973 listed a recall of a diarrhea remedy, to the retail level, resulting from excessive saccharin levels in the product. It seems unlikely that there existed any threat to the user, but if there was, it would seem to be "present" and not "potential." In the food industry, the concept of fraud, deception, etc. makes the FDA definitions a little more meaningful.

Use of "Subrecall"

According to *Food Chemical News* of November 8, 1971, the FDA has amplified the instructions to its field offices by establishing something called a subrecall, otherwise referred to as market withdrawal, which among other things includes, "removals of products from the market involving no violations."

Presumably, this "no violation" means no violation of the Food and Drug Act. The other classification of subrecall is stock recovery, which is defined as, "removal of products from the market, none of which products have left the direct control of the manufacturer."

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[4] *Id.* at 3 (footnotes omitted).
[5] 36 Fed. Reg. 11514 (1971).
[6] *Id.* at 11515.
[7] *Id.*
[8] *Id.*

Against that framework I will attempt to distinguish between the company's responsibilities to the public, to its stockholders and to the government regulatory agency, the FDA. At Abbott Laboratories, in those situations where our medical personnel have evaluated the problem and have found that to allow the product to remain on the market could constitute a hazard to health, we will recall to the end of our identifiable chain of distribution. This generally means to the level of dispensing doctors, retail druggists and/or hospitals. We have, in those circumstances, customarily used our detailing force to effect a physical recovery of the product to the exclusion of their preferred duty of selling. In addition, we have customarily sent letters and, on occasion, telegrams to those same groups of people.

We feel that the procedure of recalling to the retailer or hospital level in those instances where there is a hazard to health, is in the best interest of our stockholders. It is our responsibility to mitigate losses in those instances where our products may in fact pose a threat to the well-being of our intended purchasers. There is, of course, no satisfactory way of balancing the risk of unwarranted claims for damages which occasionally follow a recall, but that simply raises another question of our responsibility to the stockholders to defend against or settle unwarranted claims. There is another responsibility to our stockholders, and that is to assure ourselves that there is in fact a hazard to health before informing the FDA of our concern that we may be facing a recall situation.

Supplying Data to the FDA

There is also a question of when data is to be given to the FDA. I feel that we have an obligation to give the FDA full and complete data and I feel that we have an obligation to recall from the market products that are hazardous to health. However, we also have the responsibility to our stockholders to assure that there is a hazard to health or at least reasonable cause to believe that there is a hazard to health prior to instituting a recall. I do not intend to smuggle into that statement the concept that if we cannot prove to ourselves without any possible lingering doubt that there is a hazard to health, then we should simply bury the situation. Not infrequently, waiting for total certainty is a luxury that cannot be afforded.

I have not addressed, so far, the situations which the FDA has classified as subrecalls. If a product has not left the control of the manufacturer, I do not believe there should be any significant regulatory impact. The duty to the consumer and to the stockholder is

consistent. If the product is found to be defective before release, it should not be released on the market. I suppose that there may be some instances where this could give rise to a duty to inform the FDA, although I have not been able to think of an example of a situation where one would feel an obligation to report such an occurrence.

"Recall" When No Health Hazard Is Present

There remain, then, those situations where the product has gone to the market; it represents no conceivable health hazard; and yet the company wishes to bring it back. I feel some compulsion to inform the FDA about such occurrences simply to avert any unwarranted excitement on their part. Again, all the facts involved should be presented to the FDA and care should be taken to assure that the actual and not some spurious reason for recovery is provided to the FDA. Obviously, if there is no hazard to health involved, management has determined on other grounds that it is to the advantage of the public and the stockholders to recover such material. One does not sit down with a checklist of advantages and disadvantages in a situation like that—it's simply a judgment call by the people charged with making the decision.

Recent experience, however, suggests that the FDA is overdoing the publication of recalls. I will not provide examples of such, because it is a subject of some current soul-searching at the FDA. Suffice it to say that it is my fondest wish that the FDA would refine its procedure for publication. Manufacturers removing products from the market for minor defects will not long continue a program of informing the FDA of their actions, if the fallout is a frequent spate of adverse publicity.

By and large, I believe that the recall procedure, when properly employed, is a most useful tool. It has very significant advantages to the FDA, since it relieves them of the burden of multiple seizures where there is in fact a hazard to health. I believe that, as originally employed, it had advantages to stockholders and the public in that it expedited recovery and removal from use of hazardous products. I am very pleased that the FDA has indicated an intention to return to its earlier practice of requesting recalls and of publicizing them only in those cases where there is a hazard to health. I'd be even happier if they would follow through on their announced policy.

[The End]

The Future of Diagnostic Kits and Reagents

By ADRIEN L. RINGUETTE

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THERE ARE A NUMBER of recent developments which significantly affect the regulation of diagnostic kits and reagents. Among these are new final regulations, which are not based on any specific statutory mandate. Other developments include the likelihood of new medical devices legislation, recent decisions of the Supreme Court, and a fundamentally new regulatory philosophy of the Food and Drug Administration (FDA).

On March 15, 1973, the Commissioner of Food and Drugs published his final regulations on the subject "In Vitro Diagnostic Products for Human Use."[1] He noted that a total of 47 comments had been received responding to his initial proposal of August 17, 1972,[2] and after

[1] 38 Fed. Reg. 7096 (1973). These final regulations, entitled *Labeling Requirements and Procedures for Development of Standards for In Vitro Diagnostic Products for Human Use*, constituted the first comprehensive regulatory program for *in vitro* diagnostic products as a class. Included were provisions concerning detailed labeling requirements, procedures for establishing, amending or repealing standards, confidentiality of submitted information, court appeal, regulatory action, establishment registration, product listing and good manufacturing practices.

[2] 37 Fed. Reg. 16613 (1972). This proposal, entitled *Proposed Establishment of Procedures for Developing Statements of Policy or Interpretative Regulations*, contained the basic provisions ultimately adopted, with some modification, in the final regulations of March 15, 1973. Publication of proposed regulations was anticipated, since the Commissioner of Food and Drugs had announced on January 19, 1972, that in the near future proposed regulations governing *in vitro* diagnostic products would be issued. This announcement appeared in a *Federal Register* statement entitled *Notice to Manufacturers, Packers and Distributors* (37 Fed. Reg. 819 (1972)). The Notice urged manufacturers (1) to gather evidence that their products are accurate and reliable and that they conform to good manufacturing practices, (2) to test their products before marketing to insure the dependability and consistency of their results, (3) to perform premarket testing of their products relative to predisposing test conditions or patient abnormalities, and (4) to assure the adequacy of directions for use in the labeling of their products.

evaluating some of these comments, he added Part 167, "In Vitro Diagnostic Products for Human Use," to Chapter 21 of the Code of Federal Regulations.

As the Commissioner indicated, these products are intended for use "in the collection, preparation and examination of specimens taken from the human body."[3] They are not used in or on the body, and are thus characterized as *in vitro* as distinguished from *in vivo* products. It has been established that FDA jurisdiction extends to *in vitro* as well as *in vivo* products, notwithstanding the fact that they are only indirectly used in patient care.[4] Furthermore, the term "diagnostic products" refers to the fact that these are products which are intended for use "in the diagnosis of disease or in the determination of the state of health in order to cure, mitigate, treat, or prevent disease or its sequelae."[5] This definition encompasses both devices, as defined by Section 201(h),[6] and drugs, as defined by Section 201(g),[7] of the Federal Food, Drug, and Cosmetic Act, hereafter referred to as the Act.

Legal Basis for the Regulations

Significantly, the Commissioner chose not to further classify *in vitro* diagnostic products as either drugs or devices within the meaning of the Act. Nevertheless, the Commissioner made clear that if necessary to bring violative products into compliance, and pending the enactment of new device legislation, products will be regarded and classified

[3] 21 C. F. R. § 167.1(a) (1973) defines "*in vitro* diagnostic products" in part as "those reagents, instruments and systems intended for use in the diagnosis of disease or in the determination of the state of health in order to cure, mitigate, treat, or prevent disease or its sequelae. Such products are intended for use in the collection, preparation and examination of specimens taken from the human body. These products are drugs or devices as defined in section 201(g) and 201(h), respectively, of the Federal Food, Drug, and Cosmetic Act (the act) or are a combination of drugs and devices, and may also be a biological product subject to section 351 of the Public Health Service Act."

[4] In 1969 the Supreme Court held in *United States v. Bacto-Unidisk*, 394 U. S. 784 (1969), that an antibiotic sensitivity disc, which is impregnated with an antibiotic drug, is within the scope of the Federal Food, Drug, and Cosmetic Act, even though not administered to the patient and thus used only indirectly in patient care. The decision did not dispose of the issue of whether particular *in vitro* diagnostic products are drugs or devices; however, it did put to rest the contention that such products are not subject to the Act at all.

[5] 21 C. F. R. § 167.1(a) (1973).

[6] 21 U. S. C. § 321(h) (1970).

[7] *Id.* § 321(g).

as drugs under the Act.[8] Drugs which are further classified as new drugs, of course, are subject to premarketing clearance controls under Section 505[9] of the Act, whereas devices are not. Both drugs and devices, however, are subject to the adulteration and misbranding provisions contained in Sections 501[10] and 502[11] of the Act, and regulations based upon these provisions therefore apply to *in vitro* diagnostic products as a class.

A brief look at the regulations of March 15, 1973 will throw further light on the FDA position. There are two principal operative sections. Section 2 contains comprehensive and detailed requirements for the labeling of *in vitro* diagnostic products.[12] Then Acting Commissioner Sherwin Gardner, in a statement delivered before a Congressional committee on May 30, 1973, characterized them as the most comprehensive labeling requirements ever issued by FDA. As he stated, they require "full directions for use including warnings, precautions, statements regarding history of the tests, procedures for obtaining results, possible interfering agents, cautionary procedures and quality controls, expected results and their meaning and bibliographies of pertinent references."[13] These requirements, it would seem, are grounded in Section 502 of the Act, which contains the statutory provisions pertaining to the labeling of drugs and devices.

Product Class Standards

Section 3 of the regulations establishes a procedure for the issuance of product class standards for *in vitro* diagnostic products.

[8] On August 17, 1972, proposed *in vitro* diagnostic product regulations (37 Fed. Reg. 16613 (1972)) comments were received objecting to the treatment of these products as a class without any effort to classify them as drugs or devices. In the preamble to the March 15, 1973, final regulations (38 Fed. Reg. 7096 (1973)) the Commissioner responded that "until new device legislation is enacted and where the authority inherent in section 505 of the Federal Food, Drug, and Cosmetic Act is necessary to protect the public health, products will be regarded and classified as drugs under the Act. The FDA believes it is not in the public interest to spend time determining which *in vitro* diagnostic products are drugs and which are devices for purposes of this regulation. Such a determination will be made only when necessary to bring violative products into compliance."

[9] 21 U. S. C. § 355 (1970).

[10] *Id.* § 351.

[11] *Id.* § 352.

[12] 21 C. F. R. § 167.2 (1973). This section concerning labeling requirements prescribes the kinds of information which must appear on the product label and, if applicable, the outside container or wrapper and accompanying labeling such as a product insert.

[13] Statement by Acting Commissioner of Food and Drugs Sherwin Gardner, May 20, 1973, before the Subcommittee on Intergovernmental Relations, House Committee on Government Operations.

These are defined as statements describing performance requirements necessary to assure accuracy and reliability of results, specific labeling requirements necessary for the proper use of a particular class, and procedures for testing products to assure satisfactory performance.[14] Then Acting Commissioner Sherwin Gardner in his testimony of May 30, 1973 commented that "The procedure for establishing these standards *to the extent appropriate under present law* parallels the procedure set out in the proposed medical device legislation."[15] However, since there is nothing in existing law specifically authorizing the issuance of product class standards for drugs or devices, this authority must be inferred from the general provisions of Sections 501 and 502 of the Act dealing with the adulteration and misbranding of drugs and devices. Section 505 of the Act provides for the premarketing clearance of new drugs, and does not constitute a basis for the issuance of product class standards.

In terms of fundamental purpose and design, the *in vitro* diagnostic product regulations may be contrasted with the regulations of May 11, 1972[16] establishing procedures for the classification of over-the-counter (OTC) drugs. An essential purpose of the OTC drug regulations is to promulgate monographs establishing conditions under which OTC drugs are generally recognized as safe and effective (GRAS/GRAE) and thus exempt from classification as new drugs and from the requirement of premarketing clearance under Section 505 of the Act.

In contrast, the basis in the diagnostic product regulations for the establishment of a product class standard is the need "to reduce or eliminate unreasonable risk of illness or injury associated with exposure to or use of an *in vitro* diagnostic product. . . ."[17] There is no administrative determination of the conditions under which such products will be regarded as drugs, let alone new drugs. Thus, in my judgment, no prerequisites are established on the basis of which premarketing clearance under Section 505 of the Act can be imposed upon these products, notwithstanding the assertion in the preamble that the Commissioner has the authority to do so.

The question naturally arises whether or not there is a sound legal basis for the *in vitro* diagnostic product regulations. That these regulations are considered by FDA as substantive is clearly indicated

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[14] 21 C. F. R. § 167.2 (1973).

[15] Statement by Acting Commissioner of Food and Drugs Sherwin Gardner, May 20, 1973, *supra*, note 13.

