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Food Drug Cosmetic Law JOURNAL

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

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

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TO THE READER

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Wesley E. Forte, attorney for Borden, Inc. presents four current problem areas in administrative rule-making. Should it be a regulation or only a guideline? What should the format of a proposal be? When should public hearings be held? Are they fact-finding excursions or adversary proceedings? The article, beginning on page 476, is entitled "General Principles of Administrative Rule-Making Under the Federal Food, Drug and Cosmetic Act."

William W. Goodrich, in "The Food and Drug Administration's View on Procedural Rules," the article beginning on page 481, states that one of the principal concerns of agency counsel over the thirty years since enactment of the 1938 Food, Drug and Cosmetic Act has been "procedure apart from substance." Mr. Goodrich traces the history of the methodology of hearings before the Commissioner of the Food and Drug Administration, reflecting the triangular conflict of counsel, the FDA and industry.

In his article, "The Right to Self-Medication—A Continuing Conflict Between Congressional and Agency Policy," beginning on page 487, *Bruce J. Brennan* cites several instances in which the Federal Trade Commission and the Food and Drug Administration, respectively, have attempted to redefine the terms "self-diagnosis" and "self-medication" in order to place an increasing number of medications in the prescription category. The author states that these attempts have put the agencies in a position "contrary to historical public health policies."

The EEC on the Way to a Common Market for Drugs: Its Meaning for Foreign Imports.—In the article beginning on page 500, *Walter P. von Wartburg* discusses recent developments in the field of national drug control legislation affecting the Common Market, particularly inter-Member State trade in pharmaceutical specialties. Unless proposed legislation is adopted, the pharmaceutical specialty will continue to be "the one area . . which will not benefit from increased elimination of trade barriers." Dr. Wartburg, a Swiss lawyer, received his Master of Laws degree from Harvard.

Surgical Implants: Drugs or Devices, and New Device Legislation.—The article by *Vincent A. Kleinfeld* of Kleinfeld and Kaplan, Washington, D. C. attorneys, which begins on page 510, is concerned with one of the most significant and controversial issues in the field of medicine currently unresolved. Mr. Kleinfeld's proposed solution is best summarized in his own words: "As far as important devices used by the surgeon and the physician are concerned, . . . it would be extremely advisable if some prestigious scientific societies were to establish standards for them. These could be related to specifications and safety, and the tremendous delays and expense of government controls might be avoided. It seems to me . . . that this procedure is at least worth trying; if it does not work legislation can always be enacted."

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General Principles of Administrative Rule-Making Under the Federal Food, Drug and Cosmetic Act

By WESLEY E. FORTE

The Following Article Was Presented at the Joint Meeting of the Food and Drug Committee of the Administrative Law Section, and the Food, Drug and Cosmetic Law Division of the Corporation, Banking and Business Law Section, American Bar Association, held in Philadelphia on August 7, 1968. Mr. Forte Is an Attorney for Borden, Inc., New York City. The Two Succeeding Articles in This Issue Were Presented at the Same Meeting.

DURING THE LAST SEVERAL YEARS, the most controversial problems in Food and Drug Law have involved the substance and procedure of administrative rule-making. The Food and Drug Administration (FDA), acting under the Federal Food, Drug and Cosmetic Act of 1938 and the Fair Packaging and Labeling Act (FPLA) of 1966, has attacked the problems of the 1960's by the increased use of administrative regulations rather than by an increase in individual enforcement actions. Thus, we have been confronted successively by Dietary Food Regulations, Fair Packaging and Labeling Regulations, and Good Manufacturing Practice (GMP) Regulations. The general purposes underlying these regulations are, I believe, noncontroversial. If vitamin and mineral-fortified foods are promoted by false and misleading labeling, if consumer commodities do not bear

their mandatory information prominently and conspicuously, and if foods and drugs are being produced under insanitary conditions, we all agree that these practices should be stopped. However, as lawyers, we have a concern not merely with what should be done but with how it should be done. Indeed, we have a special responsibility for the procedural aspects of administrative action, since lawyers are virtually the only group qualified by training and experience to cope with this problem.

Adminstrative rule-making is dependent upon the powers delegated to the agency by Congress. Under the Federal Food, Drug and Cosmetic Act of 1938, the FDA can issue (1) guidelines, (2) interpretive rules, and (3) in some situations, substantive regulations having the force and effect of law.

