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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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In his article "Advertising of OTC Drugs; Proposed TRR on Warning," *Frank P. DiPrima* states that since it would be bad public policy to encourage consumers to rely on advertising in order to obtain specific use information, efforts should be directed towards encouraging consumers to read labels. Mr. DiPrima is staff Vice President of Schering-Plough Corporation. His article begins on page 96.

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William P. Pendergast, a member of the law firm of McMurray and Pendergast, states in his article that review proceedings provide the only means available for challenging the propriety of FDA regulations. His article "Is Cosmetic Litigation Hopeless?" begins on page 129.

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Advertising of OTC Drugs; Proposed TRR on Warnings

By FRANK P. DiPRIMA

Mr. DiPrima is Staff Vice President of Schering-Plough Corporation.

TWO YEARS AGO, Congress enacted the Magnuson-Moss Amendments[1] to the Federal Trade Commission Act (FTC Act), granting the Federal Trade Commission (FTC) the authority to make, under specified procedures, legislative Trade Regulation Rules (TRR). The grant of legislative authority enables the FTC to "define with specificity" commercial practices which are "unfair or deceptive" and, thus, unlawful under Section 5(a)(1) of the FTC Act. This confirmed the rule in *National Petroleum Refiners Association v. FTC*[2] (the *Octane* case) which appeared to establish that the FTC has such authority.

Non-Prescription Drugs

The FTC's response has included commencement of two separate proceedings proposing rules which would profoundly affect the advertising of non-prescription drugs.

The first, issued as a proposal in November 1975,[3] would forbid, in advertising, the making of claims for which a non-prescription drug has been placed in "Category II" (as unsafe or ineffective) in any final monograph issued under the Food and Drug Administration's "OTC Review." This is the so-called "Claims TRR." Except for its prospective effect on future monographs, it seemed to be a non-controversial proposition on which

[1] Pub. L. 93-637.
[2] 482 F. 2d 672 (CA DofC 1973); *cert. denied* 94 S. Ct. 1475 (1974).
[3] 40 *F. R.* 52631 (Nov. 11, 1975).

to base a rulemaking proceeding. So it seemed, until an FTC staff interpretation, made from this same podium last year, read the proposed rule as permitting in advertising only the exact claims language appearing in over-the-counter (OTC) monographs, and banning even exact synonyms.[4] The "Claims TRR" is not the subject of my talk today, so suffice it to say that the synonym interpretation should be and will be contested on constitutional, statutory and public policy grounds.

Antacid Warnings TRR

The second, or so-called "Antacid Warnings TRR," is my subject today. Unlike the "Claims TRR," the Notice[5] which began the proceeding did not take the form of a predrafted proposed rule, but rather of a series of questions seeking to determine whether there is a general need to recite cautions in OTC drug advertising, and whether specific cautions, required by the Final Monograph to appear on the label of certain antacids, should also be required in advertising. The questions are prefaced with statements that the FTC "has reason to believe" certain premises about adverse reactions, consumer knowledge and consumer readership of labels.

No one doubts that the FTC staff intends to commence parallel rulemaking proceedings covering each drug category for which an OTC Final Monograph is issued, and no one doubts that the outcome for all categories depends in large part on the results of the "Antacid Warnings TRR" proceeding, about to begin. The proceeding is perhaps the most important in the history of non-prescription medicines promoted to the public, and, thus, we urgently need to consider the legal and public policy bases for any requirement that label cautions for OTCs be recited in advertising.

Basic Issues

Let me end the suspense and say that I think any such requirement is decidedly a bad idea—bad law and bad public policy. As I see it, the most basic issues are the following.

First, the proposed requirement ignores the basic difference in function between advertising and labeling. If the method of use of any commodity requires explanation, consumers know they should look to the package or other material accompanying the product to find it. For automobiles, this information is in the owner's manual; for appliances, in a booklet inside the shipping box; for household repair compounds, on the

[4] Herzog, Richard B., 31 FOOD DRUG COSMETIC LAW JOURNAL 147 (March 1976).

[5] 41 *F. R.* 14534 (April 6, 1976).

package; for processed foods requiring further preparation, on the package. Similarly, statutes governing regulated consumer commodities, such as hazardous substances or insecticides, invariably require that directions and warnings appear on the label, and that is where they appear. Non-prescription medicines are no exception, and I do not think the FTC staff would seriously contend that many consumers do not know enough to look on the package or label for use information.

For none of these items—autos, appliances, household compounds, insecticides—would consumers expect to find explicit directions, how to and how not to use the product, in advertising media such as broadcast commercials and billboards. Yet, in most or all of these categories, incorrect use involves more serious risk than is the case with antacids.

Functional Difference Between Advertising and Labeling

In my opinion, the functional difference between advertising and labeling is generally understood. A consumer needs to know how to use a product, and how not to, at the time he wants to use it. If the information accompanies the product, then the information is there when he needs it. He expects advertising to be commercially partial and has a right to expect that it be truthful. But when he wants to use the product, and wants to find out how, even a naive consumer does not think he is supposed to turn on the television to catch a commercial or drive in the country to find a billboard.

Statutory Authority

Second is the question of statutory authority. If a rule is beyond the scope of the statutory grant, then it is void. Thus, if a practice cannot reasonably be called "unfair or deceptive," then any attempt to ban it is a nullity. Can the failure to recite cautions in advertising be reasonably considered "unfair or deceptive"?

There is no doubt that concealment of, or failure to reveal material facts may be "deceptive." This public policy is manifest both in the Federal Food, Drug and Cosmetic Act at Section 201(n) and in the FTC Act at Section 15. It is also common sense. This is the FTC's stated theory, and indeed it is the only conceivable basis for finding failure to recite warnings in advertising to be a violation of Section 5.

But if the product is properly labeled with all required directions and cautions clearly disclosed, and if the ad is otherwise truthful, then a consumer has not been deceived or treated unfairly by failure to recite cautions in the ad. This is based on my premise that consumers know

where to look for information on how to use a product. They know they are supposed to read the label. This accordingly cannot constitute a failure to reveal a material fact. Under no reasonable construction is the action "unfair or deceptive," and, thus, the rule would be outside the enabling statute and the Commission's authority.

This result would be even more logically inevitable if the ad directed the consumer to "read the label" or "follow label instructions." Reciting cautions on the label and then telling the consumer in the advertising pieces to read it cannot possibly constitute deceptive concealment.

Congressional Intent

Third, the issue which is closely related to the first two, is Congressional intent: how did Congress intend manufacturers to provide, and consumers to receive, usage information for non-prescription drugs?

Two statutory provisions are most relevant, and should be read together, as they were enacted three months apart. The Wheeler-Lea Amendments[6] to the FTC Act, enacted in March, 1938, amended Section 5(a)(1) to ban "unfair or deceptive acts or practices. . . ." The same amendments added to the FTC Act new Sections 12 through 15, creating special remedies for preventing the dissemination of any "false advertisement" of foods, drugs, devices and cosmetics. Except for the general language in Section 15 regarding failure to reveal material facts, the Act contained nothing about the location of usage information.

This is in sharp contrast to Section 502(f)(1) of the Federal Food, Drug and Cosmetic Act, passed three months later. Section 502(f)(1) provided that a drug is misbranded unless its labeling bears adequate directions for use and adequate warnings against unsafe use. Congress thus clearly expressed itself regarding the public policy question of where usage information is to appear. If it wished for a requirement that usage information appear in advertising, it would have said so.

Prescription Drugs

Along these lines, some 24 years later, Congress showed that it can be explicit regarding the placement of warnings in advertising when it does intend to require them. The Drug Amendments of 1962 amended Section 502(n) of the Federal Food, Drug and Cosmetic Act to require, among other things, that advertisements for *prescription* drugs (ads generally going to the medical profession and not to users) shall contain:

[6] 52 Stat. 111 (1938).

"other information in brief summary relative to side effects, contraindications and effectiveness as shall be required by the Secretary in accordance with the procedure specified in Section 701(e) of this Act; . . . ."

If Congress intended to enact the same provision for *non-prescription* drug advertising disseminated to consumers, it would have been easy enough to include appropriate language.

Congress has occupied the field and has indicated where it wants usage information, including cautionary statements, for non-prescription drugs. It is not surprising that Congress has chosen the labeling—just as it has with other regulated consumer commodities. For the FTC to require such information in advertising is as clearly contrary to Congressional intent as it would be if Congress had specifically excluded such a requirement.

Passage of the Magnuson-Moss Amendments does not change this. The operative substantive term, "unfair or deceptive acts or practices" in Section 5, has not changed, and has been in the law in substantially its present form since 1938. Neither the plain meaning of the Magnuson-Moss Amendments, nor its legislative history, gives any indication of any intent to change the substantive standard.

Since 1938, the FTC always had, and often exercised, authority to make interpretive rules defining what it thought constituted "unfair or deceptive" practices. The only change signalled by the *Octane* case and confirmed by Magnuson-Moss was that the Commission could now clearly make binding legislative rules and not merely interpretive rules.

Scope of Judicial Review

The only difference in legal effect is in the scope of judicial review. When considering an interpretive rule, a reviewing court may review the correctness of the interpretation and substitute its judgment for the Agency's. Review of a legislative rule is narrower, but such a rule is reviewable in order to determine whether it is within the statutory grant. If outside the statutory grant, or contrary to Congressional intent, then the new TRR authority under Magnuson-Moss cannot save the defective rule.

Fourth, legislative rules may also be challenged as "arbitrary and capricious" under both the Administrative Procedure Act, at 5 USCA 706(2)(A), and Fifth Amendment substantive due process. It may be "arbitrary and capricious" to ban dissemination of a truthful ad for a properly labeled product, particularly if the ad instructs consumers to read the label, as most ads for non-prescription medicines now do.

Fifth, legislative rules may also be challenged as violations of First Amendment guarantees of free speech, though it is perfectly clear that there is no right to make misleading claims. It is equally clear that there is no right deceptively to conceal material facts.

Last year, the U. S. Supreme Court in *Bigelow v. Virginia*[7] reversed a conviction under a Virginia law banning the promotion of abortions, and the Court clearly extended some measure of First Amendment protection to commercial free speech. This year, in *Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council,*[8] the Supreme Court similarly invoked the First Amendment to strike down a state statute prohibiting pharmacists from advertising prescription drug retail prices. Shortly thereafter, in *Beneficial Corporation v. Federal Trade Commission,*[9] the Third Circuit, on First Amendment grounds, set aside a Commission order requiring total excision of words "Instant Tax Refund" from the advertising of a respondent engaged in both the tax return and loan businesses; the Court held that the phrase was misleading as respondent had used it in the past, but that its non-deceptive use with proper qualifying language could not be banned prospectively. The case was remanded to the Commission to issue an order that goes "no further than is necessary for the elimination of the deception."