[16] 37 Fed. Reg. 9464 (1972).

[17] 38 Fed. Reg. 7100 (1973).

not only in the preamble[18] but in the testimony of then Acting Commissioner Sherwin Gardner on May 30, 1973.[19] This matter of the issuance of binding regulations in the enforcement of Sections 501 and 502 of the Act is a fundamental issue and was not considered by the Supreme Court in its opinions issued on June 18, 1973[20] in the several widely publicized drug cases involving issues related to the enforcement of Section 505 of the Act and the statutory definition of new drugs. The Supreme Court did not review regulations seeking to expand upon FDA's power under Sections 501 and 502 of the Act.

The Supreme Court held that it was implicit in the regulatory scheme of the Act that the FDA has jurisdiction to decide with administrative finality the new drug status of individual drugs or classes of drugs.[21] It does not follow from that holding, however,

[18] In response to the proposed *in vitro* diagnostic product regulations of August 17, 1972, a number of comments raised the point that the sections cited by FDA as authority for the regulations do not justify issuance of product class standards having substantive effect or substantive rule-making determinations of adulteration or misbranding. On this point FDA stated (38 Fed. Reg. 7096 (1973)) that the question of its authority to issue regulations of this nature had been discussed in its publication of procedures for the classification of over-the-counter drugs and that the conclusions reached there were equally applicable to the *in vitro* diagnostic product regulations.

In its OTC drug regulations of May 11, 1972, FDA took the position that "numerous Supreme Court cases . . . have upheld the right to proceed by substantive rule making rather than on a case-by-case basis, to particularize general statutory standards" (37 Fed. Reg. 9471 (1972)). Thus, FDA stated that it is "within the discretion of the Commissioner, subject to court review, to decide whether the circumstances warrant a proceeding to enforce the act through interpretive guidelines that can be collaterally attacked in enforcement litigation or through substantive rules that are binding upon court appeal." 37 Fed. Reg. 9472 (1972).

[19] *See, e.g.*, note 13 *supra*, where Acting Commissioner of Food and Drugs Sherwin Gardner, in his statement of May 30, 1973, stated that "these regulations also establish procedures for the development of *mandatory* performance standards for these products" (emphasis added) and that "any *in vitro* diagnostic product is subject to regulatory action if it fails to conform to the standards or any of the general labeling requirements."

[20] *Weinberger v. Bentex Pharmaceuticals, Inc.*, 93 S. Ct. 2488 (1973); *Ciba Corp. v. Weinberger*, 93 S. Ct. 2495 (1973); *USV Pharmaceutical Corp. v. Weinberger*, 93 S. Ct. 2498 (1973).

[21] In the *Bentex* case, Mr. Justice Douglas, writing for the Court, noted: We think that it is implicit in the regulatory scheme, not spelled out in *haec verba*, that FDA has jurisdiction to decide with administrative finality, subject to the types of judicial review provided, the "new drug" status of individual drugs or classes of drugs. The deluge of litigation that would follow if "me-too" drugs and OTC drugs had to receive *de novo* hearings in the courts would enure to the interests of manufacturers and merchants in drugs, but not to the interests of the public that Congress was anxious to protect by the 1962 amendments, as well as OTC drugs and drugs covered by the 1972 Act. 93 S. Ct. at 2494.

that the FDA can dispense with case-by-case enforcement of adulteration and misbranding provisions of the Act by the promulgation of standards which are determinative of these issues.

Problems Facing FDA

One of the problems which FDA would face in any litigation of this issue is how to rationalize the different provisions of Section 701(a)[22] and 701(e)[23] of the Act. The former confers authority to promulgate regulations for the efficient enforcement of the Act and must constitute the legal basis for the *in vitro* diagnostic products regulations. The latter confers upon FDA specific authority to issue substantive regulations in certain specific instances subject to specific procedural safeguards.[24] It would require a considerable stretching of the statutory framework to disregard Section 701(e) and to elevate Section 701(a), which contains no procedural safeguards, to a status which it has not had in more than 35 years of operations under the Act.

The philosophy of regulation which the FDA General Counsel Peter Hutt expressed in an address delivered last December seeks to overcome this problem.[25] Regarding the Act as in the nature of a constitution, that is, as establishing a set of fundamental objectives, he considers the mission of FDA as one of implementing these objectives through the most effective and efficient controls that can be devised. Elaborating on this point, he stated:

Except where expressly prohibited, I believe the Food and Drug Administration is obligated to develop whatever innovative and creative regulatory programs

[22] 21 U. S. C. § 371(a) (1970).

[23] *Id.* § 371(e).

[24] Under § 701(e) of the Act, procedures are established for the issuance, amendment or repeal of regulations issued in certain designated situations. Section 701(e) is applicable in the case of regulations concerning definition and standards of identity for foods (§ 401), foods for special dietary uses (§ 403(j)), emergency permit control (§ 404(a)), tolerances for poisonous ingredients in foods (§ 406), the establishment of appropriate tests for methods of assay for drugs recognized in an official compendium (§ 501(b)), designation of certain chemical derivative substances as habit-forming (§ 502(d)) and determinations of labeling cautions necessary for the protection of the public health on drugs found liable to deterioration (§ 502(h)).

Such regulations may be issued only in accordance with well-defined procedural rights, including that of a public hearing for the purpose of receiving evidence relevant and material to issues raised in objection to the regulations. Furthermore, § 701(f) contains express procedures for judicial review of regulations issued under § 701(e) in the case of actual controversy as to the validity of a § 701(e) regulation.

[25] Address by Peter Hutt, *Philosophy of Regulation Under the Federal Food, Drug, and Cosmetic Act*, to the Food and Drug Law Institute—Food and Drug Administration Sixteenth Annual Educational Conference, Dec. 12, 1972.

are reasonable and are most appropriate to achieve the fundamental objectives laid down by Congress.[26]

It seems clear that the *in vitro* diagnostic products regulations constitute an illustration of that perceived mission.

It is not my purpose today to dwell at length on the legal basis for these regulations. My topic is "The Future of Diagnostic Kits and Reagents," and I do not intend to focus on this issue in a narrow legal sense. One should also consider, among other things, the need for a new regulatory program, the feasibility of a legislative solution, and the reasonableness of the regulations when considered in the light of available alternatives. Let us look at some of these considerations.

Need for a New Regulatory Program

With respect to the need for a new regulatory program for *in vitro* diagnostic products, I have previously dealt with that subject at length[27] and thus will only summarize my position at this time.

By and large, the development and use of *in vitro* diagnostic products has become an important part of health care since the enactment of the Act in 1938. Early tests conducted on the blood, urine or tissues of patients were crude, and the reagents employed were made up by the physician or the laboratory worker. The instruments employed were usually obtained from commercial sources and were of a general purpose character. It is important to note that the performance of a test invariably involves, broadly speaking, some technique of measurement, and in most cases some kind of instrumentation is required. Today, *in vitro* diagnostic products range from specially prepackaged and diluted solutions to unitized disposable test systems and to automated test systems involving complicated instrumentation. Complete systems are now being marketed, including not only reagent materials, but also electronic, optical, nuclear and other measurement devices. In fact, there is a distinct trend toward the marketing of these complete systems because of the rapidly growing volume of testing done and the subsequent need for a higher degree of mechanization and automation.

With this growth and development pattern, involving complex instrumented test systems, the technologies utilized more closely ap-

[26] *Id.*

[27] Ringuette, *Regulatory Aspects of Reagents*, 27 Food Drug Cosm. L. J. 557 (1972).

proximate devices than drugs. There are fundamental differences between *in vitro* diagnostic products and drugs. The traditional concept of drug safety is based on toxicity to the patient, and again the concept of effectiveness as applied to drugs involves their pharmacological effects in the body. These considerations are not applicable to *in vitro* tests, and the sciences involved in their development and use relate to other areas.

It is therefore understandable that the premarketing clearance authority of Section 505 of the Act has not generally been invoked as a regulatory mechanism governing *in vitro* diagnostic products. This mechanism was not designed for such products and could not reasonably be applied to them. Furthermore, until the Supreme Court ruled on the *Difco* case in 1969,[28] it had not been established that such products were subject to FDA jurisdiction. Manufacturers have traditionally considered them, to the extent covered by the Act at all, as devices rather than drugs.

I believe it is a fair conclusion that there is no existing statutory mechanism for the reasonable and proper regulation of *in vitro* diagnostic products under the Act or under any other statute. The holding in the *Difco* case that antibiotic sensitivity discs are drugs rather than devices did little more than highlight the existence of a gray area between drugs and devices. In that case the evidence showed there was a close relationship between the administration of the antibiotic as a drug and its use in a sensitivity disc. It has not been established how far this holding can be extended. The increasing importance of *in vitro* diagnostic products would seem to justify the development of a new regulatory program which is appropriate for these products.

The FDA evidently considered the question of appropriate regulation of *in vitro* diagnostic products, and concluded, at least tentatively, that it is unnecessary to use the full premarketing clearance authority over diagnostic kits and reagents. FDA General Counsel Peter Hutt announced on April 11, 1972 that the FDA can handle such products under standard-making authority under existing law, and that it would soon be announcing a new procedure for the exercise of such authority.[29] Such a program was thereafter proposed in the *Federal Register* of August 17, 1972,[30] and incorporated in the regulations of March 15, 1973.[31]

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[28] *United States v. Bacto-Unidisk*, 394 U. S. 784 (1969).

[29] FDC Reports, The Pink Sheet, April 17, 1972, at 20.

[30] 37 Fed. Reg. 16613 (1972).

[31] 38 Fed. Reg. 7096 (1973).

Development of a Legislative Program

The Administration has participated in efforts to develop just such a program for medical devices through legislative means since 1969. In September, 1969, a National Conference on Medical Devices, sponsored by the Association for the Advancement of Medical Instrumentation, was held in Bethesda, Maryland. The purpose of the conference, whose participants came from all sectors, was to develop recommendations for an equitable resolution of the problems existing in the medical device field. At the conference, Dr. Herbert L. Ley, then Commissioner of Food and Drugs, described the recent developments in the courts concerning medical devices and went on to note that those cases "do provide a legal basis for dealing with some of the products in this field, but they have not lessened the need to develop a broader regulatory system. In fact, the decisions have increased the urgency for clarification."[32] As can be seen, even at this early stage, FDA was thinking in terms of a comprehensive regulatory program for medical devices.

At the same time there was continuing interest on the part of government in new legislation for medical devices. In the President's message of October 30, 1969, the President stated:

> Certain minimum standards should be established for such devices; the Government should be given additional authority to require premarketing clearances in certain cases. The scope and nature of any legislation in this area must be carefully considered, and the Department of Health, Education and Welfare is undertaking a thorough study of medical device regulation. I will receive the results of that study early in 1970.[33]

The report referred to by the President was officially released in September of 1970.[34] This report was the result of the efforts of the Cooper Committee and concluded that the need for assuring the reliability and effectiveness of medical devices necessitated explicit legislation. It was further recommended that there be undertaken a systematic review of devices presently on the market by an appropriately constituted group, broadly representative of the concerned scientific community. The objective of the review would be to categorize devices into those that should be exempt from standard setting and premarketing review, those for which standards should be set

[32] Address by Dr. Herbert L. Ley before the National Conference on Medical Devices in Bethesda, Maryland, September 1969 in 3 J. of The Ass'n for the Advancement of Medical Instrumentation 180 (1969).

[33] President's Consumer Message, Oct. 30, 1969.

[34] Study Group on Medical Devices (Cooper Committee), *Medical Devices: Summary and Recommendations*, 1970.

and enforced to assure safety and reliability, and those requiring premarketing review. It was also recommended that an acceptable plan be developed for assuring expert scientific review of the safety and effectiveness of medical devices, at the clinical application phase and prior to marketing.

Proposed Legislation

Legislation to implement these recommendations was introduced in the 92nd Congress in December, 1971,[35] and the Administration bill has been reintroduced in the 93rd Congress.[36] More recently, on August 3, 1973,[37] both Senator Kennedy and Congressman Rogers

[35] The Administration's Medical Device Safety Act of 1971, H. R. 12316, 92nd Cong., 1st Sess. (1971) and S. 3028, 92nd Cong., 1st Sess. (1971). In amending the Federal Food, Drug, and Cosmetic Act, the Bill would authorize the Secretary of Health, Education and Welfare to establish standards for devices relating to the composition, construction, properties, uniform identification or performance whenever such action is found necessary to reduce or eliminate unreasonable risk of illness or injury. The Administration's bill would also give the Secretary authority to require premarket scientific review of any device used in life-threatening situations where the composition, construction or properties of the device are such that in relation to the intended use the device presents an unreasonable hazard and there is a no more practicable means to reduce the hazard. The Administration's bill also contains provisions which would require devices to be manufactured in accordance with current good manufacturing practices, registration of manufacturers of devices and the devices themselves, increased inspection authority, maintenance of specified records, periodic reports to FDA, notification to the Government and to customers of defects in devices, and if so required by the Secretary, remedy of the defect, replacement of the device or refund of the purchase price.