Selection of the proper type of rule is often difficult in specific situations. For example, there were wide differences of opinion in regard to whether the GMP Regulations should have been guidelines, interpretive rules or substantive regulations. Some of us believed that if FDA was really following the purposes of *Smith Canning*[1] and was trying to improve the practices of the average food processing plant, it would have been more appropriate to accomplish it through guidelines. Any other approach presupposes that Congress intended to condemn the average food processing plant as insanitary and it is very doubtful whether this can be supported by a reading of the legislative history of the statute.

Proposed Substantive Regulations Procedures

The Federal Food, Drug and Cosmetic Act imposes no limitations on the procedures used to issue guidelines or interpretive rules. The Act is, however, quite explicit in regard to the procedures which must be followed in the issuance of substantive regulations. These procedures are outlined in Section 701(e)-(f) of the statute. The same procedures are, in effect, adopted under Section 6 of the FPLA.

Substantive rule-making under Section 701 begins with a rule-making proposal. This section authorizes no substantive regulations and it is therefore necessary to derive the authority for any proposed regulation from some other section of the Act.

[1] *U. S. vs. Fifteen Hundred Cases of Canned Tomato Paste (Smith Canning Co., Claimant)*, 236 F. 2nd 208 (CA-7 1956)

The form of a substantive rule-making proposal has been given little attention in the past. However, this is a likely source of future controversy. The proposal for dietary food regulations included both substantive and interpretive regulations regulating vitamin-mineral pills, vitamin-mineral fortified foods, hypo-allergenic foods, artificially sweetened foods and low sodium foods. This rule-making proposal affected virtually the entire food industry and pre-hearings on the regulations attracted over one hundred lawyers. At the request of the Hearing Examiner, these lawyers offered varying and conflicting suggestions for dividing the proposed dietary food regulations into subparts which could be considered separately. Pre-hearings considering these suggestions and other problems resulting from the wide range of FDA's proposed regulations took three weeks. The necessity for these extensive pre-hearings suggests that it may be appropriate for FDA to give more attention to the form of rule-making proposals in the future. Certainly, it is far simpler for FDA to divide its proposed regulations into subparts than it is to depend upon the Hearing Examiners and all interested parties to make such a division at a pre-hearing conference.

After a rule-making proposal is completed, it is published for comment. Typically, thirty days are allowed for interested parties to submit their views. The Commissioner of Food and Drugs then considers the comments, makes whatever revisions seem desirable, and republishes the order in final form. Persons adversely affected have thirty days in which they can file objections specifying the particular provisions of the order deemed objectionable and the grounds therefor, and request a public hearing.

Public Hearings

Many of us would be interested in learning FDA's views on two questions; (1) When is a company entitled to a public hearing? and (2) what is the nature of such a public hearing?

The Federal Food, Drug and Cosmetic Act of 1938 originally required a public hearing before the issuance of any substantive regulations. Thus, even when no objections were raised, FDA was required to hold a public hearing and to provide substantial evidence supporting the proposed regulations. The rule-making procedures under the Act were both cumbersome and time consuming.

In the mid-1950's, the Hale Amendments were enacted. Under these amendments, FDA only had to hold public hearings on proposed regulations when objections, stating the grounds, were filed. The legislative history of the Hale Amendments makes it perfectly clear that public hearings were eliminated only in regard to noncontroversial regulations and that when objections raised any relevant factual issues, a hearing was still necessary. Indeed, industry supported the Hale Amendments for these reasons.

FDA and industry lived compatibly under the Hale Amendments until last year. During 1967, objections were filed raising factual issues relating to the FPLA regulations for foods, and FDA refused to hold a public hearing on these objections. We are thus left in a state of uncertainty since it seems that even when factual issues are raised, FDA may refuse to hold a public hearing.

The other question which concerns many of us involves the nature of the public hearings which are held. Since the public hearing is on the objections, the submission of such objections cannot reasonably be viewed as the hearing itself. Furthermore, both the legislative history of the Federal Food, Drug and Cosmetic Act and FDA's consistent practice under that Act make it clear that the public hearing must include an opportunity to cross-examine witnesses on their testimony concerning the regulations.