Prior Restraint

Clearly enough, a prior restraint is lawful if it prevents only deceptive advertising. But it may be the collective holding of *Bigelow, Virginia State Board of Pharmacy* and *Beneficial* that prior restraints on advertising are valid *only* on *deceptive practices* and are *void* to the extent that they prevent non-deceptive advertising. In all three cases, an arm of government tried to proscribe commercial speech which it thought was unfair or against an articulable public policy; in all three cases, the government failed when the proscribed commercial speech was not or might not be deceptive. If this interpretation is correct, the concept of "unfair" as applied to advertising must be read out of the Act, and only "deceptive" advertising may be forbidden.[10]

Let us apply this interpretation. A TRR purporting to ban ads that do not recite cautions is a prior restraint which will be subjected by a reviewing court to First Amendment examination. If the rule forecloses ads that are not deceptive and that do not involve deceptive concealment,

[7] 95 S. Ct. 2222 (1975).
[8] 96 S. Ct. 1817 (1976).
[9] 1976-2 TRADE CASES ¶ 61,066.
[10] The author hastens to add that the concept of "unfair" is clearly alive as applied to practices other than commercial speech or advertising.

then to that extent the rule is unconstitutional. A truthful ad for a properly labeled antacid is not deceptive since consumers know where they should look to find usage information; and such an ad is certainly not deceptive if it instructs consumers to read the label.

There are many other issues: the degree of risk; the economic impact; and whether the correctness of each warning should be considered *de novo* in the TRR proceeding. Time does not permit the analysis of these questions here.

Let me instead close with one final observation. I think it would be bad public policy to encourage consumers to rely on advertising to obtain specific use information. Such a policy will inevitably lead to confusion. Our efforts should instead be directed toward encouraging consumers to read the label. This is, in my opinion, the soundest principle from which government and industry should approach the subject matter of the forthcoming proceedings. [The End]

RULES FOR CARCINOGENICITY TESTING OF FOOD-PRODUCING ANIMALS ISSUED

The criteria used by the Food and Drug Administration for accepting assays used to measure carcinogenic residues in the edible tissues of animals administered carcinogens have been published by the agency. The new regulations establish the lowest limit of reliable measurement for the regulatory assay required for carcinogenic residues by the anti-cancer clauses of the Federal Food, Drug, and Cosmetic Act and establish procedures and criteria for evaluating and approving assays and for establishing the premarketing withdrawal period for use of compounds likely to produce carcinogenic residues.

All new animal drug applications, feed additive petitions, and appropriate color additive petitions submitted subsequent to March 23, 1977 are subject to the regulations. The requirements of the regulations will also apply to all pending petitions and applications unless the Commissioner determines that compliance with the anticancer provisions of the FDC Act can be adequately assured by requiring completion of one or more of the required studies subsequent to approval.

Because the regulations were proposed in 1973, and the final regulations resolve some issues not specifically dealt with in the proposal, the FDA has given interested persons until April 25, 1977 to file further comments. The FDA is interested in receiving comments on four specific areas of the regulations: the acceptable level of risk for use in the modified Mantel-Byran calculation; the concept of comparative metabolism; alternative mechanisms for dealing with endogenous compounds; and mechanisms for statistically differentiating target tissue containing the market residue from blank target tissue.

CCH Food Drug Cosmetic Law Reporter ¶ 41,845, 74,654—74,654.18, 74,791.11, and 65,311.5

Regulatory Developments at the BVM— Underlying Direction and Unintended Consequences

By JAMES F. MONGIARDO

Mr. Mongiardo Is an Attorney with Schering-Plough Corporation.

THE FLOOD OF *FEDERAL REGISTER* NOTICES, relating to the Food and Drug Administration (FDA) and more specifically to the Bureau of Veterinary Medicine (BVM), this past year has appeared to many to be a haphazard avalanche of efforts whose sole design is simply to increase regulatory powers. This feeling is understandable given the sheer volume and far-reaching scope of the rules and regulations which were published. Upon closer analysis, however, these pages and pages of proposals and explanatory preambles do have some underlying direction which, however, will inevitably lead to certain results which most assuredly have not been contemplated by the rulemakers.

In order to properly analyze the underlying direction of the major regulatory efforts of the past year, the first public document which should be examined is not a *Federal Register* publication but rather an internal FDA memorandum. On November 19, 1975, FDA General Counsel Richard Merrill set forth in detail what he considered to be the appropriate scope of review of New Animal Drug Applications (NADAs) by members of his staff. This memorandum analyzed this review in terms of mixed questions of law and fact. The conclusions reached by Mr. Merrill from an attorney's viewpoint appear to be consistent with basic legal principles. From a scientist's viewpoint, however, the conclusions in effect mean that every decision is subject to scrutiny by a non-scientist attorney in the Office of General Counsel (OGC).

Science and Law

The tension between "science and law" which prompted Mr. Merrill's memorandum was evident not only in the relationship between BVM and OGC but also in many of the major regulatory proposals issued this past year. This will be discussed later since it is part of a larger trend which should first be reviewed.

A basic change in FDA regulatory philosophy occurred in 1971 when Peter Barton Hutt became General Counsel. Instead of a case-by-case approach to establish policy and resolve regulatory problems, Mr. Hutt believed that the FDA's regulatory policies should be publicly available and that everyone should be treated in an identical manner through the establishment of detailed regulations and guidelines. This philosophy was accepted within the Agency and, as a consequence, the FDA began vast rulemaking efforts attempting to establish detailed regulations. Coupled with these efforts was a decision that hearings were ordinarily a waste of valuable resources and that the summary judgment powers of the FDA could, in nearly all instances, effectively replace what was at one time believed to be a statutorily conferred right to a hearing.

The net result of this rulemaking philosophy and desire to avoid hearings has inevitably led to what can be referred to as increasing "legalism." In order to establish vast regulatory schemes, the FDA had to not only propose regulations but also detail in their preambles the rationale for the rules under consideration and why those rules should be adopted after adverse comments. By their very nature, these rulemaking proceedings require the close guiding hand of General Counsel to both develop and to extend regulation to areas which were once commonly believed beyond the scope of the Federal Food, Drug and Cosmetic Act.

Similarly, summary judgment proceedings require expert legal advice to frame a comprehensive document which will satisfy the procedural requirement that no material issue of fact be in dispute after publication of the notice of opportunity for hearing and receipt of comments. OGC, as a consequence, became an integral part in not only the development of new regulations but also the removal of new drugs from the market.

Approval of New Human Drugs

While the Office of General Counsel is not involved in the approval of new human drugs, Mr. Merrill's memorandum indicates that OGC is very much involved in the approval of new animal drugs. Thus, from the BVM's viewpoint, just about any decision which it can make will somehow involve OGC in a very significant manner.

With these two factors in mind, namely increasing legalism and tension between science and law, an analysis can now be made of six major regulatory developments during the past year. These include the proposed Current Good Manufacturing Practices (GMPs) regulations, the proposed Good Laboratory Practices (GLPs) regulations, the BVM Stability Guidelines, the effort to remove from the market diethylstilbestrol (DES), the effort to remove from the market several nitrofurans, and the BVM freedom of information (FOI) guidelines.

While all six of these major regulatory developments can be analyzed in terms of increasing legalism, four present excellent examples of this underlying direction to FDA regulatory action. These include GMPs, GLPs, Stability Guidelines and the FOI guidelines.

Regulatory Policies of the FDA

The proposed GMPs, GLPs and the BVM Stability Guidelines attempt to set forth in painstaking detail the regulatory policies of the FDA in these critical areas of regulatory concern. Instead of being guides as to acceptable parameters in the laboratory, manufacturing and stability testing, these proposals and guidelines leave little room for individual discretion. In lieu of a competitive industry with a range of standards, the FDA has determined that certain minimum practices must be met by all, even if in developing these minimum practices a composite highest standard is selected which in reality is met by no one. One of the most heavily regulated industries is in effect being regulated to almost the ultimate degree by not only having to preclear all products before marketing but also by having to establish and maintain costly and extremely high standards in these three key areas.

The FOI guidelines also present an excellent example of increasing legalism. Not content with the original BVM FOI guidelines, the Office of General Counsel developed a much more comprehensive and detailed set of rules which must be satisfied in order to write an acceptable summary of safety and effectiveness data for inclusion in an NADA. As is the problem with any detailed set of regulations or guidelines, certain parameters are established which are subject to dispute. With the FOI guidelines, the focus of the dispute between industry and the FDA has been whether the names of investigators and institutions should be part of this summary. Without insistence by OGC that such a requirement be in the guidelines, it is doubtful whether the BVM would have required such disclosure given the lack of such a requirement in the initial guidelines deemed inadequate by OGC.

From these four examples we can see that increased legalism has stretched the regulatory control of the FDA to (and possibly beyond) the outer reaches of statutory mandate. This underlying direction to the FDA regulatory action has produced highly detailed regulations and guidelines leaving little discretion to the regulated industry. It has also produced some other consequences which are appropriate for discussion after examining the efforts to remove DES and the nitrofurans from the market.

Residue Assay Sensitivity

The FDA proposed a regulation to determine the minimum requirement for residue assay sensitivity for clearance of drugs which induce cancer when ingested by man or animal under the exception to the Delaney Anti-Cancer Clause (Section 512(d)(1)(H) of the Act) (SOM proposal).[1] Numerous comments on the 1973 proposed regulation were submitted and presumably are under consideration by the FDA.[2] The Commissioner has not taken final action on the SOM proposal.

It is basic to resolving the DES and nitrofurans withdrawal proceedings that the FDA take final action on the SOM proposal. By doing so, the FDA will be able to establish a proper regulatory basis for determining the minimum requirements for residue assay sensitivity, thus making it possible to determine what constitutes an adequate test method for DES and the nitrofurans.

Without the benefit of a finalized sensitivity of method document, the FDA has been forced to create new substantive law to compensate for the lack of scientific agreement. Thus, in the DES notice of opportunity for hearing, the FDA for all practical purposes eliminates the Act's Section 512(d)(1)(H) exemption for suspect carcinogenic animal drugs by arguing that a test method is not adequate unless it is sensitive enough to detect residues at a level that has been shown to be safe. In other words, there is no statutory exemption since approval for a suspect carcinogenic animal drug could be denied or withdrawn even though no residue was found in human food.

Nitrofurans

Similarly, with respect to nitrofurans, the FDA concludes that they can be withdrawn from the market on the basis of a modified version of the SOM proposal which is initially but conclusively established in the notice of opportunity of hearing to remove furazolidone from the market. In other words, the FDA is making a major substantive policy decision

[1] 38 *F. R.* 19226 (July 19, 1973). [2] See 41 *F. R.* 19914 (May 13, 1976).

without any opportunity for comment since the notice sets forth and adopts as FDA policy a new version of the SOM proposal. There is no exception to the Administrative Procedure Act[3] or other valid statutory basis for such action.

This apparent tension between science and law has resulted in not only extremely complex and time-consuming proceedings to remove new drugs from the market but has also caused science to take a back seat to the law. Instead of framing withdrawal proceedings in terms of the true scientific issues involved, issues are framed in terms of applicable statutory provisions. This can lead to real distortions such as in the nitrofurans removal proceedings. There, consideration of metabolites is statutorily impermissible under the language of Section 512(d)(1)(H)(ii) of the Act when the Delaney Anti-Cancer Clause is used as a basis for regulatory action, but statutorily permissible in the resolution of safety issues under Section 512(d)(1)(B) if this provision of the Act is used as the basis for regulatory action. Thus, metabolites may or may not be considered based upon the legal theory employed by the FDA in the notice to remove these new animal drugs from the market. This from a scientist's viewpoint is nonsense.

Increased Legalism Within the FDA

This tension between science and law has inevitably fostered increased legalism within the FDA. A natural adjunct but unintended consequence of this increased legalism has been a regulatory pattern which is becoming more and more anti-competitive.

The more detailed the regulations, the higher the standards created, the more difficult it is for the small manufacturer to stay in business. Regulation has a cost which must be absorbed in the price of a product. The greater the volume, the less impact regulations have upon the profitability of a manufacturer. Unfortunately, the converse is also true.