[36] Medical Device Safety Act, H. R. 6073, 93rd Cong., 1st Sess. (1973) and S. 1446, 93rd Cong., 1st Sess. (1973). In reintroducing the Administration's Medical Device Safety Act, Senator Javits gave recognition to the efforts to develop suitable amendments to the Administration Bill and noted that "the most significant amendment provides for a new definition of medical devices." Senator Javits expressed his belief that "we should stand ready to consider all reasonable amendments developed by responsible groups. . . ."

[37] Medical Device Amendments of 1973, H. R. 9984, 93rd Cong., 1st Sess. (1973) and S. 2368, 93rd Cong., 1st Sess. (1973).

In numerous respects this legislation parallels the provisions of the Administration's Medical Device Safety Act. However, there are important new or modified provisions, some of which reflect cooperative efforts with FDA to develop suitable amendments to the Administration Bill. Following is a discussion of some of the important differences.

The legislation provides for the appointment of scientific classification panels to review and classify devices on the basis of safety and effectiveness. Panel recommendations, which must be submitted to the Secretary within one year, would classify devices as requiring premarketing scientific review, requiring standards or exemption from either scientific review or standard-setting procedures.

Standards issued under this legislation would relate to the "safety and

(Continued on the following page.)

have introduced similar legislation which incorporates a number of amendments to the Administration bill, some of them after a consensus had been reached among government, professional and trade groups. They have, in addition, introduced some new amendments.

Dr. Charles C. Edwards, then Commissioner of Food and Drugs, more recently Assistant Secretary for Health and Scientific Affairs, has repeatedly stressed the need for medical device legislation that fully takes into account the difference between devices and drugs. As he has stated: "The notion that legislation will necessarily treat devices as drugs is ill-conceived and invalid."[38] Clearly, the concepts enunciated by the Cooper Committee and reflected in the Administration position were intended to establish a sound yet flexible regulatory program.

Thus, the proposed legislation would create two levels of regulatory authority, first, a program for the promulgation of performance standards, and second, a program for scientific review prior to marketing. The various bills differ somewhat in their mechanisms, but are derived from the Cooper Committee recommendations.

The Administration, as well as various interested professional and trade groups, have agreed upon the desirability of a clarification of the term "devices" so that articles such as *in vitro* diagnostic products commonly regarded as devices can be regulated under the appropriate provisions of medical devices legislation. Dr. Edwards so indicated in an address given on November 14, 1972,[39] and such a clarification was included in the bills introduced by both Senator Kennedy and Congressman Rogers.[40] Indeed, Congressman Rogers made the following statement on the floor of the House on August 3, 1973:

(Footnote 37 continued.)
effectiveness" of the device. Otherwise, standards would be established in substantially the same manner as under the Administration Bill. Under premarketing scientific review procedures the emphasis would be on whether such review is necessary to ensure the safety and effectiveness of the device whereas under the Administration Bill the emphasis is on those devices used in life-threatening situations.

Although there are some differences between the Senate and House Bills on this point, both provide for informed consent of human participants in certain tests involving medical devices. Furthermore, this legislation contains an exemption for custom devices ordered by a physician, procedures for product development protocols for custom devices, a provision on federal preemption, and the new definition of device which includes *in vitro* reagents.

[38] Address by Charles Edwards, *Medical Devices, A Time for Decision*, to the Association for the Advancement of Medical Instrumentation, Mar. 19, 1971.

[39] Address by Charles Edwards to the Scientific Apparatus Makers Association, Nov. 14, 1972.

[40] 119 Cong. Rec. S. 15623 (daily ed. Aug. 3, 1973) (Introductory statement by Senator Edward F. Kennedy to S. 2368, Medical Device Amendments of 1973); 119 Cong. Rec. H. 7495 (daily ed. Aug. 3, 1973) (Statement by Congressman Paul G. Rogers).

Recent Court decisions have demonstrated that considerable confusion exists over the high degree of similarity between the present statutory definitions for the terms "drugs" and "devices." Indeed, the Food and Drug Administration's regulatory history in attempting to regulate devices is replete with examples of battles over phraseology, definition, and prosecution. A definition that will clearly define what is a device as opposed to a drug is of concern not only to the Food and Drug Administration but to the device manufacturers who must comply with the law; and it is obvious that to have the kind of consistent enforcement that will protect the consumer, there must be a consistent, legally sound definition.[41]

Thus, *in vitro* diagnostic products are expected to be covered by medical devices legislation when this is enacted.

The question has arisen, since there is a general consensus that *in vitro* diagnostic products should be covered under medical devices legislation, whether or not the FDA should proceed with its regulatory program. Dr. Edwards answered that question for the FDA on November 14, 1972 in the following manner:[42]

The big question is: How does FDA regulate these products in the absence of anticipated legislation? Does the FDA simply mark time until Congress passes such legislation? We should not; indeed we cannot, and will not. Authority to set performance standards for product classes of diagnostic products is explicit in the Food, Drug and Cosmetic Act.

Interim Regulatory Program

In the development of its interim regulatory program FDA has relied heavily on the advice of its Diagnostic Products Advisory Committee. This is as one would expect, for in recent years FDA has employed this technique increasingly as the means by which policy is established and consensus on regulatory programs sought. Examination of the pending legislation on medical devices suggests that advisory committees are likely to play an even more important role in the future.[43]

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[41] *Id.*

[42] *Supra*, note 39.

[43] Both the Administration's Medical Device Safety Act and the Kennedy-Rogers Medical Device Amendments of 1973 provide for use of expert advisory committees. Both authorize the Secretary to appoint independent advisory committees under certain circumstances in the course of development of device standards. These committees would address matters requiring the exercise of scientific judgment and report and make recommendations on the device standard.

In the case of products subject to premarketing scientific review, standing advisory scientific panels would be employed. In addition, the independent advisory committee mechanism would also be available in this instance.

Provision is also made in both bills for an Advisory Council on Devices to advise the Secretary on policy matters relating to carrying out the provisions of the Act. Furthermore, the Kennedy-Rogers legislation would utilize expert classification panels for initial classification of medical devices. *See* note 37, *supra*.

To protect the public interest best in developing any regulatory program I suggest that there is a need for widespread comment and airing of views from all sectors. In developing a program for diagnostic products, for example, it is essential that FDA tap the combined know-how of government, a representative cross section of the medical profession, scientists from outside medicine, and industry. Dr. Edwards, in an address advocating additional legislation for medical devices, stated:

> Basic in our thinking is the concept that there must be the maximum involvement from the scientific community—the engineers, physicians, academia, hospitals, as well as the industry—in examining the present and in developing and operating an action program for the future.[44]

Furthermore, he has indicated that the FDA is "not inflexible" and is "anxious to listen, to talk to industry and the profession."[45]

FDA has selected the advisory committee mechanism as the means of meeting this objective in the case of diagnostic products. Further evidence of FDA's goals on this point is revealed in an examination of the nature and functions of advisory committees under the pending Administration bill.[46] One provision in the bill provides for the establishment of an Advisory Council on Devices, whose purpose is to advise the Secretary on matters of policy.[47] The bill goes on to provide that the makeup of the Advisory Council shall consist of "manufacturers and other persons with special knowledge of the problems involved in the regulation of various kinds of devices . . . , members of the professions using such devices, scientists expert in the investigational use of devices, engineers expert in the development of devices, and members of the general public representing consumers of devices."[48] The legislation recently introduced by Senator Kennedy and Congressman Rogers[49] strongly reaffirm the concept of industry participation in the advisory committee structure.

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[44] Address by Charles Edwards to the Medical-Surgical Manufacturers Association, Dec. 9, 1970.

[45] *Supra*, note 38.

[46] *Supra*, note 43.

[47] Section 708(a), Administration's Medical Device Safety Act, *supra*, note 36.

[48] *Id.*

[49] Section 511(b) of the Medical Device Amendments of 1973, for example, provides that classification panel members "shall possess adequate skill in the use of or experience in the development, manufacture, perfection, or utilization of such devices and may be nominated by appropriate scientific, trade and consumer organizations." This section also requires that "notwithstanding any other provisions of law governing the appointment and compensation of employees of the United States, the Secretary may appoint individuals associated with or employed by persons manufacturing or using medical devices or persons otherwise potentially affected by the provisions of this Act, to such panels. . . ."

It seems clear that in each instance what is sought in the Administration approach as well as that of Senator Kennedy and Congressman Rogers is widespread representation, as appropriate, for purposes of achieving a consensus on the action to be taken.

Also relevant is the Federal Advisory Committee Act, enacted by the 92nd Congress. The term "advisory committee" encompasses both the present FDA Diagnostic Products Advisory Committee and the advisory committees which would be created under the proposed legislation. Sections 5b(2) and (3) of the Federal Advisory Committee Act require that any legislation establishing, or authorizing the establishment of an advisory committee, must:

> (2) require the membership of the advisory committee to be fairly balanced in terms of the points of view represented and the functions to be performed by the advisory committee;
>
> (3) contain appropriate provisions to assure that the advice and recommendations of the advisory committee will not be inappropriately influenced by the appointing authority or by any special interest, but will instead be the result of the advisory committee's independent judgment.[50]

The purpose of these provisions is to insure balanced representation on advisory committees and to avoid undue influence on government decisions, through advisory committees, by persons who will be affected by those decisions. The statute requires that "to the extent they are applicable" these points must be followed by agency heads and other federal officials in creating advisory committees.[51]

Although no guidance is offered by the statute or the legislative history as to the meaning of the phrase "to the extent they are applicable," it appears that the provisions of subsections 2 and 3 should be applicable to all advisory committees.

It is recognized that under certain circumstances the requirements of fair balance and avoidance of inappropriate influences could come into conflict. However, there is a fundamental need to distinguish between the issues of fair balance and conflict of interest. That it may be necessary under certain circumstances for an advisory committee member to remove himself from certain deliberations on the ground of conflict of interest does not constitute so great an obstacle as to justify no participation at all. To eliminate such persons from membership on advisory panels often may make it impossible to fulfill the requirement of fair balance. It is suggested that advisory committees should

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[50] Federal Advisory Committee Act, Pub. L. No. 92-463, 86 Stat. 770 (1972).

[51] *Id.*, § 5(c).

be fairly balanced in original composition and that adjustments should be made in the course of committee deliberations to deal with and avoid conflict of interest matters as they arise.

In light of the attitudes reflected in the proposed medical devices legislation and the Federal Advisory Committee Act with regard to the makeup of advisory committees I turn now to the extent to which the existing Diagnostic Products Advisory Committee meets the objective of fair balance. At the outset it is clear that FDA is to be congratulated for the quality and nature of the present membership of its Diagnostic Products Advisory Committee. There is substantial and excellent representation from the field of laboratory medicine. Within the field of laboratory medicine, disciplines such as pathology, hematology, clinical chemistry, microbiology, medical technology and immunology are represented on the committee. These disciplines are important users of *in vitro* diagnostic products. It is evident that in its selection FDA has selected those disciplines without which a committee of this nature could not function. However, we would suggest that the deliberations of the group could benefit from the presence of representatives from other groups having experience with *in vitro* diagnostic products. For example, practicing physicians who use *in vitro* diagnostic products in their day-to-day medical practice would be very important. Furthermore, patient users of *in vitro* diagnostic products, such as diabetics, could also bring an additional dimension to the advisory committee's activities. There is a growing tendency to include consumer representatives on advisory committees even where technical issues are presented. This type of representation has generally worked better than many had anticipated. I believe as well that the committee would benefit from the participation of industry representatives. There is a continually developing body of scientific and technical information within industry which is essential to developing a sound regulatory program.

Conclusion

In conclusion, I wish to state that there is general consensus on a number of important points affecting the future of diagnostic kits and reagents. The first is that there is a need for the development of a new regulatory program covering these products, since existing law, to the extent that it can be applied, is inappropriate and inflexible.

There also seems to be general agreement that it is essential for Congress to develop the new regulatory program in the general field of medical devices, which includes *in vitro* diagnostic products. The broad outlines of this legislation have been generally agreed upon among many segments of the public, although there are some matters which will need to be worked out during the legislative process.

With specific reference to *in vitro* diagnostic products, however, the FDA has undertaken to proceed with an interim regulatory program which is substantially modeled after the proposed legislative program, notwithstanding the absence of final action by Congress. This is undoubtedly due to the gray areas between drugs and devices which exists by virtue of the *Difco*[52] case. As the regulations of March 15, 1973 indicate, the FDA has reserved the right, for enforcement purposes, to treat *in vitro* diagnostic products as drugs, and where appropriate, as new drugs subject to the premarketing clearance provisions of Section 505 of the Act.[53] Admittedly, this is an uncomfortable situation both for the FDA and industry, and therefore, in my judgment, a considerable amount of restraint would appear to be in order on both sides.

Dr. Edwards has urged that the industry proceed with compliance with the interim regulatory program which the FDA has devised. In his speech of November 14, 1972, he particularly encouraged the industry not to fuel the drug-device controversy as a delaying tactic. He also stated:

> We do not intend to follow lock-step administrative procedures which may be inappropriate, unnecessary, or which put undue restrictions on the manufacturer. We view the *in vitro* diagnostic products area as one which will permit industry innovation and yet allow our agency to achieve reasonable regulation while we both wait on more specific legislation.[54]

If a consensus is to be achieved on this new regulatory program as an interim program pending the enactment of new legislation, I believe it is imperative that all interested groups endeavor as nearly as possible to reach a consensus, along the lines which Dr. Edwards has urged, which will serve the public interest by assuring the reliability of *in vitro* diagnostic products while at the same time encouraging the development of worthwhile techniques and products.