In the dietary food regulations hearing, FDA expressed the view that since the government was engaged in rule-making, the hearings were mere "fact-finding excursions" for the expression of viewpoints of interested persons and were not adversary proceedings. Industry lawyers took a contrary view, and this question of nomenclature was believed relevant to procedural matters such as discovery and cross-examination during the hearing.

While a public hearing is a fact-finding hearing, there are usually very definite adversary relationships involved in such hearings. For example, FDA's proposed dietary food regulations would eliminate many products from the market or would compel substantial changes in their composition. The FDA and sellers of these products are thus in an adversary relationship. Such relationships also exist among industry representatives. For example, during the dietary food regulations hearings, there was an attempt by the sugar producers to raise questions concerning the safety of artificial sweeteners, and

to ban all artificial sweeteners from the market. The sugar producers were threatening the right to sell artificially sweetened products and therefore the very existence of producers of artificial sweeteners. Again, this was an adversary relationship.

When substantive regulations threaten to preclude products from the market or to compel labeling changes which make it significantly more difficult to sell these products, it would seem that those involved in such proceedings should be given every possible procedural safeguard, including the right to full and unfettered cross-examination, to make certain that the findings of facts represent the actual facts. Such safeguards are needed then as much as they are needed in the fact-finding portion of a lawsuit. Indeed, since the Commissioner has a greater discretion in making findings of fact than would a trial judge, and since criminal penalties can be imposed for violations of FDA rules, it is arguable that there is a greater need for procedural safeguards in such hearings than in most lawsuits. It would seem that the FDA should freely extend every possible procedural safeguard to all those involved in § 701 Hearings.

Conclusion

In reviewing the general principles underlying FDA rule-making, there are at least four current problem areas under the Federal Food, Drug and Cosmetic Act. They are:

(1) Selection of the type of rule, regulation or guideline to be used by FDA;

(2) The form of substantive rule-making proposals and the complications that can result from promulgating extremely complex and extensive rule-making proposals;

(3) The right to a public hearing when factual issues are raised; and

(4) The nature of the public hearing, that is, adversary proceeding or fact-finding excursion.

Each of these problem areas threatens to give rise to controversy, and all of us hope that when differences of opinion do arise, FDA will give due consideration to industry's viewpoint. Such consideration would reduce FDA-industry conflicts in future years.

[The End]

The Food and Drug Administration's View on Procedural Rules

By WILLIAM W. GOODRICH

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

THE TOPICS FOR DISCUSSION here are important ones, and I am sure that we can all profit by the suggestions offered.

I thought that I fully understood the difference between interpretive rules and substantive rules, but the *Abbott Laboratories*[1] decision taught me something new.

And the discussion of the proposed regulations for Good Manufacturing Practices in Food Establishments surely tells me that we will need to give them more study before they are finalized.

The Food and Drug Administration's (FDA) point of view on rule-making—indeed on all administrative procedures—is that these are tools by which we carry forth our public responsibilities.

To the extent that the tools are clumsy, obsolescent, or obsolete, they should and must be improved. To the extent that they impede the expeditious dispatch of FDA's business, and to the extent that they fail to serve the legitimate concerns of the regulated industries, they are failures which must be corrected. But the manipulation of procedures for form's sake, for delay, or for some theoretical reasons has little to commend it.

Procedure Versus Substance

The modern era of Food and Drug law was born in the troubled years of 1933-1938. Fresh on the Congressional minds was the great

[1] *Abbott Laboratories v. John W. Gardner, HEW Secretary*, CCH Food Drug Cosmetic Law Reports ¶ 40,258 (U. S. Sup. Ct. 1967), 387 U. S. 136.

controversy about Secretary Wallace's handling of the rate-making proceeding which gained Supreme Court attention in the several "Morgan" cases.

And most of the opposition to the modernization of the 1906 Food and Drug Act, during the stormy passage of the 1938 Act through the Congress, concentrated upon its procedures, and the personalities of its sponsors, rather than upon the merits or demerits of its substantive provisions.

It is understandable, then, that procedure apart from substance has been one of our principal concerns over most of the 30 years since the 1938 Act passed the Congress.

I myself first came to FDA on a legal assignment dealing with administrative procedure. The Walter-Logan Bill to regulate the procedures of administrative agencies was a matter of the highest interest to most of the Government, as well as to the practicing bar.