The FDA's efforts with GMPs, GLPs and Stability Guidelines will have one major unintended consequence. These efforts will substantially increase the cost of doing business and force marginal manufacturers out of the new animal drug business. Even financially healthy small animal drug manufacturers will find it difficult to compete. Unless this trend toward increasingly more detailed regulation with ever higher minimal standards is reversed, the number of manufacturers will decrease until only a few major companies remain.

[3] 5 USC Sec. 553.

The proposed GMPs, GLPs, Stability Guidelines and FOI guidelines all reflect the increasingly legalistic approach by the FDA to resolve regulatory problems. Instead of attempting to resolve major questions through the traditional case-by-case approach, the FDA has determined that only grand rulemaking proceedings will be used to guide Agency policy. This rulemaking approach has resulted in comprehensive and detailed regulation leaving little room for discretion and imposing a heavy regulatory burden with its concomitant costs. The tension between science and law which is so keenly evident in the BVM has resulted in DES and nitrofurans removal proceedings which will be extremely complex and time consuming given the failure by the FDA to initially resolve the basic scientific issues involved in these proceedings.

The long-term consequences of failing to resolve the tension between science and law and the FDA's increasing legalism will be an Agency whose proceedings and regulations will be most anti-competitive and result in an industry where only large manufacturers can successfully remain in business. **[The End]**

TIMED-RELEASE ANIMAL DRUGS NOW HAVE THEIR OWN REGULATION

A new regulation intended to ensure the safety and effectiveness of timed-release dosage form drugs for animals has been issued by the Food and Drug Administration. Such drugs have previously been subject to provisions of a regulation governing timed-release drugs that was issued prior to the regulatory distinction between drugs for use in man and those for use in other animals effected by the Animal Drug Amendments of 1968. According to the new regulation, timed-release dosage form animal drugs are regarded as new animal drugs that require approval of a new animal drug application prior to marketing. NADAs for such drugs must demonstrate that the release of active ingredients proceeds at a safe and effective rate and that, if the drug is intended for food-producing animals, food from treated animals would not be unsafe due to residues of the drug.

CCH FOOD DRUG COSMETIC LAW REPORTER, ¶ 74,651.06

Proposed Revisions of the Current GMP Regulations

By J. J. WITTICK, Ph. D.

Dr. Wittick Is Associate Director of Quality Control, Merck and Co., Inc.

I WILL ATTEMPT TO SUMMARIZE FOR YOU the animal health industry views on the proposed revisions of the current good manufacturing practice (GMP) regulations which were published for public comment in the February 13, 1976 issue of the *Federal Register*. These regulations are the so-called "umbrella" GMP regulations and apply to all human and veterinary drugs in finished dosage form. Finished dosage form drugs are defined in the proposed revisions as "drug products".

The views of the industry on these proposals are accurately represented in the comments filed by the Animal Health Institute (AHI) since the member companies of this organization produce nearly 85% of the veterinary "drug products" manufactured and sold in this country.

As the main thrust of its response to the proposals, AHI requests that the proposed revisions apply only to human drug products, leaving the existing regulations as the standard for veterinary drug products. In effect, there would be established a set of GMP regulations for veterinary drug products separate and distinct from those for human drug products.

Drug Recalls

There are a number of arguments in favor of the AHI position. First, there is every reason to believe that the animal drug industry is already producing drug products which are safe and effective. An examination of lists of human and veterinary drug recalls, as reported by the Food and Drug Administration (FDA) over the past several years, reveals that the fraction of recalls involving veterinary drug products which can be related to GMP problems is small and decreasing. In 1974, there were 19 such recalls representing 7.3% of a total of 258; in 1975, there were

24 out of 433 or 5.5% and, during the first four months of 1976, there were only 3 out of 167 or 1.8%. Thus, there is no evident need for drastic revision of the regulations under which this record was achieved.

A second argument stems from a survey of AHI member companies conducted to determine the extent to which the principal changes proposed by the FDA reflect existing practice within the industry. While there was some variation from one proposed change to another, the survey results indicated that, if the proposed changes were implemented, the degree of compliance by members of the industry would fall somewhere between 20 and 25 percent. The implemented proposals, therefore, could hardly be called "current" good manufacturing practices for the veterinary drug industry and it is clear that an independent review of veterinary drug manufacturing procedures is necessary before standards derived from human drug manufacture are applied to veterinary facilities.

Veterinary and Human Medical Practice

Finally, a very basic rationale for separate GMP regulations arises from the substantial difference between veterinary and human medical practice. The veterinarian is generally concerned not with the well-being of any individual animal but with the well-being of an entire herd or flock of animals being raised solely as part of our food-producing process. Obviously, the goals of veterinary medicine here are vastly different from the goals of human medicine. As the practice and goals differ, so can the standards for human and veterinary drug manufacture differ and the differences should be reflected in separate GMP regulations. This would be consistent with the fact that the regulations are currently administered by separate bureaus within the FDA itself.

I should add at this point, that there are some companies, including my own, which would prefer to operate under a single set of "umbrella" GMP regulations, provided they are written in terms broad enough to accommodate both human and veterinary drug products when their manufacturing needs differ. The AHI proposes this approach if the FDA does not recognize the need for separate GMP regulations for veterinary drugs. In that event, several significant defects in the proposed regulations should be corrected before they are finalized. Let me now mention a few of these.

In Section 210.1(b) of the proposed regulations it is stated, in effect, that a violation of any provision of the GMP regulations would, of itself, render the product involved "adulterated" and the person responsible for the violation subject to regulatory action. There appears to be unanimous agreement among pharmaceutical manufacturers that this is an erroneous

interpretation of the Food, Drug and Cosmetic Act and is contrary to the legislative background of the GMP regulations. Section 210.1(b) should be rewritten to provide that the GMP regulations are "interpretive" only.

Another defective aspect of the proposals involves the use of terms such as "prevent", "eliminate", "no potential for", "shall be kept free of", and so forth. These absolutes create unrealistic regulations which are impossible to satisfy. One provision, for instance, would require that buildings be kept *free of* rodents, birds, insects and other vermin. With this as a "substantive" regulation, an FDA inspector could find one gnat in a warehouse, all the drug products in the warehouse would become instantly adulterated and, ultimately, the company president and his director of quality control would be handcuffed and dragged off to rot in prison for the rest of their lives. And the gnat might have come in with the FDA inspector! Such absolute terms should be modified to define the goals of the GMP regulations without mandating their achievement.

Quality Control Unit

In Section 211.22, the responsibilities of the "Quality Control Unit" are defined. According to the proposal, the "Quality Control Unit" is expected to "approve or reject all procedures or specifications impacting on the identity, strength, quality and purity of the drug product". Such responsibility is far too broad for any single organizational unit. Research, product development and production must each share this responsibility within its area of expertise and each area's accountability must not be diluted by transferring the approve/reject function to the "Quality Control Unit."

Of great concern to the animal health industry is the proposal that production activities involving penicillin be performed in facilities separate from those used for other drug products. It is recognized that some humans are quite sensitive to penicillin and that adverse reactions might result from cross-contamination of a non-penicillin drug product with small amounts of penicillin during the manufacturing process. In the AHI, we are unaware of any data which demonstrate that animals are similarly sensitive to trace levels of penicillin. Affidavits to this effect from two men prominent in the field of animal health were filed with the AHI comments on the proposed regulations. These support the industry position that the existing GMP regulations contain adequate precautions against penicillin cross-contamination of veterinary drug products.

Inflation Impact Assessment

Finally, I will discuss the inflationary impact the proposed regulations would have on the animal health industry. The FDA filed an Inflation Impact Assessment which has been criticized by the human pharmaceutical industry as being vastly understated. After an examination of the FDA document, the AHI criticized it as having ignored the animal health industry altogether. The AHI then conducted a survey of its membership and compiled figures which, when projected to include the entire animal health industry, amounted to increased costs of $10.6 million in recurring annual expenses plus $30.3 million in nonrecurring costs. Even ignoring the understatement of the human drug industry impact, these figures, when added to the FDA estimates, push the total impact over the $100 million minimum required to establish a major inflationary impact. Therefore, the AHI feels that the FDA Inflation Impact Assessment is defective, that a full FDA inflation impact analysis should be prepared and that the regulations should be modified to minimize the economic impact on the industry.

There are numerous additional sections of the proposed regulations which are objectionable to the animal health industry for one reason or another. Just to name a few, the AHI objected to the requirement for increased testing of containers and closures, questioned the need to validate component supplier's test methods, objected to the use of retained samples for stability testing and denied the need for an annual review of all production records.

Overall, the AHI comments were detailed and thorough and, I believe, truly reflect the current status of GMPs in the animal health industry. We can only trust that the FDA will agree. **[The End]**

FDA Update

By LARRY R. PILOT

Mr. Pilot Is Director of the Division of Compliance, Bureau of Medical Devices and Diagnostic Products, Food and Drug Administration.

I SINCERELY APPRECIATE THE OPPORTUNITY to be with you again this year for several reasons; but, there are two reasons in particular. In the first place, the Food and Drug Law Institute is an excellent forum for the advancement, exchange and circulation of ideas which are of primary interest to those who enforce the law or have a direct responsibility to assure that a firm or client is complying with the law. In the second place, the law we are discussing is no longer on the drawing board; but a reality which we in the Food and Drug Administration (FDA) are busily attempting to implement.

Medical Device Amendments of 1976

It is this subject that I intend to discuss with you so that you will have a better understanding of what we have accomplished, what we are now doing, and in what direction we are heading. In addition, I have some views about the responsibility and attitude of attorneys, associations and firms about their relationship to the FDA and the attitude of the FDA with regard to the implementation of the Medical Device Amendments of 1976. On this point, I would like to reflect on history and project into the future more before I get into the specifics which relate to implementation of the law.

Since 1970, the Agency has been embarked on an active campaign to create a new awareness of the regulatory importance of medical devices. In the absence of new legislative authority, the Agency took certain initiatives to expand its interest in and authority over devices. Starting with a simple effort to identify manufacturers and devices and continuing through the application of *in vitro* diagnostic product regulations, development of draft good manufacturing practices (GMP) and classification of devices.

as well as pursuit of appropriate regulatory actions, the FDA sought to broaden the scope of its knowledge of the device industry. This was done in order to provide the public with the kind of regulatory supervision over devices that was appropriate to the benefits and risks involved. Some of these activities were undertaken in anticipation of the passage of new legislation and others because action was necessary and appropriate as a solution to a problem or a remedy for a violation. Regardless of the reason, it is our opinion that these efforts resulted in benefit to the public.

Now that the Act has been amended and the explicit authority of the Agency clearly enunciated in the law, it is our responsibility to apply our experience, background and dedication to the implementation of the new authority provided in the 1976 Medical Device Amendments. This will not always be easy because the Medical Device Amendments are very complicated and not always as easily understandable as the draftsmen anticipated. Regardless of this, we recognize that it is our responsibility to determine how the Act can be best applied and to proceed with such application. In many cases, it will be necessary for us to publish regulations in order to clarify or resolve how we intend to proceed, while in other cases it will be necessary only to apply specific provisions of the Act as intended by Congress. We are aware of the fact that there has been an attitude of uncertainty on the part of many observers relative to how the FDA will implement the device amendments and we are sensitive to that concern. There is room for difference of opinion and there are procedural safeguards throughout the Act to protect those who might be unfairly disadvantaged. It was for this reason, in part, that we scheduled meetings for the public as soon as possible after the passage of the device amendments. During our ten meetings throughout the country, we reached over 5,000 people. We learned a lot from the audience and we hope that the audience learned something from us about how we were going to proceed. Certainly, we could not answer every question that an individual had on his mind, and we cannot do that now; but, we did try to identify for the public something about our immediate concerns and what they could expect in the future.