[The End]

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[52] *United States v. Bacto-Unidisk*, 394 U. S. 784 (1969).

[53] 38 Fed. Reg. 7096 (1973).

[54] *Supra*, note 37.

The Over-the-Counter Drug Review— Helping the Client Make Decisions

By DANIEL F. O'KEEFE, JR.*

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ON MAY 11, 1972, the Commissioner of Food and Drugs issued a final order establishing procedures for the classification and review of all over-the-counter medicines (numbering between 100,000 and one-half million products according to the Food and Drug Administration (FDA)) from the standpoint of safety and effectiveness.[1] Under the procedures, FDA would determine, on a category-by-category basis, which drugs are "generally recognized as safe and effective" (GRAS/GRAE) and which are not "misbranded" and those which do not fall within those categories and are therefore illegally on the market if they do not have an approved New Drug Application (NDA).

While there are many issues involved in the Review, it is very plain that it represents for manufacturers and distributors of over-the-counter medicines the advent of great challenge and change. Many products available to the public will be reformulated and relabeled and the legal status of products may be altered. In a broader perspective, Dr. Charles Edwards, Assistant Secretary for Health, Department of HEW, and former Commissioner of Food and Drugs, initiated the review progress and has espoused its usefulness to the

* Mr. O'Keefe was Vice President, Legal Affairs and Secretary of The Proprietary Association. He wishes to point out that the views expressed in this paper are his own and are not necessarily the views of The Proprietary Association. He is now President of the Food and Drug Law Institute.

[1] 21 C. F. R. § 130.301 (1973). *See also* 37 Fed. Reg. 9473 (1972).

government as a conceptual tool. It would not be surprising to see the concept of advisory review panels with industry and public participation expanded to encompass problems in prescription drugs, food, cosmetics and other areas, particularly where difficult decisions involving safety are presented. The process has the benefit of helping to insulate the beleaguered FDA from making, on its own, controversial judgments in sensitive areas, and of helping the agency obtain the advice of independent (outside-the-agency), expert assistance on scientific issues.

The Over-the-Counter (OTC) Drug Review presents management and their attorneys and scientific advisors with difficult and complex decisions on which they should focus attention *now*. On April 5, 1973, the FDA published the first proposed "monograph." It dealt with antacid products.[2] Antacid products were chosen by the FDA as the "pilot" project, and a great deal was learned both by government and industry during the process.

This paper is designed to provide the reader with an insight into the Review process and some of the legal/regulatory issues, as well as to provide a framework for advising the client on decision making in connection with the Review.

Background, Scope and Procedures for the Review

Under the Federal Food, Drug, and Cosmetic Act,[3] "new drugs" are defined as those drugs which are "not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective [as labeled]. . . ."[4] Thus, any drug which is so "generally recognized" as safe and effective is not a "new drug"—regardless of when it was introduced on the market—and therefore is not subject to the extensive government controls to which a "new drug" is subject. In addition to those drugs which are GRAS/GRAE, the law exempts from the definition of "new drug" (1) any drug marketed prior to passage of the Federal Food, Drug, and Cosmetic Act of 1938, the labeling of which still contains the same representations concerning its use and (2) any drug marketed on the day preceding the enactment of the 1962 Drug Amendments if such drug was generally recognized as safe on that date and not "covered by" an effective NDA and if the labeling still contains

[2] 38 Fed. Reg. 8714-24 (1973).
[3] 21 U. S. C. §§ 301-92 (1970).
[4] *Id.* § 321(p)(1) (1970).

the same representations concerning its use.[5] These are the so-called "grandfather" provisions.

It is important to note that, while GRAS/GRAE status or "grandfather" provisions exempt drugs covered by any of those provisions from "new drug" control, *any* drug, GRAS/GRAE or not, "grandfathered" or not, is liable to seizure, injunction, and criminal prosecution if it is misbranded.[6] A drug is deemed misbranded if, among other things, its labeling is "false or misleading in any particular,"[7] if its labeling does not bear "adequate directions for use,"[8] or if it is "dangerous to health when used in the dosage, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof."[9] Thus, *any* drug deemed unsafe or ineffective in the context of its label claims is liable to regulatory action.

The intent of the FDA to define, by administrative rule making, the parameters of both GRAS/GRAE and misbranding is made clear in its final procedural regulation.[10] Under current interpretations, the FDA may initiate proceedings in court to challenge a drug as not GRAS/GRAE, and not covered by one of the "grandfather" provisions, and hence a "new drug." The Agency also may challenge *any* drug as misbranded. However, the burden of proof is on the government to establish the fact of a violation of law. In the OTC Review, the FDA is proposing to define the parameters of the critical terms by regulation.

The FDA also intends the OTC Review to cover *all* over-the-counter drugs (except homeopathic medicines) including "grandfathered" drugs, drugs marketed under the GRAS/GRAE provisions, those possessing a pre-1962 approved NDA and those already reviewed under the Drug Efficacy Study Implementation (DESI) reviews. Although the OTC Review theoretically has no impact on OTC's covered by an approved post-1962 NDA, the FDA has stated that the Review will cover such drugs and that an adverse finding under the Review "may or may not" affect the NDA.[11]

The procedures for the Review are set forth in title 21 of the Code of Federal Regulations.[12] The following several paragraphs outline the content of that important document.

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[5] Drug Amendments of 1962, § 107(c), 76 Stat. 780 (1962), *amending* Federal Food, Drug, and Cosmetic Act § 201(p), 21 U. S. C. § 321(p) (1970).

[6] 21 U. S. C. §§ 331(a), 332-34 (1970).

[7] *Id.* § 352(a).

[8] *Id.* § 352(f)(1).

[9] *Id.* § 352(j).

[10] 21 C. F. R. § 130.301(a)(9) (1973). *See also* 37 Fed. Reg. 9464-73 (1972).

[11] 37 Fed. Reg. 9466, ¶ 24 (1972).

[12] 21 C. F. R. § 130.301 (1973). *See also* 37 Fed. Reg. 9473 (1972).

The Panels and the "Mission"

Under the FDA's order, the Commissioner will appoint advisory review panels of seven "qualified experts" to evaluate the safety and effectiveness of OTC drugs, to review OTC drug labeling and to advise him on the content of monographs establishing conditions under which OTC drugs are GRAS/GRAE and not misbranded—and therefore permitted to be marketed without an NDA.[13]

Seventeen separate panels will be appointed to review twenty-seven different therapeutic categories, including two "catch-all" categories planned for miscellaneous products—one for internal products and one for external products.

The panels may consult with any individual or group, and interested persons may request the opportunity to present oral views to the panel, as well as to submit written data and views.[14]

Information to Be Requested From Industry and Others

Notices in the *Federal Register* regarding each category will request manufacturers and others to submit data and information on a particular category to the FDA for panel review. Information sought will include (1) labeling; (2) a statement of the quantities of active ingredients; (3) animal safety data on individual active components, combinations and finished products; (4) human safety data (including marketing experience and medical literature) on the ingredients, combinations and finished products; (5) efficacy data (including marketing experience, controlled and uncontrolled studies and medical literature) on the ingredients, combinations and finished products; and (6) a summary setting forth the medical rationale and purpose for the drug and its ingredients and the scientific basis for the conclusion that the drug and its ingredients have been proven safe and effective for the intended use.[15]

If controlled studies are not submitted, the summary is to include an explanation of why such studies are not considered necessary.[16]

Standards for Safety, Effectiveness and Labeling

The panels and the Commissioner, in establishing monographs, are to apply the following standards to determine that a category of drugs is GRAS/GRAE and not misbranded:

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[13] *See* 21 C. F. R. § 130.301(a)(1) (1973).

[14] *Id.* § 130.301(a)(3).

[15] *Id.* § 130.301(a)(2).

[16] *Id.*

Safety means a low incidence of adverse reactions or significant side effects under adequate directions for use and warnings against unsafe use as well as low potential for harm which may result from abuse under conditions of widespread availability. *Proof of Safety* shall consist of adequate tests by methods reasonably applicable to show the drug is safe under the prescribed, recommended, or suggested conditions of use. This proof shall include results of significant human experience during marketing. *General Recognition of Safety* shall ordinarily be based upon published studies which may be corroborated by unpublished studies and other data.[17]

Effectiveness means a reasonable expectation that, in a significant proportion of the target population, the pharmacological effect of the drug, when used under adequate directions for use and warnings against unsafe use, will provide clinically significant relief of the type claimed. *Proof of effectiveness* shall consist of controlled clinical investigations as defined in § 130.12(a)(5)(ii), [well-controlled investigations], unless this requirement is waived on the basis of a showing that it is not reasonably applicable to the drug or essential to the validity of the investigation and that an alternative method of investigation is adequate to substantiate effectiveness. Investigations may be corroborated by partially controlled or uncontrolled studies, documented clinical studies by qualified experts and reports of significant human experience during marketing. Isolated case reports, random experience and reports lacking the details which permit scientific evaluation will not be considered. *General recognition of effectiveness* shall ordinarily be based upon published studies which may be corroborated by unpublished studies and other data.[18]

The *benefit-to-risk ratio* of a drug shall be considered in determining safety and effectiveness.[19]

With respect to combinations: "An OTC drug may combine two or more safe and effective active ingredients and may be generally recognized as safe and effective when each active ingredient makes a contribution to the claimed effect(s); when combining of the active ingredients does not decrease the safety or effectiveness of any of the individual active ingredients; and when the combination, when used under adequate directions for use and warnings against unsafe use, provides rational concurrent therapy for a significant proportion of the target population."[20]

In the proposed antacid monograph, the statement is made, in effect, that each active ingredient must contribute at least 25 percent of the total acid neutralizing capacity of the product.[21]

Labeling shall be clear and truthful in all respects and may not be false or misleading in any particular. It shall state the intended uses and results of the product; adequate directions for proper use; and warnings against unsafe use, side effects, and adverse reactions in such terms as to render them likely to be read and understood by the ordinary individual, including individuals of low comprehension, under customary conditions of purchase and use.[22]

I will divert for a moment to mention that on April 5, 1973 the FDA proposed "general conditions" for all OTC drugs.[23] This pro-

[17] *Id.* § 130.301(a)(4)(i) (emphasis added).

[18] *Id.* § 130.301(a)(4)(ii) (emphasis added).

[19] *Id.* § 130.301(a)(4)(iii) (emphasis added).

[20] *Id.* § 130.301(a)(4)(iv).

[21] Proposed Reg. § 130.305(a), 38 Fed. Reg. 8723 (1973).

[22] 21 C. F. R. § 130.301(a)(4)(v) (emphasis added).

[23] Proposed Reg. § 130.302, 38 Fed. Reg. 8714 (1973).

posal would require, among other things, all OTC drugs to be manufactured in accord with current Good Manufacturing Practices Regulations (GMP's), to contain only "safe and suitable" inactive ingredients, to be packaged appropriately, to contain on their labels a general warning to keep medicines out of the reach of children, to contain only levels of active ingredients which are reasonably required to achieve the intended effect and, importantly, the advertising for a product is to recommend its use only under the conditions stated in the labeling. The intent of the FDA in this proposal is somewhat unclear. In some cases, for example, violation of a GMP might result in a charge of adulteration, not misbranding or lack of GRAS/GRAE status. Yet the proposal implies the general conditions must be met fully to be within the monograph.

Content of the Monographs

Each panel is to submit to the Commissioner a report, including a recommended monograph establishing conditions under which the drugs involved are GRAS/GRAE and not misbranded.[24] The monographs may include conditions relating to active ingredients, labeling indications, warnings and directions for use, prescription (Rx), or OTC status, and any other conditions necessary for safety and effectiveness.[25]

The report is also to include a statement of active ingredients, claims or other conditions reviewed and excluded from the monograph as not GRAS/GRAE or as resulting in misbranding.[26]

In addition, the report is to include a statement of active ingredients, claims or other conditions reviewed and excluded from the monograph because of insufficient data.[27] In this case the panel may recommend what testing is required.[28] There will be provided a "reasonable time" in which to obtain this data—two years in the case of the proposed antacid monograph.[29]

Procedures for Finalization of Monographs

The FDA Commissioner must publish in the *Federal Register* a proposed order containing (1) the Commissioner's proposed monograph (this presumably may or may not be the same as the panel's recommended monograph) (referred to hereinafter as "category I" or

[24] *Id.* § 130.301(a)(5).
[25] *Id.* § 130.301(a)(5)(i).
[26] *Id.* § 130.301(a)(5)(ii).
[27] *Id.* § 130.301(a)(5)(iii).
[28] *Id.*
[29] 38 Fed. Reg. 8715 (1973).

the "white list"), (2) a statement of what is excluded from the monograph as not GRAS/GRAE and as misbranded (referred to hereinafter as "category II" or the "black list"), (3) a statement of what is excluded from the monograph because of insufficient data (referred to hereinafter as "category III" or the "gray list"), and (4) the full report of the panel.[30]

Sixty days will be provided for comment on the proposed monograph, and thirty additional days will be provided for a somewhat unique procedure—reply comments.[31]

After evaluation of all comments, the Commissioner will publish in the *Federal Register* another administrative rarity—a "tentative final monograph."[32] Written objections may be filed within thirty days and a request for an oral hearing may be made.[33]

The Commissioner may schedule a "nondelegable" oral hearing.[34] He will decide, when the requests are made, how much time to allow for the oral hearing.[35] It is not clear whether the FDA intends to hold a trial-type hearing or whether only oral argument will be permitted.