Ashley Sellers, a long time participant in the activities of both the Administrative Law Section and the Food and Drug Division of the American Bar Association (ABA), had a special assignment to study the variety of procedures being followed in the United States Department of Agriculture (USDA), to prepare monographs which would explain them in detail, and to suggest means of improving the entire administrative process. I was one of his assistants. A code of procedure for FDA hearings, considered at the time to be a model code, was developed with his assistance and placed into effect about the time the law itself became fully effective. The main difficulty it encountered in actual operation was in identifying and establishing the proper role the hearing examiner should play in the formal rule-making process. And the ultimate solution, after trial and error, was to require the examiner to certify the record to the head of the agency for the issuance of both the tentative and the final decision on the merits.

The justification for this is nowhere better stated than in the Attorney General's Manual on the Administrative Procedure Act (APA) (which, of course, was not published until several years later). That report says:

> Even in formal rule-making proceedings subject to sections 7 and 8, the Act leaves the hearing officer entirely free to consult with any other member of the agency's staff. In fact, the intermediate decision may be made by the agency itself or by a responsible officer other than the hearing officer. This reflects the fact that the purpose of the rule-making proceeding is to determine policy. Policy is not made in Federal agencies by individual hearing examiners; rather it is formulated by the agency heads relying heavily upon the expert staffs which

have been hired for that purpose. And so the Act recognizes that in rule-making the intermediate decisions will be more useful to the parties in advising them of the real issues in the case if such decisions reflect the views of the agency heads or of their responsible officers who assist them in determining policy. In sharp contrast is the procedure required in cases of adjudication subject to section 5(c). There the hearing officer who presides at the hearing and observes the witnesses must personally prepare the initial or recommended decision required by section 8. Also, in such adjudicatory cases, the agency officers who performed investigative or prosecuting functions in that or a factually related case may not participate in the making of decisions. These requirements reflect the characteristics of adjudication discussed above.

Thus, the APA itself, endorsed the procedure that had been established and followed by FDA from its earliest beginnings in formal rule-making.

Procedural Methods: A History of Controversy

These procedures were severely challenged in *Willapoint Oysters Inc. v. Ewing.*[2] Another prominent member of the Administrative Law Section—Al Stephan, a winner of the 1938 Ross essay prize for a paper entitled "The Extent to Which Fact Finding Boards Should be Bound by the Rules of Evidence"—contested us at every step of an elaborate and protracted administrative proceeding.

The record was long; the controversy was sharp. The review proceeding was conducted with great care. Our brief alone ran to 70 closely-printed pages. The Court's Opinion covered 32 such pages. And that Opinion has guided us through the years in our understanding and application of the APA.

Despite the fact that the Court held the separation of functions provision of section 5(c) of the APA inapplicable to formal rule-making on the record, the Department in 1964 transferred the Hearing Examiner function out of the Office of the General Counsel (where it had been since 1938) to avoid the appearance of any conflict between this function and its supervision.

Even earlier than that—as long ago as 1954 when the Pesticide Chemicals Amendment was enacted and placed into effect—a serious concern had arisen about the propriety of the procedural methods applicable to rule-making in highly technical fields.

We may recall that the International Apple Association had been most instrumental in 1938 for the procedural restrictions placed upon

[2] *Willapoint Oysters, Inc. v. Ewing,* 174 F. 2d 676, 694 (CA-9 1949) cert. denied, U. S. Sup. Ct., 338 U. S. 860 (1950).

the Department in promulgating tolerances for added poisonous substances "required in the production" of food.

The Pesticide Chemicals Amendment stands as a monument to the failure of procedural restrictions to produce the needed tolerances and thus to protect the public health. A protracted hearing was held. The record exceeded 5,000 pages. There were hundreds of extensive exhibits. The industry later told Congress that the proceeding had cost nearly a half-million dollars to Government and industry, to the land grant colleges, and to agricultural organizations. But it produced no results. The facts developed through a trial-type hearing simply would not support the establishment of safe tolerances.

And so a new law—with emphasis upon informal procedures, with provision for a scientific review panel, and with other features more suited to the development of facts and policy in this difficult field—was enacted.

This law has yielded the controls necessary for public protection. And it has served the needs of agriculture, the pesticide producers, as well as the Nation's health interest. There have been a few appeals to scientific review panels, but the hearing experience has not been repeated.