FDA Responsibility

In a way, that is what we are trying to do through meetings such as this. It is important for the public to understand that the FDA has been assigned a tremendous responsibility and that it must move cautiously to implement these responsibilities so that the consumer will derive the greatest possible benefit from the legislation. The Congressionally mandated classification process illustrates a recognition that the FDA should

give priority to its regulatory activities and utilize the assistance of scientists, health professionals, consumers and representatives of industry. Whether we are concerned about classifying devices or taking a regulatory action, we are constantly aware of the need to evaluate the importance of a particular issue to the consumer and apply the most appropriate and efficient method to accomplish an objective. We are not interested in being involved for the sake of activity alone. Our interest must be timely and relate directly to the substance of an issue so that the impact of our effort can be measured by the ultimate benefit to be derived by the consumer. How well we do in the future will be difficult to measure, but the process will be simplified if consumers, health professionals and industry will take some initiative by bringing issues to our attention and providing constructive suggestions on how to cope with these issues. In the meanwhile, we will continue to look to the device amendments and the legislative history for guidance.

Registration of Device Establishments

Since the enactment of the device amendments, we have taken positions on a number of issues, implemented certain programs and proposed some regulations in the *Federal Register*. We are completing the registration of device establishments and expect that this phase of registration will be completed shortly. To date, we have experienced few problems and I believe we have accomplished this objective with little or no measurable trauma to the industry. We will not be able to complete the product listing phase of this effort by the end of the year because we are still finalizing our plans for product listing, but we will complete this process during the first half of 1977. We are implementing Section 510(k) relative to premarket notification and so far this has been accomplished without major difficulties. Proposed regulations relative to these activities and investigational device exemptions have been published and proposed regulations will be published shortly on classification procedures, product listing, good manufacturing practices, transitional devices, and procedures for the handling of applications of state and local exemption under Section 521 of the Act.

Proposed Regulations

Rather than discuss these proposed regulations in detail, I suggest that you make it a policy to review these regulations if they affect you and comment in writing to the Agency. It would be nice to develop and publish proposals for which there was a favorable consensus on the part of all interested parties; this, however, has not been

the case to date. Therefore, you and the general public must recognize that a proposal does not represent a final position, but represents an opportunity for interested parties to provide the Agency with the benefit of their views, expertise and suggestions. After all, what we are interested in doing is to comply with the law as efficiently as possible without imposing burdens which go beyond any possible benefit to be derived by the consumer.

Earlier, I indicated that there are some provisions of the law which can be implemented in the absence of procedural regulations. If it develops that a particular regulatory situation could be resolved through the application of the "banned devices", or "notification and other remedies", provisions of the device amendments, then we will proceed to pursue those remedies in accordance with the procedures outlined in Sections 516 or 518 of the Act. At present, we have some cases which are active and for which we may apply either Sections 516 or 518 of the Act. Mention of this fact may be unsettling to some of you; however, I will remind you that Congress recognized the importance of these remedies and provided procedural safeguards to protect the innocent. Where we believe one or more of these remedies are the remedies of choice, we will proceed to comply with what we believe is the intent of Congress.

There are a number of other areas where we must develop regulations before we can fully implement the authority conferred by the device amendments. These relate principally to records and reports and restricted devices. In addition, there are a number of areas where the Agency will attempt to develop and implement regulations in order to clarify the intent and scope of the FDA's interest in a particular area. For the sake of discussion, let me suggest two areas of interest that relate to the marketing of devices which will receive more attention on our part in the future. These relate to labeling and advertising for restricted devices.

Labeling

With regard to labeling, we have, on many occasions, advised manufacturers to carefully review labeling for their devices in order to make sure that labeling contains sufficient information to enable the user to safely and effectively use the device as the manufacturer intended. The importance of providing complete information is particularly critical for devices which are reusable and for which unique maintenance schedules or procedures are required. For some devices, manufacturers advise purchasers that they will provide maintenance

for the device, while in other cases the manufacturer may provide complete information on the type of maintenance which must be undertaken by the user. I am aware of the fact that some purchasers are unhappy with certain manufacturers because the manufacturer refuses to supply schematic diagrams, details on reuse or resterilization of a device or other information that a purchaser may believe is necessary to the continued successful use of a device. In this area, I caution the manufacturer and user to be considerate of the other's position. If the user must have certain information in order to successfully use a device, then the manufacturer should supply it. However, if the manufacturer has good reasons for not wanting to supply certain information, then he should make this known to the purchaser along with an appropriate explanation. Accordingly, the purchaser should be sensitive to the legitimate concern of the manufacturer. For example, we have investigated several incidents where the user has tampered with a device to the extent that the device has malfunctioned and resulted in injury to the patient. In some cases, users have ignored the explicit advice of manufacturers. I recognize that this subject is sensitive and troubles many manufacturers and users, but it is a subject which is going to have to be discussed in greater depth by users and purchasers before a clear and acceptable position can be enunciated.

Advertising of Restricted Devices

On another subject, I believe it is in order for manufacturers to review their policies with regard to the advertising of restricted devices. This is an area where we will begin to express greater interest and exercise more authority. In this regard, it might be useful for the industry as a group, and manufacturers individually, to consider the history of the government's and Congress' interest in industry practices relative to prescription drug advertising and learn a lesson. Perhaps an example may be useful to reflect my concern in this area. Earlier this year, I attended a professional meeting where a wide range of sales and advertising practices were being employed to promote specific devices or firms. Some firms invested a great deal of money to sell their message and any objective observer would conclude that the costly carnival-like atmosphere created by some firms was out of place for the promotion of health-care products to the health profession. Now, I appreciate the importance of advertising; and, during my experience with the drug and device industry, I have attended hundreds of meetings and observed all types of sales practices. However, I

must admit that the lavish effort undertaken by some firms during that meeting represented a surprising first for me and creates a concern in my mind about the possibility that continuation of such practices will eventually lead to investigation by some government agency or Congress. This could result in the kind of public scrutiny which will reflect poorly on the entire device industry. My advice to the device industry on this point is for individual firms to review their present policies to see whether changes are necessary, and for trade and professional associations to undertake efforts to establish appropriate guidelines or codes of ethics. There is no doubt in my mind that the device industry is going to receive more public attention in the future and, whether we are talking about advertising, clinical investigation, safety or efficacy, it does not take too much perception to figure out what some of the major public issues of tomorrow will be if something is not done voluntarily today.

Responsibility of Industry Representatives

On this last point, I would like to make a few observations about the responsibility of industry representatives and attorneys and offer some personal comments. Implementation of the Medical Device Amendments of 1976 will be difficult and the public will expect a great deal from the FDA, the industry and the profession. It is important that industry recognize and remember the spirit in which this legislation was developed and strive to be constructive rather than obstructive as we attempt to implement various provisions of the Act. The legislative history reflects clear support for the application of certain types of regulatory controls; but, during the last few months, we have witnessed a reaction from some trade associations that appears incompatible with the position taken by them prior to the enactment of the device amendments. In some cases, I believe that this reaction has been over relatively minor issues and may have been directed more toward recruitment efforts than providing a service to the membership. In the long run this attitude will probably result in the creation and continuation of an adversary relationship that will not result in any clear benefit either to the industry or to the consumer. In particular, I have observed that some company attorneys are beginning to involve themselves in issues that relate to policies of science and administration rather than to law. In other words, many nonlegal issues are being transformed into the appearance of legal issues through the mere persistence of attorneys. This is true for issues ranging from classification to registration; and, it is my belief that these attorneys

could better serve their clients by stepping into the backgrounds and allowing scientific and administrative issues to be resolved by scientists and other technical personnel. Lest I be misunderstood, I want to make clear that it is possible that not every position we take or idea we advance is correct or legally sustainable in court. There is room for reasonable men to differ on an issue and we invite and welcome comments from any interested party. However, I am concerned about unnecessary efforts which place too much legal emphasis on issues and result in both industry's and the FDA's energy being diverted from the accomplishment of our mutual objective to provide every possible and practical benefit to the public. If we are wrong, we are not afraid to admit it and take whatever steps are necessary to correct our position consistent with our responsibility to take that course of action which results in the greatest possible protection to the consumer.

Imported Devices

Finally, let me describe for you some of the subjects we are interested in pursuing from a regulatory standpoint over the next year, and invite you to exercise your initiative through the development of approaches and concepts which can be transmitted to us. The approach to the handling of imported devices is something we are concerned about and would like to hear more discussion on: we are interested in pursuing the possibility of developing a uniform law on devices for adoption by the states; and learning more about issues relating to the substance of state and local preemptions. We would like to hear more discussion about the type of restrictions which should apply to devices; and we would like some greater input on the types of services the FDA should provide for small manufacturers. The GMPs will be published as a proposal; and we will begin to develop more specific GMPs and use our advisory committee to assist us in developing an approach and strategy for the implementation of GMPs. In addition, we will be developing regulations on records and reports, expanding our field activities and taking new initiatives to assure that manufacturers and others subject to the law are in compliance.

Positive Approach

In summary, I suggest you consider and reflect upon the issues I have discussed and develop a positive approach toward the implementation of the Medical Device Amendments of 1976. If you have ideas about how we should administer particular sections of the Act, let us know and make constructive and well thought-out suggestions

to us. If you have questions about particular issues, do not consider retreat to a formal administrative procedure or jawbone a possible legal issue with the threat that you may take the FDA to court. We invite and encourage you to write or visit us about your particular concern. There are manifold numbers of questions to be asked; but, we recognize that we do not have all the answers and it will take time to satisfy everyone's curiosity about a particular issue.

Our request for input from the industry and professional groups is not merely a means of giving lip service to or placating those affected by the Act. The wide variety and complexity of medical devices and necessarily diverse manufacturing practices makes it impossible for one agency to have all the answers or expertise needed to make valid, reasonable and responsible decisions. This is why we value and invite outside assistance from every segment of the public. I hope you will do your part to respond so that when we meet you next year we can reflect with pride on the accomplishments recorded during 1977. **[The End]**

EXPERTS ASKED TO TESTIFY ON LAETRILE

Qualified experts have been requested by the Food and Drug Administration to submit testimony to the agency on the legal and scientific status of Laetrile, a substance widely promoted as a cancer cure. The FDA asks that the written testimony, to be filed by March 25, address the following questions: Is Laetrile generally recognized by experts as a safe and effective anti-cancer drug? and is Laetrile a drug that, having been marketed before the 1962 amendments to the Federal Food, Drug, and Cosmetic Act, qualifies for an exemption from the requirements of pre-market approval? The FDA will hold a hearing on May 2 to allow persons to present oral arguments on the issues raised by the written testimony; requests to make such presentations will be accepted until April 22.

Also known as amygdalin and vitamin B-17, Laetrile is currently the most highly publicized unproven cancer remedy in the United States. Although it has been claimed that Laetrile cures and prevents cancer, the FDA believes that the substance, the most widely tested of all cancer "cures," has not been proved safe and effective as an anti-cancer drug and is not exempt from agency regulation. The testimony presented to the FDA will be used to compile an administrative record, recently requested by a court of appeals, on the new drug and grandfather issues pertaining to Laetrile. The administrative record will be submitted to a U. S. District Court that has before it a case involving a cancer patient seeking to obtain Laetrile.