The Commissioner will then issue a final monograph.[36] This final monograph will constitute final Agency action from which appeal lies to the courts.[37]

Legal Effect of the Final Monograph

The regulation provides that any product which fails to conform to an applicable monograph "is liable to regulatory action."[38] The preamble to the regulation states that "[d]evelopment of a specific enforcement policy can await promulgation of final monographs. . . . The Commissioner at that time may adopt whatever enforcement policy is best suited to guarantee full compliance by all OTC drugs with the provisions of the act."[39] Thus, the legal effect of the monograph is not spelled out.

It should be noted here, however, that in the government's brief before the U. S. Supreme Court in *Weinberger v. Bentex Pharmaceuticals, Inc.*, it characterized the May, 1972 regulations as *"a procedure for determining in substantive rule making*, by therapeutic class, whether

[30] 21 C. F. R. § 130.301(a)(6).
[31] *Id.*
[32] *Id.* § 130.301(a)(7).
[33] *Id.*
[34] *Id.* § 130.301(a)(8).
[35] *Id.*
[36] *Id.* § 130.301(a)(9).
[37] *Id.* § 130.301(a)(10).
[38] *Id.* § 130.301(a)(12).
[39] 37 Fed. Reg. 9472, ¶ 91 (1972).

particular OTC products not covered by NDA's are generally recognized as safe and effective and not misbranded. . . ."[40]

Products not conforming to the monograph will be permitted time in which to conform.[41] The monograph may be amended.[42] Also, deviations from the monograph may be permitted under abbreviated NDA procedures.[43]

Rationale for the Review—Pro and Con

In its notice of proposed rule making establishing the procedures for the OTC Review, the FDA set forth its rationale for the mechanism chosen.[44] In essence, the FDA expressed its concern that some OTC formulations do not have their claimed effect and are not adequately labeled for their safe and effective use by laymen. The notice stated that the review of prescription drugs was near completion and that estimates of the number of OTC products on the market vary from 100,000 to one-half million.[45] The Agency also stated that it could carry out its responsibility under the Act either by initiating separate court action with respect to each OTC drug deemed in violation of the law or deal with OTC drugs through rule making by therapeutic classes on an industry-wide basis.[46] It chose the rule-making approach in view of (a) the limited resources of the FDA to review each OTC drug on the market, (b) the burden on the Agency, courts, the industry and the scientific community of proceeding on a case-by-case basis, (c) the difficulty of applying the "grandfather" clauses, (d) the length of time required to proceed on a case-by-case basis, (e) the "inequity" of permitting some products to remain on the market while similar products have been the subject of legal action, and (f) the point that most OTC drugs are compounded from relatively few active ingredients.[47]

In the preamble to the final procedural regulation, the FDA made it clear that, in its judgment, it has the legal authority to issue substantive rules defining the conditions under which drugs may be marketed as "generally recognized as safe and effective" and not misbranded.[48] At the same time, the Agency stated that development of a specific enforcement policy could await promulgation of final mono-

[40] Brief for Petitioners at 24, *Weinberger v. Bentex Pharmaceuticals, Inc.*, 41 U. S. L. W. 4858 (U. S. June 18, 1973).
[41] 37 Fed. Reg. 9471, ¶ 81 (1972).
[42] 21 C. F. R. § 130.301(a)(11) (1973).
[43] *Id.* § 130.301(a)(13).
[44] 37 Fed. Reg. 85-86 (1972).
[45] *Id.* at 85.
[46] *Id.* at 86.
[47] *Id.* at 86.
[48] 37 Fed. Reg. 9471-72 (1972).

graphs at which time the Commissioner could adopt whichever enforcement policy (substantive or interpretive) was best suited to guarantee full compliance by all OTC drugs with the provisions of the Act.[49] As previously noted, the legal position of the FDA was further clarified by the government's brief in *Weinberger v. Bentex Pharmaceuticals, Inc.*[50]

From the industry point of view, neither The Proprietary Association, representing manufacturers of those over-the-counter medicines promoted to the public, nor the Pharmaceutical Manufacturers Association, representing manufacturers of prescription medicines and of those over-the-counter products promoted to the health professions, have objected to the concept of the Review per se. Both associations and practically all manufacturers which filed comments did object, however, to the concept that the FDA has the legal authority to issue binding, substantive regulations defining GRAS/GRAE and misbranding. As The Proprietary Association stated in its comments on the proposed regulations: "FDA does have power to promulgate statements of policy and interpretive regulations. But it does not have power to promulgate 'binding substantive rules' [with respect to the over-the-counter review]. . . ."[51]

Thus, at least a large portion of the industry has not objected to the issuance of interpretive regulations under the basic review mechanism set forth by the FDA, but has spoken out against the promulgation of substantive rules, binding on a reviewing court, emanating from that procedure.

The basic industry position with respect to the so-called substantive/interpretive issue is grounded on two factors, legal and practical. Without belaboring the point, the industry feels strongly that the Food and Drug Administration simply does not have statutory authority to issue substantive rules in this area. From a practical standpoint, industry is concerned about the basic fairness of a situation in which seven "experts" review a category of products (twenty-seven categories divided into 200,000 products equals about 7,400 products per category), where the panels are inundated with reams of data from various sources, where the panels consist of "outside" experts who are busy with their own affairs, where the focus of the panels is on kinds of ingredients and dosage levels rather than on products

[49] *Id.* at 9472, ¶ 91.

[50] *See* text accompanying note 40 supra.

[51] Comments of The Proprietary Ass'n on Proposal Entitled "Over-the-Counter Drugs; Proposal Establishing Rule-Making Procedures for Classification" (Dep't of HEW, filed March 2, 1972).

per se, where there are a relatively limited number of panel meetings and where the end result—even with "procedural safeguards"—may result in the issuance of law itself.

A second major concern of industry is that persons with expertise in the categories of OTC drugs under review be panel members. There are important differences between prescription and over-the-counter drugs and expertise in evaluating one class of pharmaceutical product does not necessarily imply expertise in evaluating the other. OTC drugs are generally intended for the relief of subjective symptoms of mild, usually self-limiting conditions and generally are not for the cure of disease states. Often, scientific experts are well-versed in evaluating the far more potent (and often less safe) prescription products which have considerably more dramatic effects because of their strength, but see the results of self-medication only where it has failed.

A third major concern of the industry has been the criteria for reviewing safety and effectiveness of OTC drugs. Because the symptoms for which many OTC's are intended are highly subjective, many are concerned that the measurement of the relief of subjective symptoms is a very sophisticated business and that scientific techniques are not yet sufficiently developed to make these fine measurements.

Recent Court Decisions

Several recent court decisions have a bearing on the entire drug industry, including the OTC Review. They are briefly highlighted here.

On June 18, 1973 the U. S. Supreme Court issued four opinions deciding five consolidated drug cases before it. Of particular importance in connection with the OTC Review, the Court ruled in *Weinberger v. Hynson, Westcott & Dunning, Inc.*,[52] *CIBA Corp. v. Weinberger*,[53] and *Weinberger v. Bentex Pharmaceuticals, Inc.*[54] that the FDA has jurisdiction to decide with administrative finality the "new drug" status (including determination of GRAS/GRAE and "grandfather" status) of individual drugs or classes of drugs. The precise issues of whether the FDA can do so by substantive rule making and, if so, what procedural safeguards are legally required, were not before the Court and are thus unresolved. However, in *Bentex*, the Court did

[52] 41 U. S. L. W. 4848 (U. S. June 18, 1973).

[53] 41 U. S. L. W. 4857 (U. S. June 18, 1973).

[54] 41 U. S. L. W. 4858 (U. S. June 18, 1973).

take note of the OTC Review and appeared to endorse a general approach by the FDA as opposed to case-by-case litigation.[55] The Court clearly was impressed with the argument that the case-by-case approach would "severely undermine" the regulatory scheme of the Act.[56] In *USV Pharmaceutical Corp. v. Weinberger*,[57] the Court characterized the procedures under the misbranding provisions of the Act as a "slow cumbersome method . . . utterly unsuited to the need."[58]

Of general relevance to the substantive/interpretive issue is the ruling in *National Petroleum Refiners Association v. FTC*.[59] There the court held that the Federal Trade Commission has the legal authority to promulgate substantive, legally binding trade regulation rules under the general authority of the Commission to "make rules and regulations for the purpose of carrying out the provisions" of, among other things, section 5 of the FTC Act. While the laws and legislative histories obviously differ, many of the arguments which could be raised to challenge or support substantive rule making by the FDA would be similar to those used in connection with the FTC. Incidentally, the Circuit Court remanded the *National Petroleum* case to the District Court to consider the validity of the procedure of the Commission which resulted in the rule.

The Supreme Court also set forth—in a somewhat vague manner—the kind of evidence needed to establish "general recognition" of effectiveness. In *Hynson*, the Court defined the proof necessary to establish general recognition of effectiveness as "at least 'substantial evidence' of effectiveness for approval of an NDA."[60] Thus, adequate and well-controlled investigations would appear necessary—perhaps a higher test than that required for NDA approval and considerably more than "generally recognized" by many in the Food and Drug bar. In *Bentex*, the Court conceded, however, that "in some cases general recognition that a drug is efficacious might be made without the kind of scientific support necessary to obtain approval of an NDA," noting, however, that the "reach" of scientific inquiry is the same.[61] Query—What did the Court in *Bentex* have reference to? The OTC Review procedures of the FDA permit waiver of a requirement for

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[55] *Id.* at 4861.

[56] *Id.*

[57] 41 U. S. L. W. 4861 (U. S. June 18, 1973).

[58] *Id.* at 4864.

[59] No. 72-1446 (D. C. Cir. June 27, 1973) *rev'g* 340 F. Supp. 1343 (D. D. C. 1972).

[60] *Weinberger v. Hynson, Westcott & Dunning, Inc.*, 41 U. S. L. W. 4848, 4854 (U. S. June 18, 1973).

[61] *Weinberger v. Bentex Pharmaceuticals, Inc.*, 41 U. S. L. W. 4858, 4861 (U. S. June 18, 1973).

adequate and well-controlled studies. Was the Court referring to proprietaries? They were mentioned in *USV* as those OTC drugs "often made up of old, established ingredients."[62] The Court, in *USV*, indicated that such products, which first came on the market between 1938 and 1962 and were never the subject of new drug regulation, would be entitled to "grandfather" protection.[63] The Court said that "grandfather" protection is available *only* to those drugs never the subject of an NDA.[64]

The Court in *Hynson* expounded somewhat on the right to a hearing in a withdrawal proceeding stating that the FDA may deny a formal hearing "where it is apparent at the threshold that the applicant has not tendered *any* evidence which *on its face* meets the statutory standards as particularized by the [FDA's] regulations."[65] In a footnote, the Court stated that a denial of a hearing in such cases would apply to those "regulations that are precise."[66] Presumably, where a regulation calls for the exercise of subjective judgment or discretion, it would not be proper—though the Court said "might not be proper"—to deny a hearing.[67]

Another court decision is worthy of note in connection with the OTC Review. Recently, the U. S. District Court for the District of Columbia ruled in *Warner-Lambert Co. v. FTC*[68] that the company had no standing to challenge an agreement between the FDA and the FTC outlining their separate responsibilities with regard to proprietary medicines. The company sought to protect itself from having to face two simultaneous proceedings—one by the FTC, with regard to product advertising, the other by the FDA under the OTC Review—concerning one of its proprietary medicines. The court also ruled that there is a rational basis for each agency to pursue its individual proceedings. With respect to the OTC Review proceeding by the FDA, the court noted that although there was no evidence of record that the plaintiff was required to respond to the proceeding before the FDA (presumably by submitting data and views as previously outlined), "its failure to respond may be at its peril. . . ."[69]

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[62] *USV Pharmaceutical Corp. v. Weinberger*, 41 U. S. L. W. 4861, 4864 (U. S. June 18, 1973).

[63] *Id.*

[64] *Id.* at 4865.

[65] *Weinberger v. Hynson, Westcott & Dunning, Inc.*, 41 U. S. L. W. 4848, 4851 (U. S. June 18, 1973).

[66] *Id.* n. 17.

[67] *Id.*

[68] F. D. Cosm. L. Rep. ¶ 40,934 (D. D. C. June 14, 1973).

[69] *Id.* at 40,039.

While many of the legal issues surrounding the OTC Review are unresolved, industry attorneys can take little comfort in the thrust of recent decisions.

Advising the Client with Respect to the OTC Review

From a practical standpoint, it seems to me that lawyers should not permit themselves to be carried away by the sound of their own rhetoric and should not overly be swayed in advising clients of the likelihood of courtroom success in challenging the OTC Review on the basis of fine legal distinctions.