When that law was placed into effect, regulations were developed to take advantage of many useful procedural steps and to accommodate the scientific review technique: to provide for such things as pre-hearing conferences, the submission of documentary evidence in advance, excerpting and indexing of the record, and the handling of records and the assurance of adequate cross-examination of *ad hoc* scientific advisory committees.

In 1958, when the Food Additive Amendment was passed, it too was concerned with the methods by which food safety should be shown, and Congress made a special provision to assure that all findings, whether on the petition or on a record, would be based upon a fair evaluation of the entire record, underlining the need to observe the letter and the spirit of the *Universal Camera* decision.

In 1962, when the Kefauver-Harris Drug Amendments were passed, Congress had a say about what would be considered "substantial evidence" to support claims of effectiveness for drugs covered by the new drug and antibiotic certification procedures.

And in February 1966, we revised the rules of practice for all hearings to take account of what we had learned from our hearing and other rule-making experience. We think our procedures, on paper at least, are as modern as any we know of—and we have had few recommendations for their change.

Some feel that the regulations require revision to wholly isolate anyone in the General Counsel's Office from the Commissioner in any matter in any way related to a public hearing. Others suggest that the hearing examiners should be under no control of the Commissioner, much less that of lower employees of the Agency. While the *Willapoint* decision addressed itself to the separation of functions point, and ruled upon it, we have been sensitive to the need to assure that decisions required to be made on the record are made on the basis of an adequate and independent review by the Commissioner or by his Deputy or by an Assistant or Associate Commissioner of the record, the arguments, and the exceptions. And in adjudicatory hearings, of course, the hearing examiner makes the tentative decision which is final unless excepted to and thus taken to the Agency for independent review and final decision.

But the major problem of procedure that has confronted the Agency over the years is not this. Rather it is the problem of *protracted,* trial-type proceedings in which the administrative process has been strained almost to the breaking point by delays and by great financial expense.

Only recently, the Pink Sheet raised the question whether the hearing process could actually deal with the complex problems that beset it.

In this connection, it is well to recall that the Federal Food, Drug and Cosmetic Act is unique among our public laws in requiring formal rule-making on the record.

Professor Davis has pointed out, in his *Administrative Law Treatise,* that:

> A trial is designed for resolving issues of fact, not for determining issues of law, policy or discretion. In rule making, the method of trial has no place except when specific facts are in issue, and even then it should seldom be used when the disputed facts are legislative.

Discussing specifically Food and Drug Administration hearings, he says:

Unlimited cross-examination by adversaries seems as inappropriate in these cases as in an argument before an appellate court. Questions addressed to speakers are useful and appropriate, but they should not be in the nature of cross-examination by an adversary for the purpose of confusing or destroying; they are most useful when asked for the purpose of clarifying and constructing.

Mr. Davis recalls the experience of an agency which applied trial techniques in a desire to satisfy "the most aggressive proponents of formalism."

And after the "deed" was done, he says, it was apparent that the proceeding had produced no information or opinions that could not have been obtained by less wasteful and time-consuming methods.

When the Hale Amendment to simplify FDA procedures was passed years ago, it promised to end excessive delays, protracted proceedings and mountainous records.

That promise has not been fulfilled.

Conclusion

Sooner or later, we may have to explore entirely new methods of presenting evidence and arguments in formal rule-making, such methods as narrative summaries of fact and written arguments of the kind recommended by Professor Davis.

But for today, all of us—and this includes the private bar quite as much as agency personnel—will have to share responsibility for success or for failure of the existing methodology. **[The End]**

SAM D. FINE NAMED ASSISTANT COMMISSIONER FOR FIELD COORDINATION

Sam D. Fine has been named Assistant Commissioner for Field Coordination for the Food and Drug Administration. He succeeds A. Harris Kenyon who is now serving as a special advisor for field activity coordination to Charles C. Johnson, Administrator of the new Consumer Protection and Environmental Health Service. Mr. Fine began his career with the FDA as a Junior Chemist in the St. Louis District in 1939. He subsequently served in the Cincinnati District, as Chief Chemist of the Denver District, as Director of the Kansas City District and, most recently, as Director of the Dallas District.

The Right to Self-Medication— A Continuing Conflict Between Congressional and Agency Policy

By BRUCE J. BRENNAN

Mr. Brennan, formerly an attorney with the Food and Drug Administration, Is Now in Private Practice in Washington, D. C.