CCH Food Drug Cosmetic Law Reporter, ¶ 41,843

Update

By MARGARET GILHOOLEY

Ms. Gilhooley Is an Attorney with the Office of the General Counsel, Food and Drug Administration.

I. Cosmetic Ingredient Review.

YOU HAVE ALREADY HEARD ABOUT the principal feature of the Cosmetic, Toiletry and Fragrance Association (CTFA) Cosmetic Ingredient Review program. The Food and Drug Administration (FDA) believes the CIR program promises to provide increased assurance to the public that the safety of cosmetic ingredients has been substantiated. Accordingly, the FDA is going to designate a contact person to follow the activities of the CIR program closely, and to be a focal point of communication between the FDA and the program. The contact person will attend public meetings of the CIR's program expert panel and will monitor the results and recommendations of the CIR program. The CIR program is a private program, and its decisions do not legally obligate industry or the FDA in any way. The FDA will decide independently what regulatory action to take with respect to cosmetics. Thus, if the CIR program determines that a certain cosmetic ingredient is not safe, the FDA will independently assess whether any regulatory action is needed. The FDA may also initiate action to restrict the uses of ingredients, even if the CIR program is still reviewing an ingredient or has determined that an ingredient is safe.

The procedures of the CIR program make most of its processes open and public. We think this is very important in making the program credible and in giving the public, and the FDA, more access to the safety data relating to cosmetics. Our principal suggestion for improving the CIR program further would be for the program to select the expert panel through a process completely independent of industry. In sum, then, this is an important industry initiative, and

the FDA hopes that the CIR program will provide a vigorous, thorough-going, no-holds-barred examination of the safety of cosmetics ingredients.

II. Legislation.

You have already heard some comments on S. 1681, the Senate-passed bill on cosmetic safety. The FDA believes that its authority to regulate cosmetics needs to be strengthened, but it opposed S. 1681, as reported from committee and passed by the Senate, because the bill contained cumbersome procedures and did not adequately strengthen our authority.

The FDA wants new legislation that gives us more effective authority to monitor and enforce industry's obligation to market safe cosmetics that have been adequately substantiated for safety before marketing. S. 1681 had its positive aspects since it confirmed that manufacturers have to substantiate the safety of their ingredients. But, it made our authority to issue regulations to require the submission of substantiation information, and for other purposes subject to formal rulemaking requirements (Section 103(g) of S. 1681).

When formal rulemaking procedures apply, the FDA must hold a courtroom-type trial before an administrative law judge. This can be a lengthy process. The FDA prefers notice-and-comment procedures, since they are more efficient, and more suited to the type of issues involved in rulemaking of general applicability. Notice-and-comment procedures are not a mere rubber-stamp though. We have to publish a proposal in the *Federal Register,* analyze the comments and respond to each when we publish the regulation. In our view, these procedures, along with judicial review, provide an adequate check against the possibility of arbitrary action by the FDA.

Regulations

Another problem with S. 1681 is that it specified in some provisions that the FDA could issue regulations, and did not say so in other provisions. This could create the implication that we do not have the authority to issue regulations with respect to all the substantive obligations that would have been created by the bill. We believe we should have the authority to issue regulations with respect to all these matters and the authority should be clearly conveyed in order to avert the possibility of prolonged litigation about the issue.

S. 1681, as originally introduced, contained a provision that would have freed the FDA from the burdens of having to prove an interstate commerce connection in enforcement actions. In this country, we have a national market, and all cosmetics in commercial distribution affect interstate commerce. It can be a time-consuming effort to have to prove an interstate commerce link for particular cosmetics, as we presently have to do in seizure actions. We believe all cosmetics in commercial distribution should be subject to the Act. Unfortunately, the bill that passed the Senate no longer contained this needed reform.

Thus, we continue to believe that we need new cosmetic legislation, but S. 1681 did not meet the need.

I will note one other legislative development. Congress passed the Toxic Substances Act, giving Environmental Protection Agency additional jurisdiction over substances that harm the public or the environment. An exception was provided for products regulated by the FDA, including cosmetics. As a result, there may be increased interest in the classification of products as cosmetics or as products beyond the FDA jurisdiction.

III. Major Pending Cosmetic Litigation.

An earlier panelist has already spoken to you about "Cosmetic Litigation: Is It Hopeless?" For those who put their hopes in statistics, I have made a tabulation of the results so far in the pending cosmetic cases. Of the major cases, involving cosmetics that are pending, a decision on the merits, at the District Court level, has been reached in three of the cases. Interestingly enough, the FDA has prevailed on the merits in all three of these cases. The FDA places its hopes, of course, not on mere statistics, but on the merits of its positions, and on this score we continue to be hopeful about cosmetic litigation. By the way, I am not one of the FDA litigators, and the credit for all the hard work done on these cases so far belongs to several other lawyers in our office.

The three cases in which the FDA won at the District Court level are: *Almay v. Mathews*, (Civ. Action No. 76-1781), concerning the hypoallergenic regulations (21 CFR 701.100); *Cosmetic Toiletry and Fragrance Assn. v. Schmidt*, (D. D. C. Civ. Action No. 75-1715), concerning the FDA regulation (21 CFR 740.11) requiring warning statements on aerosol containers about storage and disposal and the hazards of intentional misuse; and *Consumers Union v. HEW*, (D. D. C. Civ. Action No. 75-120) relating to whether the Federal Advisory

Committee Act is applicable to certain meetings between the FDA and CTFA about the CIR program (or the REAS program as it was earlier called). All three cases have been appealed to the U. S. Court of Appeals for the D. C. Circuit, and the appeals are still pending.

No decision has been reached on the merits of the other pending lawsuits. The Independent Cosmetic Manufacturers and Distributors (ICMAD) brought two related lawsuits against the FDA (*ICMAD v. Mathews,* Civ. Action Nos. 75-1413, 75-1845), both of which are now pending in the U. S. Court of Appeals. Oral argument was scheduled for December 14, 1976.

Cosmetic Ingredient Labeling Regulation

Just before Thanksgiving, the U. S. Court of Appeals granted a stay of the effective date of the cosmetic ingredient labeling regulation. The Commissioner published a notice in the *Federal Register*[1] that explains the effect of the stay. In brief, the Court stayed the November 30 effective date for labeling packages, but the effective date of May 31, 1976 for ordering new labeling remains in effect. Thus, cosmetic ingredients must continue to be declared in all new orders of cosmetic labeling.

Two lawsuits are pending involving the trade secret status of two different cosmetic ingredients. The lawsuits have been brought by Carson Products and Fabergé. The lawsuits challenge the FDA's determinations that certain ingredients or combinations of ingredients are *not* trade secrets. If the ingredients are not trade secrets, as the FDA maintains, the ingredients have to be declared in the list of ingredients. The court papers relating to the trade secret claims have been placed under a protective order by the courts, and cannot be made public since disclosure would destroy the claimed trade secrets.

Pending Litigation

Hopeful as we are about the pending litigation, the FDA has no hopes of ending litigation. If we are active, and keep issuing regulations, we are going to continue to be sued. We are prepared for that; there are many litigators in the office prepared to work hard. Nor, would we want to be immune from litigation. At the FDA, we believe in the checks and balances of the American system of government. If people think that the FDA has acted illegally or arbitrarily, they should be able to get an independent determination from the courts

[1] 41 *F. R.* 53477 (Dec. *, 1946).

about their legal rights. The possibility of judicial review keeps us attentive and objective about the legality and rationality of what we are doing. When the Bureau drafts a regulation or proposes compliance action, and when we in the General Counsel's office are reviewing the proposal, we are always asking: "Can this stand up on judicial review; do we have enough support for this action?" Thus, the real benefits of cosmetic litigation do not always occur in the courtroom; they occur at the administrative level. The possibility of litigation makes us at the FDA take a good hard look at the appropriateness of what we are doing. No matter how the cases turn out in the courts, we all can be hopeful about cosmetic litigation because at the administrative level, cosmetic litigation really works.

Stays of Regulation

While we are talking about litigation, I want to add a few words about stays of regulation pending litigation about them. The FDA will grant an administrative stay pending review if there is irreparable injury, the case is not frivolous and is being pursued in good faith, sound public policy reasons support the stay *and* delay is not outweighed by the public interest. The criteria we look at are indicated in the Sec. 2.9 of the procedural regulations proposed.[2] We believe that those who want a stay of a regulation should first ask the Agency for a stay before they petition one from the courts. (See Sec. 2.11(e) of the proposed procedural regulations). We will not routinely grant stays pending litigation. If we did, we fear we could be routinely sued, and would routinely have to stay our regulations while litigation proceeded. Simply obtaining a delay in the implementation of regulations can be beneficial to a company, even if it does not succeed in overturning the regulation, and does not expect to succeed. Furthermore, the FDA issues regulations to enforce the obligations of the Act. If we routinely stayed regulations during every lawsuit, we would delay giving the public the kind of consumer protection we believe the public has a right to expect. In addition, very often, no stay is really needed, since regulations have long effective dates, and review at the initial court level may be completed before the regulation becomes effective.

This does not mean we will not in practice grant a stay. For example, we granted an administrative stay[3] with respect to the hypoallergenic case pending judicial review of the case brought in the

[2] 40 *F. R.* 40682 at 40723 (Sept. 3, 1975).

[3] 40 *F. R.* 31606 (July 28, 1975).

District Court. After the District Court upheld the regulations, we revoked the stay.[4] *Almay* then sought a judicial stay from the Court of Appeals, but the Court denied the petition.

Thus, to sum up, administrative stays are not routinely granted but they will be granted in some cases. A decision to grant a stay involves a balancing of equities, and the decision turns on the situations of the specific case.

IV. Major New Regulatory Developments.

A. *Fluorocarbons.*

The FDA has initiated action to phase-out non-essential uses of fluorocarbons in FDA regulated products. This action has a significant impact upon cosmetics because chlorofluorocarbons are widely used as propellants in cosmetics aerosol containers, such as hair sprays, deodorants, and fragrances. As the first step,[5] the FDA proposed that a warning statement be required on all aerosolized products subject to FDA's jurisdiction that contain chlorofluorocarbons. The FDA is taking the action because chlorofluorocarbons may destroy the protective ozone layer in the stratosphere. Depletion of the ozone layer may increase ultra-violet radiation and lead to an increase in skin cancer and changes in the world's climate. In the same issue of the *Federal Register,* the FDA stated its intention to phase-out within a reasonable period all non-essential uses of chlorofluorocarbons in the FDA regulated products and invited the submission of information on related issues.

CTFA petitioned the FDA to change the names of certain propellants, for purposes of cosmetic ingredient labeling, from functional names, for example, "Propellant 11" to chemical names, for example "Chlorofluorocarbon 11." The FDA proposed this change in the same issue of the *Federal Register*. The comment period for all these actions closes on January 25, 1977.

B. *Color Additives.*

The FDA took a number of actions with respect to color additives in foods, drugs, and cosmetics, including terminating the provisional listing for carbon black, and requiring additional studies of other provisionally listed colors.[6]

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[4] 41 *F. R.* 32583 (Aug. 4. 1976).
[5] 41 *F. R.* 52071 (Nov. 26, 1976).
[6] 41 *F. R.* 41852-68 (Sept. 23, 1976).