Even if the monographs are interpretive, courts undoubtedly will give them great weight in evaluating specific situations, and non-NDA'd products not within a monograph clearly will be, in the government's view, illegally on the market.

Certainly, from the standpoint of the manufacturer-client, the legal issues and rationale of the Review are important matters—but not of overriding practical importance now. Perhaps the most important aspect of the legal status of a monograph presents itself when a client has a product outside an applicable monograph.

Regardless of the lawyer's or the client's view of the fairness or legality of the Review, it is a *fact*. It is going on *now* and it presents an *opportunity* to gain clear GRAS/GRAE status for products. Also, it is being conducted thus far by the FDA in a manner which makes it possible for companies to know when they have products "in trouble."

Certainly, the worst trauma that any client can experience with regard to the Review is to find himself presented with a monograph which places his major product on the "black list." It is far worse if he has to say "that's the first time I ever heard about that!"

Since the Review is being conducted with unprecedented openness, it is possible to be very aware of where a client's products stand in the Review and to do something about it.

I will now attempt to provide a framework for analyzing the manufacturer-client's situation and to present a method of coping with the Review.

There are, of course, many intricacies involved in the Review. While situations will vary a great deal, a general framework for assisting the client can be developed. In analyzing the problem, the most important point is that *decisions should be made consciously, re-*

viewed frequently on the basis of new information, and the analytical process should begin now.

The following is a brief outline of a suggested framework for decision making. The elements will be discussed in turn.

(1) Identify Important Products and Set Priorities

(2) Evaluate Key Products

(3) Know the Panel

(4) Possible Submission of Data to the FDA

(5) Follow the Progress of the Panel

(6) Analyze the Proposed Monograph

(7) Analyze the Tentative Final Monograph

(8) Analyze the Final Monograph—Alternatives

Identify Key Products

The first and rather obvious step is to identify key products of the company which will be affected by the Review and to begin to set priorities in the analytical process. Certainly, one standard is the product's contribution to profit. The degree of effort and expense involved to assure that a product manages to survive the Review will be dependent in part on its importance from the company's standpoint. In some cases it may not be worthwhile to spend extensive funds on legal and scientific analysis and in development of new data.

Evaluate Key Products

In each case, three major areas for evaluation will be present; namely, legal, scientific and "general" management. One logical method of approach would be to assemble the three disciplines together initially to review the client's product line, assess the general situation and relative importance with respect to each product, separate to do some work on the important products, and reassemble later for evaluation.

Certainly, the legal basis on which a product is marketed (GRAS/GRAE, "grandfathered," NDA) should be reexamined. Also, it will be vital to inventory whatever documentation is available on the safety and effectiveness of the ingredients in the product, similar combinations and the product itself. The standards for evaluating proof

of safety and effectiveness at this stage should be that set forth by the FDA in its final procedural regulations.[70]

The attorney and the scientific advisors to the company might want to consider a joint paper which defines the product category,[71] compares the kind of data on hand against that which the FDA requires for the product, and which assesses the *likelihood* of obtaining GRAS/GRAE status under the FDA's regulation. Such a paper might also take into account additional data (studies, etc.) which may be obtained, its cost, and when it can be available, as well as an analysis of competing products and the likely actions of their manufacturers.

This material could then be reviewed with general management and form the basis for conscious decision making, close cooperation between legal and scientific talent, close surveillance by "management" of the situation, and careful follow-up as the process of the Review continues.

Know the Panel

Once it has been determined which panel or panels will review the product, it will be important to examine the makeup of the panel. The FDA makes known the membership on the panel, and it would seem well worthwhile to research both the background and writings of panel members with the company's product in mind. It may be possible from such an analysis to gain insight into the likely views of a given panelist on a particular product as well as into points which should be emphasized to the panel as the opportunity arises. Such an analysis will be helpful in evaluating reports on the panel's progress and will aid in the decision-making process as to whether to submit further information to the panel, the nature of such information, and whether or not to request an oral presentation before a panel.

Possible Submission of Data to the FDA

The submission of data is a voluntary matter. It is important to keep in mind, nevertheless, that whether or not data is submitted, it is highly desirable to have a client's product covered by the panel's "white list."[72] Whether or not a company submits data, the FDA

[70] *See* 21 C. F. R. § 130.301(a)(4)(i)-(vi) (1973). For a description of the standards, see part IC *supra*.

[71] In some cases, the fact that a given product will be placed in a given category for review will be rather clear. In other cases, a given product may be under review by several panels. *See* 37 Fed. Reg. 9465, ¶ 12 (1972).

[72] *See* text accompanying note 30 *supra*.

will likely take the position that the final monograph defines the outer limits of GRAS/GRAE and misbranding and if a client's product is not covered by the "white list," the Agency will take the position that it is illegally on the market. Eventually, the FDA will be comparing the monographs against specific products.

Considerations in favor of submitting data would include a company decision to seek "official" GRAS/GRAE status for the product and a belief by the company that it has—or can obtain—the data which will enable it to succeed. Obviously, if data is available or can be obtained which is likely to convince the panel that the product is GRAS/GRAE, it may well be desirable to submit it.

Another consideration generally in favor of submitting data is the extent to which competing products have differing formulae. A competitor's product may be similar to that of a client and counsel may be tempted to rely on the competitor's submission. If there are important differences, however, the competitor's filing may not cover the client's product and may even contain information adversely affecting the client's product. (Data submitted is made public, but not until 30 days after a proposed monograph is issued.)[73]

Some considerations against the submission of data would include: (1) that data simply is not available and cannot be obtained at a reasonable cost in comparison with the value of the product; (2) that counsel is willing to take a chance on the monograph and reformulate or relabel the product if necessary to comply with the resulting monograph; or (3) that counsel is willing to fight in court. Also, if a client's product is identical to that of another company's and counsel considers it quite likely that that company will submit data, counsel may choose to take a chance and hope to ride on the competing company's presentation. Another reason for not submitting data is a decision that counsel prefers to submit a new drug application for the product. Here, however, keep in mind that the FDA, as a result of this process, might seek to remove NDA'd products from that status and subject them to the monograph procedure.

In any event, if a company decides to submit data—and quite frankly, in most instances it seems that would be the wise course—it is important to reserve one's legal rights to challenge at any stage in the proceeding by incorporating such a comment along with the submission of material.

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[73] 21 C. F. R. § 130.301(a)(2) (1973).

In deciding *what data should be submitted,* a few additional points are noteworthy. First of all, the FDA has been releasing a bibliography on each particular category under review. An analysis of this bibliography will assist in determining whether it is favorable or unfavorable toward a product and whether additional data is available which might help one's case.

Also, and this is quite vital, the FDA has asked that a summary of data be prepared. Recognizing the practical reality that the panels are "flooded" with considerable data, it is vital that this summary support one's case as well as possible and state crisply and succinctly the data relied upon. Here again, the study of the panel, the bibliography and the data accumulated becomes helpful in the preparation of such a document. Generally speaking, "testimonials" are just not going to be very impressive to the scientific personnel who will be making the panel's decisions.

At this stage in the procedure—namely where counsel has decided to submit data—one must remember that the audience to convince is a panel of scientific experts who are guided by their usual way of evaluating products as well as by the standards set forth in the FDA's final procedural regulations. Counsel should orient his case to that audience with those considerations in mind. One should also know that the Supreme Court, in *Hynson,* denigrated "a showing of general recognition of effectiveness [in a withdrawal proceeding] based merely on expert testimony . . . and clinical observation . . . ."[74]

A word here on "confidentiality of data" should be added. In its regulation, the FDA takes the position that it will make available to the public all material submitted to the Review panels thirty days after the publication of a proposed monograph, except to the extent that the persons submitting it demonstrate that it still falls within the confidentiality provisions of the law.[75] Apparently, FDA expects a demonstration—with the burden falling on the manufacturer—that the particular material is, in fact, protected by the confidentiality provisions of the statutes. While many associations and individual companies have taken a position that this procedure is not authorized by law, it appears that the FDA will make available the data wherever possible as mentioned previously. Confidentiality, then, may become somewhat of an academic question. Certainly, it is if the material is released despite counsel's objection.

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[74] *Weinberger v. Hynson, Westcott & Dunning, Inc.*, 41 U. S. L. W. 4848, 4854 (U. S. June 18, 1973).

[75] 21 C. F. R. § 130.301(a)(2) (1973).

In view of this situation, it would seem that *before* submitting data to the FDA for the Review, counsel should undertake a review of that data, determine precisely what is protected under the statutes, so mark that data, keep that data separate from other materials submitted, claim that data as confidential, support the claim in submitting the material to the FDA and renew the claim when the proposed monograph has been issued. This should be pursued carefully so that the company is aware of the FDA decision on the matter before thirty days after the proposed monograph issues, at which time the data would be made public.

If the company disagrees with the FDA's judgment, it might consider court action enjoining the FDA from releasing particular data. The important point is that rather than claiming confidentiality for much of the data that is submitted, the claim should be restricted to that data which is truly confidential and on which the company is prepared to pursue its position. In other words, counsel would try to force the FDA to sustain its position on a fairly narrow, but important point to a client, if the Agency wishes to make that data public.

Another point relating to the submission of data which is worthy of note is a provision in the FDA's requests for information which states that submissions by manufacturers must contain a statement, signed by the person responsible for the submission, that to the best of his knowledge it includes unfavorable information as well as favorable information available to him pertinent to evaluation of the safety, effectiveness and labeling of such a product.[76] The basic intent of this provision has been defined by the Commissioner of Food and Drugs as "intended only to preclude the submission of favorable information without the inclusion of unfavorable information which, in the exercise of reasonable judgment, would present an unbalanced or inaccurate picture."[77]

Follow the Progress of the Panel

As previously noted, the Review procedure is being conducted with unprecedented openness in the sense that the FDA has appointed an "industry liaison" to each panel who has the privilege of attending all the sessions of the panel (save some Executive Sessions) and who

[76] *See e.g.*, 38 Fed. Reg. 10306-08, 13763-64 (1973).

[77] Letter from Charles C. Edwards, M.D., Commissioner, Food and Drug Administration to James D. Cope, Executive Vice President, The Proprietary Association, Sept. 22, 1973.

has the function of informing industry of the progress of the panel. A "consumer liaison" is also appointed to each panel with a similar function for consumer organizations. To date, the FDA has appointed a representative of The Proprietary Association to perform this function. The Proprietary Association holds periodic briefings for industry and, in so doing, provides interested manufacturers (nonmembers as well as members of the Association) with the opportunity to become informed on the progress of given panels. Also, the FDA has indicated its intention to establish an information office to answer questions about the Review process or the status of a given panel.

Thus, there are a number of sources of information on the progress of a panel and it is usually possible to determine whether or not a product is "in trouble" fairly early in the process. For vital products, it is equally imperative that the attorney and his client be aware of potential problems in connection with the product as the panel moves forward. This knowledge will enable a conscious decision to be made as to what, if anything, should be done about the situation. For example, some companies have requested and have been granted the opportunity to appear before panels to make an oral presentation. There really is little reason to be uninformed of the outcome of a given panel's deliberations before they are published in the *Federal Register* as a proposed monograph. The alert attorney and company will know the status of their product through the process and will be able to take steps best to accommodate the situation.

Analyze the Proposed Monograph

As previously noted, once the panel submits its report, the FDA evaluates it, may or may not change it, and publishes a proposed monograph in the *Federal Register* for comment, together with the full report of the panel. The first proposed monograph, relating to antacid products, was published in the same form as was recommended by the panel. Time is permitted (60 days) for the filing of written comments on the proposal and for reply comments (30 days).

The monograph and report contain basically three elements: namely, ingredients, dosages and label claims which are considered by the panel as "GRAS/GRAE" (the "white list"), those which are not (the "black list"), and those on which further work is needed to determine in which category the particular ingredient or claim falls (the "gray list"). Thus, it is possible for astute individuals to compare the monograph and report with individual products and to iden-

tify those products to which the panel did not give a "clean bill of health."

Experience to date has indicated that some degree of publicity attaches to products, for one reason or another, on the proposed "black" or "gray lists," and these products may be disadvantaged as a result. While this is deplorable with respect to a proposed monograph, it has proven difficult to avoid and is a fact of life with which companies and their attorneys must reckon.

Analyze the Tentative Final Monograph

After receipt and analysis of comments and reply comments, the FDA then publishes a "tentative final monograph" which is the subject of written objections, and manufacturers may request the opportunity to appear before the Commissioner in an oral hearing.

Publication of proposed and tentative final monographs will provide notice of which ingredients probably will be approved and which may not be. This will give your client time in which to consider and plan his course of action when the final monograph issues. For example, he may want to develop standby formulae and labeling and he will want to watch his inventory situation.

Analyze the Final Monograph—Alternatives

After this process, the Commissioner issues a final monograph which, in effect, defines GRAS/GRAE and misbranding as the government sees it. If your client's product is entirely within the monograph, he will be passing out cigars and congratulations.

If not, for whatever reason, you have further work to do. There are, of course, any number of reasons why a product may not be within a monograph and there are any number of factual and legal situations in which that result can occur.

For example, a given product may find itself not "GRAS/GRAE" because of the presence of an ingredient, because of its presence in a specific quantity, because of a label claim, because of the absence of a label warning, etc. The "defect" may result in the product's being on the "black list" or the "gray list." The product itself might be "grandfathered," or it may have an ingredient or claim that simply is not covered by the monograph. The problem may be either minor or major in nature.

Here again, if the situation has been followed closely, the attorney and his client will have a good idea as to the likely status of the product as the process moves along, and a discussion of alternatives, given the outcome, will not be a "first round."

A brief analysis of a few of the major alternatives available to a company whose product—for whatever reason—is not in a monograph may be helpful.

First, a company may reformulate or relabel to conform its product to the monograph. This probably can be done in most situations if the company so chooses and, in most situations, it appears likely that trademarks will not be threatened. Also, a reasonable time is expected to be permitted for such action on the part of a company. In the case of a "grandfathered" product, such a change may result in the loss of its "grandfather" status and, of course, the company would risk a later modification of the monograph which excludes the reformulated product for one reason or another. Certainly, an advantage of this alternative is the ability to remain on the market and there may be less adverse press.

Secondly, if the product is on the "gray list" requiring further testing, it would probably be possible to reformulate, relabel, or alternatively, to do the required tests. Here again, analysis of costs, time and likely results would be essential. In the interim, however, the product apparently would be permitted to remain on the market pending completion of the tests. The FDA will establish the time within which the tests are to be conducted.

A third possibility would be to submit an NDA on the product or an abbreviated NDA on that aspect of it which does not conform with the monograph.

Another alternative would be to file a declaratory judgment action seeking to have the court establish the product as GRAS/GRAE and not misbranded, or to file a declaratory judgment action seeking court clarification of the status of the "monograph," or its "illegality."

A fifth alternative would be to petition to amend the monograph as provided in the regulations. It is extremely doubtful that this alternative would be realistic for at least a period of time after the monograph is finally issued, in view of the extensive opportunity to accomplish change throughout the process of the Review.

A last alternative would be simpy to do nothing. This would encompass awaiting action by the FDA in an enforcement proceed-

ing. However, the Drug Listing Act of 1972[78] requires manufacturers to list each product with the Food and Drug Administration and to file information on it, as well as to file changes in ingredients and labeling semiannually. Thus, the FDA will have a mechanism whereby it can identify nonconforming products. Also, there may be some question, depending upon the facts involved, as to whether the monograph can be questioned at this stage if the client fails to challenge it when the final monograph is issued.

A word about "grandfather" may be appropriate here. The so-called "grandfather" clause simply protects products which have been on the market for a long period of time from having to assume the burden of proving their safety and/or effectiveness. The burden, thus, is on the government to establish that a product is, in fact, not as safe or effective as its label claims. "Grandfather" status has never been a protection against a misbranding charge. Undoubtedly, the FDA had that point well in mind when it stated that the monographs would define "misbranding" as well as GRAS/GRAE.

In any event, whether or not a product is "grandfathered," it is susceptible to action by the FDA if the Agency thinks the product is misbranded. While the burden is on the government to prove its case, even if the resulting monographs are interpretive rather than substantive regulations, it seems highly likely that the courts will give those monographs great weight in an enforcement proceeding.

A great deal is involved in a decision to challenge a monograph in court. Obviously, it should be undertaken with the greatest of care and with the most thoughtful legal advice possible.

Conclusion

While the OTC Review is a complex process demanding much effort by attorneys and their clients, the effort is well worthwhile from the point of view of both the client and the public. Regardless of the outcome of the legal questions concerning the Review, the monographs will have far-reaching effects on the OTC medicine industry. The precedent of the process may have even more far-reaching effects on other industries as well. The Review, as presently being conducted by the FDA, enables attorneys and their clients to be informed and to participate, and thus provides manufacturers and counsel with a unique opportunity to make decisions with respect to it in an orderly, informed way. **[The End]**

[78] Pub. L. No. 92-387 (Aug. 16, 1972).

Cosmetics Workshop
Product Experience Reporting

By GEORGE L. WOLCOTT

Dr. Wolcott Is Vice President and Medical Director of John H. Breck, Incorporated. His Paper Was Presented at the Seventeenth Annual Educational Conference of the Food and Drug Law Institute held in Washington, D. C. on December 11, 1973.

AS THE COSMETIC INDUSTRY prepares to provide reports about product experiences to the Food and Drug Administration (FDA), considerable attention is being given to the development of procedures for screening out unreportable experiences and there are a number of important questions concerning certain definitions in the FDA Voluntary Product Experience Regulations.

The Cosmetic, Toiletry and Fragrance Association (CTFA), for example, is attempting to develop screening procedures that would be suitable for companies having an established and adequate consumer relations staff, as well as for smaller companies with little or no existing capability for handling product experience matters.

Screening Procedure

Our company also is developing a screening procedure and, quite surprisingly, it is not an easy accomplishment. We utilize a highly skilled and experienced consumer relations staff to handle product complaints. One of our objectives is the restoration of consumer goodwill, which was apparently present when the complainant purchased one of our products. We carefully investigate every complaint and extensively study all personal injury complaints.

On the basis of the very low incidence of personal injury complaints received by our company over a period of several years, I could

argue, from a strictly practical standpoint, that there is no great need for our company to screen out unverified or unreportable experiences. During this period of several years, our company has received an average of one personal injury complaint (unscreened) for each million units of products sold.

Not knowing whether our experience is similar to or different from that of other companies in our industry, but with the knowledge that our low incidence experience does embrace a considerable number of complaints not caused by the use of our products, we would be doing disservice, not only to our industry, but also to FDA by not attempting to eliminate those product experiences which are not actually caused by product usage.

Hair Sprays—Claims of Personal Injury

Let us examine very briefly our company's experience with personal injury complaints allegedly caused by hair sprays. Again, during the period of several years during which we sold more than 250 million units of hair spray, we received 112 complaints alleging personal injury. As you will recognize, this is an incidence of about 0.44 personal injury complaint per million units. Of the 112 total complaints received, 56 were in the category of scalp and/or skin irritation, 15 complaints involved hair breakage or hair loss, 14 complaints alleged malcoloration of hair or discoloration of hair, 9 complaints related to transient eye irritation, 6 complaints related to irritation of the external ear canals, 5 complaints involved stinging sensation in the mouth or nose, 4 complaints related to hair catching on fire, 2 complaints involved chronic lung problems and one complaint involved a hand injury related to explosion of the aerosol container. Although I have not attempted to screen each of these complaints, I would estimate that approximately one-half of them would not be reportable under any reasonable screening procedure.

In spite of extensive investigation, we know of no evidence that hair sprays cause loss or breakage of human hair. Although we have listed discoloration or malcoloration of hair in the "personal injury" category, we do not consider it a reportable experience for the very reason that health or safety is not involved.

Claims alleging that hair spray set hair afire pose unusual problems. It is surprising that most people do not realize that unadorned hair will burn quite readily in the proximity of a flame or spark. The

application of a hair spray does not increase the flammability of human hair. In each of the four cases in our series, there was clear-cut evidence of a match being used to light a cigarette being brought into proximity with the hair. One of them was distinctly unusual in that a piece of the head of the lighted match flew from the cover of the book of matches into the hair of the individual. Since these were clearly not due to the use of the product, they are truly unreportable.

A recent newspaper article reported an amazing occurrence in Philadelphia. One of the city firemen was called before a review board because he had declined to cut his extra long hair. His supervisor had ordered the shortening of the hair because he considered that the fireman's hair easily could be set aflame while he was fighting a fire. The fireman protested that hair did not burn and to reinforce his belief he lit a match in the hearing room and touched it to his hair. Needless to say his hair went up in flames. But now for the payoff—the fireman explained, "It must have been my hair spray."

The extra emphasis I have placed upon the hair aflame episodes was purposeful, and illustrates clearly one the difficulties in the definition of an "unusual product experience." By kind or severity, this type of product experience certainly is unusual. On the other hand, this kind of occurrence is not a reportable product experience since it was not caused by the product.

"Frequency of Incidence"

When dealing with the problem of what constitutes an unusual product experience, the category of "frequency of incidence" may be difficult to apply. In looking over our records on a year-by-year comparison, I noted that both the number and incidence of personal injury complaints doubled in the year 1970 as compared to the year 1969. This led me to inspect our records for those two years on an individual product basis. For most of our major brands, the same surprising phenomenon occurred. There was an essential doubling of personal injury complaints for 1970 as compared to 1969. While there were some minor changes in composition of a few products, most of our brands were unchanged.

Both the number and the incidence of personal injury complaints declined during 1971 and 1972 as compared with 1970. Hence, there is a good possibility that this surge of consumer complaints during 1970 may have been a reflection of the strong consumerism attitudes

prevalent in that year. This indicates to me that both the individual company and the FDA are going to have to use both caution and wisdom in handling this category of unusual reportable experience. On a categorical basis, I would expect any FDA representative to regard a "doubling" of product experience incidence to fall within the category of "unusual reportable experience."

Those of us in the industry who have responsibility for establishing safety of cosmetic products probably have a good understanding of what FDA has in mind for the category of "unusual reportable experience." Owing to the obvious difficulties at this time in the establishment of specific guidelines, I plead for tolerance by FDA until such time as we have acquired industry data and experience upon which to promulgate better standards. **[The End]**

FOOD LABEL INFORMATION PANEL REGULATIONS REVISED

A type smaller than 1/16 inch will be permitted for the declaration of mandatory information on the principal display panel or information panel of food packages, as specified in an amendment to 21 CFR 1.8d, issued by the Food and Drug Administration. The new requirements become effective June 3, 1974.

The exemption applies to food packages designed to bear an information panel and/or an alternate principal display panel with a surface area of less than 10 square inches available for labeling, provided that nutrition information, a complete ingredient statement, and all other information required by § 1.8d appear in a type size not less than 3/64 inch in height. Food packages designed so that they have a single "obvious principal display panel" of less than 12 square inches and no other available space for labeling and food packages in which the total surface area available for labeling is less than 12 square inches may display the required information in a type size no less than 1/32 inch in height.

One comment on the proposal to exempt certain food packages sought to include in the exemption those packages with a total surface area available for labeling of less than 12 square inches. The FDA included the exemption to accommodate this request.

CCH Food Drug Cosmetic Law Reporter

Product Liability—1973

By WILLIAM J. CONDON

Mr. Condon Is an Attorney at Law in New York City. His Paper Was Presented at the New York State Bar Association Annual Meeting in New York City, January 23, 1974.

AFTER 13 YEARS, strict liability is coming of age. Initially, courts around the country seemed to be so excited by the release from the strictures of privity that they rushed headlong into an acceptance of this new concept without very much inquiry into its precise parameters. Inevitably, as time goes on, the same courts are taking a harder look at what they spawned, with a view toward determining its expanse and its limitations, if any.

Oregon, for example, espoused the doctrine of strict liability in 1965 (*Wights v. Staff Jennings*, 241 Or. 301, 45 P. 2d 624). Now, in a case which gave rise to five separate opinions, that court has delved very deeply into several of the most fundamental aspects of strict liability.

The case, *Markle v. Mulholland's, Inc.*, CCH PRODUCTS LIABILITY REPORTS, ¶ 6969, arose from the unexplained blowout of a recapped tire which had been driven approximately 6,000 miles. There were problems of proof but, for our purposes, they are subordinate to the basic questions with which three of the opinions were principally concerned.

In *Wights*, the Oregon Court had rejected enterprise liability as the basis for the adoption of the rule of § 402A of the Restatement of Torts (Second). Enterprise liability is defined as that system which places the liability on the one best able to spread the risk. This had been rejected by the Court because its logical and natural extension would require that the enterprise be strictly liable for the inevitable accident toll of all of its activities, not merely those involved in the selling of goods. What, then, does underlie the imposition of liability under § 402A? The majority opinion says that there are two aspects. Starting with the proposition that the *Wights* case had only rejected

enterprise liability as the sole basis for § 402A, it proceeds to say that necessarily a limited form of enterprise liability is involved. Otherwise, the liability would not be restricted to those engaged in the business of selling. The Court proceeded to say that something similar to the concept of merchantability also underlies the rule. Merchantability boils down to the reasonable expectation of the consumer.

Court Limitation of Enterprise Liability

Putting these two bases together, the Court reasons that enterprise liability must be limited in some way. The limitation selected in the 402A approach is that of a defect in the product. What constitutes a defect cannot be determined without first determining whether the purchaser had a right to expect that the article would be free from the condition which caused the injury. If he did, then the article is defective. But we can only determine what the purchaser had a right to expect by examining the implications express and inherent in the sale to him. These implications are analogous to those underlying a representation of merchantable quality.

Applying these principles to the facts of the case, and in the absence of any specific proof that the casing of the recapped tire was defective when sold, the Court concluded that plaintiff had made out a satisfactory case in strict liability when he showed that he had a right to expect more than 6,000 miles from a recapped tire. This was buttressed by the fact that the tread still had substantial wear left in it, thus evidencing that the seller also expected a longer life than 6,000 miles.