D. *Cosmetic/Drug Distinction.*

This does bring me, though, to the final topic that I have been asked to comment on, namely the cosmetic-drug distinction. In the past, everyone thought they knew the difference between cosmetics and drugs. All anyone had to do was to look at the explicit claims made by the product, and check how that type of claim was classified. However, as the issue is more closely examined, things do not appear to be that clear or simple. For example, take this matter of explicit claims. Some think that a product can be a drug only if it makes an explicit drug claim, but the statute does not define a drug solely in terms of products that expressly claim to be drugs. Instead the statute talks in terms of products that are "intended" to affect the structure or function of the body, or treat disease. Intention can be judged by many things in addition to express claims. The ingredients of a product, and its effect when used, are elements in judging intent.

This year the FDA had occasion to look more closely at the drug/cosmetic in connection with sunscreen products. The FDA was asked whether a product labeled solely as a suntan lotion would be considered a drug because it contained an effective sunscreen ingredient. The FDA advised that a suntan product containing a sunscreen ingredient is intended and understood to be a preventative of sunburn, and therefore, the product is a drug. The cosmetic/drug issue may get more scrutiny in other areas. Since the issues turn on the attributes of particular products and the intention in marketing them, decisions may be made on a case-by-case basis.

You may be concerned about the uncertainty that will result from the new attention to the distinction between cosmetic and drug. You should bear in mind, though, that the distinction does not always make a significant difference. Irrespective of the classification, products cannot be misbranded, or adulterated. When questions of safety arise, the data that makes a drug ingredient no longer generally recognized as safe, is likely to be sufficient to establish that the same ingredient may be injurious to health when used in a cosmetic, making any cosmetic containing it adulterated. The FDA's action with respect to chloroform is illustrative.

In addition, the cosmetic/drug distinction is not an either/or problem. We do not always have to struggle trying to decide whether a particular product is a drug or a cosmetic. It is possible for a product to be both a drug and a cosmetic. In case of doubt, you may find it

useful, as your starting point, to assume that a product is both a drug and a cosmetic.

Lastly, the confusion between the drug category and the cosmetic category is not a problem created by the FDA. The categories were relatively clear-cut years ago when industry made cosmetics that served basic cleansing and cosmetic purposes. But industry keeps adding new ingredients to traditional products, and amplifying the purpose for which they are offered. We cleanse our teeth now for all sorts of purposes, and with all sorts of ingredients. It is not that the FDA has changed the definitions; industry has changed the products. It may take a while to sort out the new answers, but that is progress for you.

[The End]

FOOD FLAVORING SAFETY REPORT AVAILABLE

As part of the safety review of "generally recognized as safe" and prior-sanctioned food ingredients, criteria have been developed for evaluating the safety of flavoring substances, the Food and Drug Administration has announced. In view of the wide public interest in the subject, the FDA has invited comments on the criteria, which are contained in a report prepared by the ad hoc Select Committee on Flavor Evaluation Criteria of the Life Sciences Research Office, Federation of American Society for Experimental Biology under contract with the FDA.

CCH Food Drug Cosmetic Law Reporter, ¶ 41,844

Is Cosmetic Litigation Hopeless?

By WILLIAM P. PENDERGAST

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IN THE TWELVE MONTHS THAT HAVE PASSED since the last meeting of this Institute, the cosmetic industry has been directly involved in, or affected by, four lawsuits with the Food and Drug Administration (FDA). They include litigation involving the aerosol labeling regulations; the delisting of the color additive, Red No. 2; the hypoallergenic labeling claim regulation; and the suit filed by *Consumers Union* in which the Union asserted that certain industry meetings with the FDA officials should have been public.[1] This is a significant amount of litigation for one industry dealing with one Agency in the course of a single year, especially in light of the fact that there have been less than four such suits involving the cosmetic industry and the FDA in the preceding fifteen years.

But an even more significant and disturbing fact about these lawsuits is that the industry lost the first three, all of which were reviews of rulemaking procedures, and was on the winning side in the fourth—the *Consumers Union* case—only because it had intervened as a defendant with the FDA in defending the propriety of Agency officials holding private meetings with industry representatives that do not have to comply with the Federal Advisory Committee Act.[2] In other words, the FDA won all the review proceedings and the industry always lost—unless it sided with the FDA. This fact is significant because it raises the issue of whether petitions for judicial review of FDA rules and decisions should ever be considered

[1] *CTFA v. Schmidt*, CCH FOOD, DRUG, COSMETIC LAW REPORTER, Transfer Binder (1975-1976); *Certified Color Manufacturers Assoc. et al. v. Mathews*, FOOD, DRUG, COSMETIC LAW REPORTER ¶ 38,073 435 F. 2d 284 (D. C. Cir., 1976); *Almay, et al. v. Weinberger*, 417 F. Supp. 758 (D. C. 1976); *Consumers Union v. C. T. F. A., et al.* — F. Supp. — (D. C. 1976).

[2] "The Court concludes that FDA was not obtaining advice or recommendations from CTFA at the meetings

(Continued on next page.)

as a method of defending the rights of the cosmetic industry or should other methods (if there be any) of asserting the legitimacy of what the industry does or the incorrectness of what the FDA proposes be developed. Furthermore, this fact, of wholesale defeat in the courts, is disturbing because it indicates either that our techniques for approaching such litigation are faulty or that the FDA in fact and in law has untrammelled discretion to do whatever it wishes to do. If it should turn out that the courts are a useless avenue in which to seek redress from inappropriate Agency action, then indeed the position of the cosmetic industry is precarious.

What I propose to do is to look at this situation, particularly these four decisions, and see if there is any pattern or line of thought that could give us guidance, tell us how to proceed in the future and to see whether our plight is indeed hopeless. The end of this year of busy litigation is an apt time to pause and determine what changes in our thinking about FDA regulations are indicated.

Regulations

First, however, it is worthwhile to recall the events that brought about this rash of lawsuits. The FDA is now enforcing the laws entrusted to it by the publication of regulations spelling out in detail what the Agency expects of the industry and issuing these regulations in such a fashion that, when final, they have the force and effect of law.[3] Therefore, if someone does not comply with a regulation, the FDA's method of enforcement is simple: all the Agency has to do, in a lawsuit, is demonstrate (a) the existence of the regulation, and (b) the failure of the defendants to comply with it. The FDA does not have to litigate the facts behind the regulation.

Concededly, this method has certain advantages for the FDA, the consumer, and the industry. Such regulations tell everyone, at the same time and in the same way, what is expected of them so that compliance throughout the country is relatively uniform. If the regulations are properly designed, then the consumer is given the protection for which the laws were enacted and the industry should be stable because it knows where it stands. Finally, the FDA bene-

(Footnote 2 continued.)
and that the parties were therefore not bound by the provisions of the Federal Food, Drug, and Cosmetic Act". Slip Opinion, *supra*, p. 9.

[3] *National Nutritional Foods Ass'n. v. Weinberger*, 512 F. 2d 688 (2 Cir., 1975), cert. den. 423 U. S. 827 (1975); *National Nutritional Foods, et al. v. FDA*, 504 F. 2d 761, 733 N. 8 (2 Cir., 1974), cert. den. 420 U. S. 946 (1975).

fits because it is not required to litigate the propriety of labeling claims or of product ingredients on a case-by-case basis. Simplicity, harmony and certainty should be the happy results.

However, this has not always been the result. For reasons too numerous and controversial to go into here, this industry, as well as others, has been forced to challenge many of these regulations by court review. One reason for this is that the review proceedings are now the only means available for challenging the propriety of FDA regulations and, as such, they account for the recent rash of litigation.

Red No. 2

This brings us to the events of the past year. The cosmetic industry, in apparent recognition of the importance of court review, challenged the landslide of regulations that descended on it and became an active participant (or interested observer in the matter of Red No. 2) in the cases noted earlier. The unfortunate results are known to all of you. I will not go into these cases in detail but instead confine myself to one certain facet that I find present in each of the review cases, a facet which I believe leads us to the problem we face and perhaps a solution. These cases, with the exception of the *Consumers Union* matter, all involved judicial review of Agency action under that provision of the APA that requires the reviewing court to "review the whole record or those parts of it cited by a party . . ." in determining whether the complaint of Agency action was arbitrary and capricious.[4] It is here—in the development of the "record"—that our problems arise.

In the aerosol case, the industry challenged an FDA regulation requiring two warnings on aerosol cosmetic products. The court, after noting that the standard of review was whether the regulation was arbitrary and capricious, stated that there was "ample evidence" in the record to justify the two warnings.[5] And later, in discussing the industries' contention that the evidence did not justify the application of one of the warning statements to aerosol fragrances, the court observed that the only record evidence provided by the industry "consisted, essentially, of: a) an informal poll of CTFA's members showing that there is no history of abuse of aerosol fragrance products; and b) claims that aerosol fragrances are inherently not subject to abuse . . . ."[6] The court found this evidence insufficient. Finally, in sustaining the regulation, the court specifically relied upon another

[4] 5 U. S. C. 706, final paragraph.
[5] *CTFA v. Schmidt, supra,* at p. 59-60.
[6] *Ibid.* p. 62.

portion of the record consisting of the report of a special (FDA appointed) committee on aerosol toxicity.[7]

Hypoallergenic Case

The hypoallergenic case was another review of an administrative record. Here, as counsel for the plaintiffs, I must disclose my bias and, because the matter is on appeal, a certain degree of diffidence in commenting on litigation *sub judice*. However, certain comments made by the District Court are relevant to my thesis. First, the court concluded that a portion of the administrative record, a consumer survey by the FTC, "clearly showed that consumers were obviously confused by the use of the term 'hypoallergenic'," and that other parts of the record justified the FDA's decision to define the word "hypoallergenic" in comparative terms.[8] The District Court did not discuss the record evidence dealing directly with the test mechanism imposed by the regulation apparently on the assumption that if there was record evidence to support the comparative definition of "hypoallergenic" (as the court found) then the test mechanism, which also is comparative, follows from that as a matter of logic and is, thus, also supported by the same record evidence.

As for the remainder of the regulation—that portion which applies its strictures to all labeling claims "related" to the word "hypoallergenic," the court found that to also be supported in the record by the same FTC survey, holding that the survey supports a "rational inference . . . nowhere refuted in the record . . ." that consumers perceive such terms the same way as the FDA found them to perceive the word "hypoallergenic."[9] Needless to say, the holdings are at issue on appeal.

In the third and final case, dealing with Red No. 2, the Court of Appeals engaged in an extensive examination of the record facts and noted that

"[t]he information available to [the FDA] indicated a statistically significant relationship between high dosages of Red No. 2 and the occurrence of cancer in aged female rats. That relationship concededly did not establish conclusive proof . . . but it was at least suggestive . . . ."[10]

The court concluded in part on the basis of that finding that there was a "rational nexus between the facts found and the decision made."[11]

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[7] *Ibid.* p. 63.

[8] *Almay, et al. v. Weinberger, et al., supra*, p. 761-762.

[9] *Ibid.* p. 762.

[10] *Certified Color Manufacturers Assoc., et al. v. Mathews, et al.*, 543 F. 2d at 297.

[11] *Ibid*, p. 298.