The majority opinion clearly implied that a complaint framed in breach of implied warranty language, such as this one, properly raised the issue of strict tort liability and should be treated as such. In *McGrath v. White Motor Corp.*, 258 Or. 583, 484 P. 2d 838, decided in 1971, the Court had suggested that henceforth, problems could be avoided if actions of this type were pleaded in tort terms. Since the *Markle* case, under consideration, had begun before the *McGrath* decision came down, Mr. Justice McAllister concurred in the result. However, he suggested that in the future, cases should be tried and decided on the basis of the language used in the pleadings. Thus, plaintiff would have an option whether to bring an action in breach of warranty or in strict liability in tort. If in warranty, the action would be tried in accordance with the provisions of the Uniform Commercial Code, com-

plete with all its limitations and defenses. If the complaint were framed in tort language, the action would be tried in accordance with the doctrine of § 402A. Justice McAllister flatly rejected the majority's view that any concept of implied warranty underlies strict liability. In his view, the sole basis for § 402A is a limited enterprise liability.

Court's Ability to Provide Relief Questioned

The most fascinating question in connection with this case was raised in the specially concurring opinion of Mr. Chief Justice O'Connell. Taking issue with the assumption underlying both of the opinions previously discussed, he questions whether the Court is free to provide relief under a theory of strict liability where the remedy for injuries resulting from a defective product is available under the Uniform Commercial Code. He reluctantly concluded that the legislature had preempted this area of the law. He reached this conclusion reluctantly because he agreed that the notice and disclaimer provision of the Code do not make much sense in the context of personal injury cases. However, he recognized that it is for the legislature to determine whether the public policy expressed in a statute is well-or-ill conceived. The Chief Justice took particular exception to the suggestion that plaintiff had parallel remedies available to him under the Code and under § 402A. He pointed out that, as a practical matter, the Court's decision rendered the 402A remedy exclusive. This is so because a plaintiff could garner no advantage from bringing an action based on warranty, but rather would only open up defenses not available in a tort action. Thus, he said, the Code is rendered without utility in this area because plaintiffs do not need it and defendants cannot have it.

Two Dissenting Opinions

To complete our discussion of this case fairly, it is necessary to give brief mention of the two dissenting opinions. The first agrees with the majority's conclusions concerning the law of products liability, but disagrees on the application of that law to the facts of this case. Essentially, his position is that a tire recapper is no different from a used car dealer and, in the absence of express warranties, is liable for negligence only.

The second dissent violently disagrees with the concept of enterprise liability having any place in the law of Oregon. Justice Bryson

said "At this point of time in the evolution of this new concept of liability, I am not willing to place the court in a position of adopting a law based on a socialistic theory." The gravamen of his dissent was that the evidence was insufficient to support an inference that the product was defective when sold by the defendant.

Application of Strict Liability Doctrine

Somewhat surprisingly, New York has been slow to join the ranks of strict liability jurisdictions. That being the case, it may not be surprising that, when New York finally did join the parade in 1973, it chose to march to a somewhat different drummer. The case was *Codling v. Paglia*, CCH PRODUCTS LIABILITY REPORTS, ¶ 6797. Involved was an automobile with an allegedly defective steering mechanism. The thrust of this decision was to extend warranty liability to an innocent bystander. However, the Court went further and enunciated a concept of strict liability. The operative language of the opinion is as follows:

"We accordingly hold that, under a doctrine of strict products liability, the manufacturer of a defective product is liable to any person injured or damaged if the defect was a substantial factor in bringing about his injury or damages; provided: (1) that at the time of the occurrence the product is being used (whether by the person injured or damaged or by a third person) for the purpose and in the manner normally intended, (2) that if the person injured or damaged is himself the user of the product he would not by the exercise of reasonable care have both discovered the defect and perceived its danger, and (3) that by the exercise of reasonable care the person injured or damaged would not otherwise have averted his injury or damages."

There are two points which immediately claim attention in connection with this case (there may be many more in time to come). The first is that the Court talks of "strict products liability." It nowhere mentions tort, nor does it refer to § 402A. Secondly, the New York doctrine has a much harsher rule with respect to contributory negligence than is the case with other strict liability jurisdictions. Note that the plaintiff's action will fail if he is himself the user of the product and could, by the exercise of reasonable care, have both discovered the defect and perceived its danger. This appears to go substantially beyond the basic concept of assumption of risk adopted in most other strict liability states.

Further, apparently also in the area of enterprise liability, a lower court in New Jersey has flatly declared that the concept of "unreasonably dangerous" has no place in strict tort liability. Thus, in New

Jersey, as in California, injury caused by a defective product will give rise to liability without inquiry as to whether or not the defect rendered the product involved unreasonably dangerous to the consumer. The net effect of this may be to restrict the appropriate inquiry to the reasonable expectations of the injured consumer rather than to those of consumers generally (*Glass v. Ford Motor Company*, CCH PRODUCTS LIABILITY REPORTS, ¶ 6946).

There remains to be discussed briefly the determinations of a few cases which, though not necessarily connected with the preceding discussion, tend to throw some light on the developing law.

One such case involved the manufacturer of an antibiotic drug. Warnings had been issued concerning the dangerous propensities of this drug. There had also been extensive promotion of the product. The prescribing physician testified that he was aware of the warnings and cognizant of the dangers of the drug. The Court held that, even if the jury believed the doctor's testimony, his intervening act of negligence would not necessarily exonerate the manufacturer. In essence, the holding was that if the negligence of the physician was reasonably foreseeable under all of the circumstances, then the manufacturer could still be liable for having placed in motion the force which ultimately caused plaintiff's injury (*Stevens v. Parke, Davis & Company*).

Relief to Allergic Persons

The law of New York has traditionally afforded very little comfort to the allergic plaintiff, particularly in the area of cosmetics. In the case of *Tirino v. Kenner Products Company*, a New York City Civil Court Justice found a basis for recovery in such cases. Plaintiff was a young child who applied a product called "Lightning Bug Glo-Juice" over his eyes. Both the container of the product and the box in which it was packaged declared the product to be "Non-Toxic." The box illustrated how a child might make use of the product, which apparently glowed in the dark. One such illustration showed a child with the product applied between the eyebrows and the eyelids. When the infant plaintiff, age 7, applied the product to this area, some of it dripped into his eyes which became red and inflamed and the eyelashes stuck together and had to be pried apart. The Court held that, while no action could be maintained for breach of implied warranty, because there was no proof that the product would be harmful to the normal user, the plaintiff could recover on a theory of express war-

ranty. Plaintiff had a right to rely on the representation that the product was "Non-Toxic" as meaning that it would not cause even an allergic injury.

Case Concerning "The Pill"

"The Pill" continues to raise very troublesome issues in products liability. One such faced the United States Court of Appeals for the Tenth Circuit in the case of *Jorgensen v. Mead Johnson Laboratories, Inc.* Mrs. Jorgensen had taken defendant's oral contraceptive product for several months in 1971. Immediately prior to November of 1971 she discontinued the use of the product and shortly thereafter became pregnant. Mongoloid twins were born in July of 1972. This action was brought by the father on behalf of the twins, alleging that the use of the product had altered the mother's chromosome structure, thus causing the mongoloid condition of the twins. The District Court had dismissed the complaint for failure to state a cause of action. The Court of Appeals reversed. The action arose in Oklahoma and there were no Oklahoma cases on the subject. The Court was thus called upon to predict what the Oklahoma Court would do. The only cases available were those wherein recovery had been denied under the Oklahoma Wrongful Death Statute brought on behalf of stillborn infants. The Court distinguished these cases on the basis that the present action is not for wrongful death, but for retardation, deformity, pain and suffering during lifetime. It was argued, of course, that the effect of the drug was on the mother, not the infants, and that the tortious conduct alleged in the complaint occurred before the twins were conceived. The Court rejected these arguments and said: "If the view prevailed that tortious conduct occurring prior to conception is not actionable in behalf of an infant ultimately injured by the wrong, then an infant suffering personal injury from a defective food product, manufactured before his conception, would be without remedy." This reasoning is somewhat specious because the fact situations are not similar. In the one case, the damage is inflicted upon a living child. In the present case the injury is obviously done to an unborn fetus. One might say that the substance of the complaint in this case is that a fetus has a right to a compatible or healthy environment in which to be conceived. The Court does not go so far. However, it is a little difficult to delineate precisely at what point, in this Court's view, the injury occurred and the right arose. In any event, the case is illustrative of the enormity of the problems which face our courts in this highly chemical world.

The United States Court of Appeals for the Fifth Circuit had also to grapple with a difficult problem. Plaintiff was an industrial insulation worker. He sued all of the insulation manufacturers whose products he had handled in his work over his career, when he was forced to retire because of disability due to asbestosis, a disease contracted through the continuous inhalation of asbestos dust. The proof showed that this disease was cumulative and that essentially, the problem simply became worse with each new inhalation until it finally manifested itself in varying degrees of disability. On this basis, the Court affirmed a recovery on behalf of the plaintiff against all of the defendants. The case involved interesting discussions of many issues which time does not permit us to discuss at length. These included the duty to warn, contributory negligence, and the statute of limitation. We have included the discussion here because the application of the doctrine of strict liability to an occupational disease is one of first impression and is therefore worthy of special notice (*Borel v. Fiberboard Paper Products Corporation,* CCH PRODUCTS LIABILITY REPORTS, ¶ 7017).

From all of the foregoing discussion, it might readily be seen that our courts are at once engaged in extending the application of strict liability into new areas, and at the same time attempting to define the limits of the doctrine itself. Of necessity, these two efforts will occasionally conflict with one another and create some unusual results. However, one has reason to hope that, within the foreseeable future, strict liability will become a well-defined doctrine and, equally important, predictable in its application. **[The End]**

PRODUCT LIABILITY CASES FOR 1973

The list of cases for 1973, grouped according to classification, is as follows: (All paragraph numbers refer to CCH PRODUCTS LIABILITY REPORTS)

FOREIGN SUBSTANCE BEVERAGE CASES

Atlanta Coca-Cola Bottling Co. v. Ergle, ¶ 6898 (Ga. Ct. App.)

Simmons v. Baton Rouge Coca-Cola Bottling Company Ltd., ¶ 7065 (La. Ct. App.)

BURSTING BEVERAGE BOTTLE CASES

Schuessler v. Coca-Cola Bottling Company of Miami, ¶ 6973 (Fla. Dist. Ct. App.)

Centineo v. Anheuser-Busch, Inc., ¶ 6981 (La. Ct. App.)

Gillispie v. Thomasville Coca-Cola Bottling Company, ¶ 6992 (N. C. Ct. App.)

Edwards v. Springfield Coca-Cola Bottling Co., Inc., ¶ 7040 (Mo. Ct. App.)

DRUG CASES

Stevens v. Parke-Davis & Co., ¶ 6911 (Cal.)

Fischer v. Mead Johnson Laboratories, ¶ 6914 (N. Y. App. Div. 2nd Dept.)

E. R. Squibb & Sons Inc. v. Stickney, ¶ 6915 (Fla. Dist. Ct. App., 1st Dist.)

Leibowitz v. Ortho Pharmaceutical Corp., ¶ 6988 (Pa. Super. Ct.)

Jorgensen v. Mead Johnson Laboratories, Inc. ¶ 6991 (CA-10)

Nichols v. Eli Lilly & Co., ¶ 6995 (CA-10)

Hoffman v. Sterling Drug, Inc., ¶ 7003 (CA-3)

COSMETIC CASES

Ford v. Barnard, Sumner & Putnam Company, ¶ 6938 (Mass.)

Tirino v. Kenner Products Company, ¶ 6950 (N. Y. C. Civil Ct.)

Briggs v. Zotos International, Inc., ¶ 6998 (U. S. D. C., E. D. Va.)

D'Arienyo v. Clairol, Inc., ¶ 7038 (N. J. Super. Ct.)

West v. Alberto Culver Company, ¶ 7043 (CA-10)

DEVICE CASES

Friedman v. Medtronic Inc., ¶ 6984 (N. Y. App. Div. 2nd Dept.)

McKasson v. Zimmer Mfg. Co., ¶ 6993 (Ill. App. Ct.)

ECONOMIC POISONS CASES

Shipton Supply Co., et al. v. Bumbaca, ¶ 6891 (Wyo.)

Charbonneau v. Wilbur Ellis Company, ¶ 7025 (Wash. Ct. App.)

Kyllo v. Northland Chemical Co., ¶ 7042 (N. D.)

Henderson v. Cominco American, Inc., ¶ 7049 (Ida.)

SEED CASES

Bickett, et al. v. W. R. Grace Company, ¶ 6876 (U. S. D. C., W. D. Ky.)

BLOOD TRANSFUSION CASES

Rostocki v. Southwest Florida Blood Bank, Inc., ¶ 6917 (Fla.)

Hutchins v. Blood Services of Montana, ¶ 6918 (Mont.)

Shepard v. Alexian Brothers Hospital, Inc., ¶ 7004 (Cal. Ct. App.)

Fruge v. Blood Services, ¶ 7052 (U. S. D. C., W. D. La.)

Gilmore v. St. Anthony Hospital, ¶ 7063 (Okla.)

Evans v. Northern Illinois Blood Bank, Inc., ¶ 7067 (App. Ct., Ill.)

ANIMAL FEED CASES

Hein v. Torgeson, ¶ 6926 (Wis.)

Valiga, et al. v. National Food Co., et al., ¶ 6943 (Wis.)

Williams v. Allied Chemical Corp., ¶ 6951 (La. Ct. App.)

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