When cases are reviewed in this manner, a definite pattern emerges which could help answer some of the questions raised earlier. In each case, the reviewing court was satisfied that the FDA had presented enough record facts to justify what it did and (and here I believe we have the most important point) that the industry had not presented enough facts to controvert what the FDA was saying. In other words, it was not that the statutory law was against us or that the courts were blindly acting as rubber stamps for the FDA—each case was an apparent failure of proof on the part of the industry —we either did not have, or failed to present, facts sufficient to prevail. Of course, it is true that the standard of review in these cases ("arbitrary and capricious") is a severe one for the industry to ever prevail on a factual basis. But this is not to say that it is an impossible task and, in any event, the courts have lately begun to recognize this problem by insisting upon an intensive judicial review of the factual basis for what agencies propose and by remanding many proceedings where the factual record is unclear or even equivocal.[12] What I draw from the many cases in this area, especially those stemming from the Supreme Court's decision in *Overton Park*[13] is that the courts are telling us to do a better job of making a factual record at the administrative level and that, if we do a convincing job there, we can prevail on court review.

Thus, to answer the question raised by the title of this paper, litigation with the FDA is not hopeless—but we do have to rethink how we have been going about it. Traditionally, when the FDA proposes regulations, companies, trade associations, and others, either by letter or as legal briefs, file comments setting forth (1) legal issues; (2) policy considerations; (3) technical problems, either in the way the regulation is set up or in the terminology used; and (4) factual problems or contentions. Such comments are desirable and fill an important need, particularly in the area of technical matters and draftsmanship. However, I suspect, perhaps because of this historical tradition of using letters and briefs at the comment stage, that we have not focused on the need to make a convincing factual record. We have, too often, looked at only half of the problem—to get the FDA

[12] *E. g. Ethyl Corp., et al. v. EPA*, 541 F. 2d 1, 34-36 (D. C. Cir., 1976), (en banc) cert. den. 96 S. Ct. 2663 (1976); *Environmental Defense Fund, Inc. v. Ruckelshaus*, 142 U. S. App. D. C. 74, 439 F. 2d 584 (1971); Wright, *The Courts and the Rulemaking Process: The Limits of Judicial Review*, 59 Cornell L. Rev. 375 (1974).

[13] *Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U. S. 402 (1971).

to change its mind—while ignoring the other half—how will a court look at our problem on review, should that be required.

I suggest, therefore, if we are to avoid repeating the history of this last year, that we must view the comment time provided for the FDA proposed regulations on two levels: *one,* as an opportunity to persuade the FDA to take whatever course of action we believe desirable (this would be the traditional comment method), and *two,* as the first step in a summary judgment type procedure in which the FDA will prevail on court review unless we make sure that the "record" contains our facts in crystal clear form based on appropriate first-hand knowledge or expert opinion. I see this as including test data fully set forth with explanation and supporting affidavits, as well as expert opinion affidavits. Nothing should be assumed and nothing should be left out. For example, a scientific fact may be obvious to both industry and the FDA scientists. Nevertheless, if it is relevant, it should be placed in the record by affidavit or other clear undisputable form. As another example, if a scientific study or consumer survey is relied upon, it should be accompanied by an affidavit of an appropriately qualified expert who will (1) attest to its reliability and (2) insofar as possible, explain any ambiguities that may appear in the report. This is important because the FDA has the habit, when it suits its purpose, of dismissing a published report or article because of something that the Agency scientists find in it that is either subject to two interpretations or otherwise incomplete. We should try to anticipate this attitude as much as possible and be sure that there are no loopholes through which the FDA can run. The point of all this—and the point I think we have sometimes forgotten—is that if our facts are not clearly stated in the record the reviewing court will not know them and cannot base a judgment on them.

To state it another way, regard the notice and comment period as a trial—as major litigation—and see to it that the record made there is as good as you would insist it to be if you were in such a trial.

If this attitude is developed (and obviously it should be restricted to major problems where controversy can be anticipated) then I think we will find that litigation challenging the FDA regulations is difficult—but not hopeless. If we state our factual case clearly and fully at the administrative record level, the FDA either will not act arbitrarily or, if it does, the courts will have before it the means and record to correct matters. Maybe it is naive or unduly optimistic, but I believe that if we work at it hard enough the system works. For the sake of all of us, I hope I am not wrong. **[The End]**

Product Liability—1976

By WILLIAM J. CONDON

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WHEN THE DOCTRINE of strict liability in tort was evolved, and proceeded to spread across the country with unprecedented speed, there was a tendency to jump to the conclusion that the problems in products liability cases would henceforth be restricted to factual issues. Strict liability would be the ultimate simplification which would eliminate all technical legal problems. The development of the law would indicate that such an optimistic view was unwarranted.

First of all, it is naive to expect lawyers and judges to dispense easily with concepts which have been their working tools for years. Anyone who has scanned annotations under the various simplified practice acts would readily recognize that this is so. There is a predilection to read the new in terms of the old, and thus, to incorporate older concepts into the meaning of new words. By the same token, there is also a tendency, where the new represents a striking change from the old, to see differences which do not exist, or to extend the new to unwarranted limits. All of these are bound to lead to a certain amount of confusion.

Different Causes of Action

In the light of this, it is not surprising that most actions which are brought in this area involve claims based upon several different causes of action. Unfortunately, the results in many of these cases simply tend to add to the confusion. Take for example, the case of *Awedian v. Theodore Efron Manufacturing Company* (CCH PRODUCTS LIABILITY REPORTS, ¶ 7641). Plaintiff slipped in a bathtub and thrust his arm through the glass of a bathtub enclosure door. He sued the manufacturer of the door in both negligence and warranty. The jury found that the defendant was guilty of negligence but that there was no breach of implied warranty.

The defendant, sued only as a manufacturer, claimed on appeal that the verdicts were inconsistent. The court disagreed, saying that the two causes of action are substantially different. In warranty, the plaintiff must show a defect and causal relationship to the injury. In negligence, on the other hand, plaintiff must show a duty, a breach of that duty and causal relationship. Obviously, there is nothing wrong with the court's statement of the law. There appears, however, to be a complete misapplication of the distinction to the facts of this case. If the manufacturer had been negligent in manufacturing this product, the result would be a defect. However, the jury of necessity found no defect under the cause of action in breach of warranty. The court fails to recognize that every recovery in products liability is predicated on a defective product. If this is so, then there is a necessary inconsistency between two verdicts on the same facts which find negligence but not strict liability (or breach of implied warranty).

Oral Contraceptive

The same problem arose in *Hamilton v. Hardy*, although in a different context. This action involved injuries suffered following the use of an oral contraceptive and the essence of the complaint was a failure to warn. The Trial Court perceived no difference between a negligence case based on failure to warn and a strict liability case based on failure to warn and hence, refused to give the instruction on strict liability because he felt it would be duplicitous and confusing. After a jury verdict for defendant, the Colorado Court of Appeals reversed. The court noted that some other jurisdictions have taken the position that in failure to warn cases, there is no difference between negligence and strict liability. This Court agrees that the evidence is the same for both but insists that the theories are different. In developing the distinction, the court points out that a negligence case is concerned with the conduct of the defendant, whereas strict liability looks only to the condition of the product. Hence, the court says that the issue in strict liability is whether the defendant's failure to warn, or to warn adequately, rendered the product unreasonably dangerous, irrespective of whether the defendant's warning comported with the warning which the reasonably prudent drug manufacturer would have given.

Followed to its logical conclusion, this case would seem to be authority for the proposition that a drug manufacturer should be strictly liable

for dangerous side effects of his drug even though he neither knew nor should have known of this particular dangerous propensity prior to plaintiff's use of the product. If this is what the court means, it is at variance with the vast majority of jurisdictions which have considered this problem.

In fairness, it does not appear that the court intended to go that far. After alluding to the controversy among some commentators as to whether the defect in a drug product lies in its dangerous propensities, or in the failure to warn, the court concluded its discussion as follows:

"Thus the question to be posed to the jury with regard to the strict liability issue is whether the manufacturer's failure to adequately warn rendered the product unreasonably dangerous without regard to the reasonableness of the failure to warn judged by negligence standards."

Strict Liability

A drug case which arose in Nebraska also involved a refusal by a Trial Court to instruct the jury on strict liability. This refusal, however, was based upon the Trial Court's belief that no case in strict liability had been proven. The issue of negligent failure to warn was submitted to the jury which returned a verdict for the defendant. On appeal, the Nebraska Supreme Court affirmed the action of the court below. Since the defendant had a favorable verdict, the question of the propriety of submitting the negligence case to the jury was not presented on appeal. Hence, the court was not called upon to determine whether one might be guilty of a negligent failure to warn without being strictly liable.

Fixed Ratio Combination

On the strict liability issue, plaintiff had introduced evidence from expert witnesses to the effect that the fixed ratio combination of the two active ingredients in defendant's product was improper drug design and, therefore, unreasonably dangerous. The uncontroverted evidence submitted by the defendant showed that everything which defendant knew concerning the dangerous propensities of its product had been submitted to the Food and Drug Administration (FDA) in its application for approval as a new drug and had likewise been included in its package inserts and other promotional literature. The evidence was clear that the side effects of which plaintiff complained had been well known since the drug was studied prior to approval.

On the basis of this evidence, the court held that it was proper to withhold the issue of strict liability from the jury. In the course of its opinion the court said:

"While approval by the Food and Drug Administration is not necessarily conclusive, its determinations, based upon the opinions and judgment of its own experts, should not be subject to challenge in a product liability case simply because some other experts may differ in their opinions as to whether a particular drug is reasonably safe, unless there is some proof of fraud or nondisclosure of relevant information by the manufacturer at the time of obtaining or retaining such federal approval."

The court went on to state its holding in the following terms:

"An unavoidably unsafe drug which has been approved for marketing by the United States Food and Drug Administration, properly prepared, compounded, packaged, and distributed, and accompanied by proper approved directions and warnings, as a matter of law, is not defective nor unreasonably dangerous, in the absence of proof of inaccurate, incomplete, misleading or fraudulent information furnished by the manufacturer in connection with such federal approval or later revisions thereof."

New Drug Application

This is the strongest statement which we have seen concerning the effect of approval of a New Drug Application by the FDA. It should be noted, however, that the finding that the product is not unreasonably dangerous nor defective, as a matter of law, cannot be made if there is proof of inaccurate, incomplete, misleading or fraudulent information furnished by the manufacturer. It is, of course, in these areas where the factual questions generally arise (*McDaniel v. McNeil Laboratories Inc.*).

Failure to Warn

On reviewing decided cases over a period of a year, one cannot help but be struck by the frequency with which the claim of "failure to warn" occurs. This has truly become a favorite avenue of attack. It is axiomatic that a failure to warn is meaningless in the absence of a duty to warn. How far these claims can be stretched may be adequately exemplified by the case of the 28-year-old man in Michigan who helped his brother-in-law assemble a swimming pool in the latter's back yard. The pool was four feet deep. Subsequently, plaintiff climbed onto a garage which was seven feet high and dove headlong into the pool. When he was injured, he sought to assert liability against the manufacturer, the seller, and his brother-in-law on the theory that they should have warned him not to dive into the pool from that height. Affirming a grant of summary judgment for all

defendants, the court said that none was under any duty to warn plaintiff of an obviously dangerous use of an otherwise nondangerous product (*Hensley v. The Muskin Corporation,* CCH PRODUCTS LIABILITY REPORTS, ¶ 7607).

Some time ago, the Court of Appeals of New York enunciated a rule that there could be no recovery against the manufacturer of machinery where the danger was open and obvious and well known to plaintiff (*Campo v. Scofield,* 301 N. Y. 468). This has become known as the patent danger rule and has been widely followed in other jurisdictions. However, the rule has been subject to severe criticism by many commentators and in some courts. The basis of the criticism is that, while public policy is directed toward the encouragement of manufacturers to produce safe products, this rule insulates the manufacturer from liability for an unsafe product if he only has the foresight to make the danger obvious.

The New York Court of Appeals has now yielded to this criticism and has overruled its earlier decision (*Micallef v. Miehle Company,* CCH PRODUCTS LIABILITY REPORTS, ¶ 7701). The impact of the new holding is that the open and obvious character of the danger involved in defendant's product will no longer insulate him from liability as a matter of law. It now becomes one of the factors to be used in determining whether plaintiff exercised that degree of care which was required under the circumstances.

Availability of Safeguards

Thus, the conduct of the plaintiff will be considered along with such other factors as the availability of safeguards, the relative cost of providing such safeguards, and the question of whether the product would lose its workability if such safeguards were provided.

To what extent the conduct of plaintiff acts as a bar to his recovery in strict liability has been the subject of considerable controversy. Most courts have adopted the view that contributory negligence, insofar as it consists in plaintiff's failure to discover the defect in defendant's product, or to guard against its existence, will not constitute a defense. However, the conduct of plaintiff, insofar as it involves proceeding in the face of a known and obvious danger, which passed at common law for assumption of risk, will bar his recovery. This distinction, while it makes a lot of sense, does not solve all the problems.

For example, before assumption of risk becomes operable to bar plaintiff's claim, it must be shown that he perceived the risk, that he appreciated the risk and that he proceeded nonetheless. The thing which sometimes arises is What is the risk that plaintiff must perceive and appreciate? In *Baker v. Chrysler Corporation*, CCH PRODUCTS LIABILITY REPORTS, ¶ 7646, plaintiff was walking on the street toward oncoming traffic. He tried to cross in front of an oncoming car but, in spite of the efforts of the driver thereof, plaintiff was struck by the car. His claim against Chrysler was that his injuries had been increased by defects in the design of the front end of the car. Plaintiff's theory was, in effect, a further extension of the so-called "second collision" theory. First we had cases in which courts held that manufacturers had a duty to design a car which was reasonably safe to collide in. Then there were claims that the manufacturer had a duty to design a car that was reasonably safe to collide with. Now plaintiff claims that the manufacturer has a duty to design a car that is reasonably safe to be struck by.

The jury returned a verdict for defendant and plaintiff appeals, complaining, among other things, that the court should not have given any instruction on assumption of risk, since he is not complaining about being struck by the car but rather about the design defects which enhanced his injuries. Since he did not know of these defects until it was too late, there was no basis upon which a jury could find that he had assumed the risk. The California Court of Appeal rejected this argument, holding that the evidence was sufficient to support a jury finding that plaintiff's conduct amounted to an assumption of the risk on his part that he would be struck by the oncoming car. In fact, the court pointed out that the trial judge's instruction had erroneously favored plaintiff because it required a finding by the jury that plaintiff had actual knowledge of the alleged defect in the automobile. This court said that for asssumption of risk the only knowledge required is that an injured plaintiff be aware that he is placing himself in danger.

We had one case this year wherein the defense of assumption of risk was not allowed, although its attempted use by defendant was equally ingenious. Plaintiff was a night auditor in a motel. He had been the victim of a holdup but had escaped with minor injuries because the gun which was fired at him was a starter pistol. He thereupon decided that he needed some means of protecting himself.

He and a fellow employee obtained several brochures about the chemical mace. After reading defendant's literature, the two employees prevailed upon their employer to buy defendant's MK-II which was about the size of a large barrel pen. Among other things, the literature said this about the effectiveness of mace:

"Rapidly vaporizes on face of assailant effecting instantaneous incapacitation. . . It will instantly stop and subdue entire groups . . . instantly stops assailants in their tracks . . . an attacker is subdued—instantly, for a period of 15 to 20 minutes."

Several months after the purchase plaintiff was again a victim of a holdup at the motel. Using the cash register as a shield, plaintiff squirted the mace at the intruder with the gun, striking him "right beside the nose." Plaintiff then dropped down behind the register, but the intruder followed him and shot him in the head. The intruder then made his escape immediately. Defendant argued that plaintiff voluntarily assumed the risk of confronting an armed intruder with its mace weapon. In effect, the argument is that one could never justifiably rely on its representations in these circumstances. Accordingly, defendant contends that the Trial Court erred in refusing to grant an instruction on assumption of risk. The Pennsylvania Superior Court rejected this argument because the conduct of the plaintiff was solidly grounded on reliance on the misrepresentations of defendant and the use of the product by plaintiff was precisely that for which the article was designed and sold.

Strict Liability In Tort

Florida joined the long line of jurisdictions adopting strict liability in tort in the case of *West v. Caterpillar Tractor Company,* CCH PRODUCTS LIABILITY REPORTS, ¶ 7719. The action arose when plaintiff's intestate walked into the path of a road grader and was killed. The grader was involved in highway construction near her home. The action against the manufacturer was brought in strict liability and breach of warranty based on an alleged defective design in that the grader did not have adequate visibility to the rear, no rear view mirrors and no appropriate warning signals. The defense of contributory negligence was interposed on the basis that plaintiff's intestate was aware of the presence of the grader and was inattentive to its activities when she crossed in its rearward path.

On certification of questions from the United States Court of Appeals for the Fifth Circuit, the Florida Supreme Court held (1)

that the doctrine of strict liability in tort, as enunciated in Section 402A of Restatement of Torts 2nd, represents the law of Florida; (2) that contributory negligence that consists in other than the failure to discover the defect and guard against its existence is a defense to both strict liability and breach of implied warranty; and (3) that both strict liability and breach of implied warranty apply to bystanders as well as users.

Negligence Statute

Florida has a comparative negligence statute. Hence, any recovery to be had against the manufacturer would be reduced by the percentage by which the conduct of plaintiff's intestate contributed. In defining contributory negligence, the court took note of the fact that other jurisdictions confine the doctrine to assumption of risk and unreasonable misuse of the product. The Florida court's holding is much broader. It said:

"The defendant manufacturer may assert that the plaintiff was negligent in some specified manner other than failing to discover or guard against a defect, assuming the risk, or misusing the product, and that such negligence was a substantial proximate cause of the plaintiff's injuries or damages. . . The fact that plaintiff acts or fails to act as a reasonable prudent person, and such conduct proximately contributes to his injury, constitutes a valid defense. In other words, lack of ordinarily due care could constitute a defense to strict tort liability."

This brief and very selective review of some of the problems encountered during 1976 may be sufficient to demonstrate my thesis that the advent of strict liability did not result in the complete simplification that some might have expected. Of course, we should not expect that all lawyers hope for, or would even stand for, too much simplification. Nevertheless, it appears that the courts are striving for further relief from the morass that is developing in some of these areas. Consequently, I am emboldened to predict that, in the foreseeable future, we will see the development of a cause of action labeled simply "products liability." This will have the virtue of permitting the courts freer latitude in their efforts to establish some clarification in areas such as allergies, failure to warn, contributory negligence, and statutes of limitations. It will have the additional virtue, and perhaps its major benefit, in freeing juries from the burden of sifting out lengthy and often confusing instructions which they must now face in cases based upon several different theories of liability.

Such a development will do little to relieve the manufacturer from his liability for the production of defective products, but it may help in getting him to understand and appreciate the basis upon which that liability rests.

PRODUCT LIABILITY CASES FOR 1976

The list of cases for 1976, grouped according to classification, is as follows: (All paragraph numbers refer to CCH PRODUCTS LIABILITY REPORTS)

Foreign Substance and Contaminated Food Cases

Krall v. Shaker Ridge Country Club, Inc., ¶ 7661 (N. Y. App. Div., 3rd Dept.)

Coffer v. Standard Brands, Inc., ¶ 7768 (N. C. Ct. App.)

Foreign Substance Beverage Cases

Kinsey v. Coca-Cola Bottling Company of Augusta, ¶ 7645 (Ga. Ct. App.)

Tarwacki v. Royal Crown Bottling Company of Tampa, Inc., ¶ 7657 (Fla. Dist. Ct. App.)

Haynes v. Coca-Cola Bottling Company of Chicago, ¶ 7722 (Ill. App.)

Bursting Bottle Cases

Fender v. Colonial Stores, Inc., ¶ 7648 (Ga. Ct. App.)

Ball Corporation v. George, ¶ 7772 (Ariz. Ct. App.)

Steele v. Royal Crown Cola Bottling Co., ¶ 7773 (Fla. Dist. Ct. App.)

Drug Cases

Smith v. The Upjohn Company, CCH, ¶ 7555 (CA-2)

Lawson v. G. D. Searle & Company, ¶ 7638 (Ill. App.); ¶ 7767 (Ill.)

Goodman v. Mead Johnson & Co., ¶ 7654 (CA-3)

Tomer v. American Home Products Corp., ¶ 7673 (Conn.)

Hamilton v. Hardy, ¶ 7682 (Col. Ct. App.)

McDaniel v. McNeil Laboratories, Inc., ¶ 7700 (Neb.)

Raymond v. Eli Lilly and Company, ¶ 7748 (U. S. D. C., N. H.)

Cosmetic Cases

Whitehall Laboratories, Inc. v. Gilliam, ¶ 7727 (Tex. Ct. Civ. App.)

Bohnsak v. C. E. B. Products, Inc., ¶ 7797 (Tenn. Ct. App.)

Defective Container Cases

Undeck v. Consumer's Discount Supermarket, Inc., ¶ 7619 (Md. Co. Spec. App.)

Kokoras v. Coca-Cola Bottling Co. of Boston, Inc., ¶ 7622 (Mass. Dist. Ct., App. Div.)

Blood Transfusion Cases

McMichael v. American Red Cross, ¶ 7578 (Ky. Ct. App.)

Glass v. Ingalls Memorial Hospital, ¶ 7612 (Ill. App. Ct.)

Foster v. Memorial Hospital Association of Charleston, ¶ 7685 (W. Va.)

Juneau v. Interstate Blood Bank, Inc., ¶ 7729 (La. Ct. App.)

Klaus v. Alameda-Contra Costa Medical Association Blood Bank, Inc., ¶ 7799 (Cal. Ct. App.)

Cramer v. Queen of Angels Hospital, ¶ 7804 (Cal. Ct. App.)

Economic Poisons Cases

Casadaban v. Bel Chemical & Supply Co., Inc., ¶ 7628 (La. Ct. App.)

Simchick v. I. M. Young & Company, ¶ 7689 (N. Y.)

Fulwider v. Flynn, ¶ 7710 (S. D.)

Larson v. Meckling Fertilizer Company, Inc., ¶ 7725 (S. D.)

Animal Feed Cases

Worden v. Gangelhoff, ¶ 7659 (Minn.)

[The End]

"Good Manufacturing Practices" Rules Proposed for Medical Device Makers

MEDICAL DEVICES REPORTS

Controversial, FDA-proposed "Good Manufacturing Practices" rules are now out for comment, spanning quality control, inspection, storage, packing, installation, records, reports and many other factors. Its expert medical/science panel classification recommendations are also updated ("classification" is at the heart of medical device controls), with final recommendations and classifications to come. Both developments are important, so you'll want to follow what happens closely.

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