IN OUR FREE SOCIETY, GOVERNMENT IS ESTABLISHED to do only those things that individuals cannot do alone. Government's function is to create a climate in which each citizen can exercise his own rights, make his own decisions, and assume his responsibilities. In relating these principles to the field of medicine, this means that the government should see that the citizen has available all pertinent information about a drug product and that such information is set forth in a truthful and concise manner, so that the citizen —except where professional medical supervision is clearly required —can make his own decisions and care for himself.

Much has been said of the right of the individual to engage in self-medication. As is the case with most rights, this right is based on human wants and needs. The right to self-medicate has grown from the demand in our society that the individual be able to determine for himself what he wishes to do in managing subjective manifestations of physical disorders. This right has a cultural basis in our society stemming from the desire of the individual to fight his own battles. This need for the public to be able to help itself overcome the minor complaints, which we regularly experience, has long

been established and continues to be recognized as a necessary part of our public health policy.

Congress' Continual Affirmation

Congress has given expression to the individual right to and the public health need for a citizen to be able to assist himself in solving minor health problems and discomforts. When called upon to consider these rights and needs, Congress has continually exhibited a reluctance to restrict the distribution of home remedies.[1]

As I shall discuss during the course of this paper, frequently an agency's actions are in conflict with the very intent of the laws which it is directed to enforce and implement. Yet, the result of the agency's implementation is as meaningful to the regulated industry or persons as the Act of Congress itself. Since the Food and Drug Administration (FDA) and the Federal Trade Commission (FTC) are staffed by reasonable people, their policies are usually rational. Depending on an individual's attitudes or point of view, these policies can either be criticized or defended by other reasonable people. This is the focal point of the conflict between these agencies' policies and the individual's right to self-medicate, as affirmed by Congress. Although I do not concede the point, the agencies' views may be just as logical as that of Congress. However, this contention misses the mark. Of all the possible policies which Congress might have adopted concerning the individual's right to self-medicate, only one was chosen. Until that is superseded by another Act of Congress the agency has no authority, no matter how logical, to establish a different policy.

[1] "And let me stop . . . to comment upon the criticism so extensively voiced by the patent medicine interest that the purpose of this bill is to stop self medication . . . [S]elf medication will continue in the future as it has in the past . . . All of the previous dealings with drugs, aside from those recognized in the official compendia, are directed toward safeguarding the consumer who is attempting to administer to himself. If this measure passes, self-medication will become infinitely more safe than it has ever been in the past." (Walter G. Campbell, Chief Food & Drug Administration, Hearings before Committee on Commerce, U. S. Senate 73rd Cong. 2nd Sess. Re: S. 2800 Feb-Mar 1934.)

"The bill is not intended to restrict in any way the availability of drugs for self-medications. On the contrary, it is intended to make self-medication safer and more effective. For this purpose provisions are included in this section (502) requiring the appropriate labeling of habit-forming drugs, requiring that labels bear adequate directions for use and warnings against probable misuse . . . ." (House Committee on Interstate and Foreign Commerce. 75th Cong. 3rd Sess., April 14, 1938, Report on S. 5.)

The Durham-Humphrey Amendments

As stated above, in 1938 Congress clearly affirmed the public health necessity of self-medication. A more thorough consideration of this same subject by Congress occurred in 1951. The legislative history of the Durham-Humphrey Amendments is abundantly clear that the intent of Congress in so amending the Federal Food, Drug and Cosmetic Act was not only to *preserve* the concept of self-medication, but to *extend* the availability of non-prescription drugs. Indeed, government witnesses, themselves, frequently remarked that the Durham-Humphrey bill was not intended to restrict self-medication. George Larrick testified that Congress through the Food, Drug and Cosmetic Act "has instructed us not to unnecessarily restrict self-medication." (Hearings before the Committee on Interstate and Foreign Commerce, House of Representatives, 82 Cong., First Sess., on H. R. 3298, May 1-5, 1951, p. 110.)

The original Durham-Humphrey bill would have made the determination as to whether a drug should be dispensed on prescription rest on whether the drug was *unsafe or ineffective* for use without the diagnosis or supervision of a physician.[2] The consideration of effectiveness in making this determination was a principal issue in the legislative debate on the bill.

In Mr. Larrick's testimony before the House Committee, prior to the reporting of the Durham-Humphrey bill to the full House, he stated concerning this consideration of the effectiveness of the drug as follows:

> The bill does not authorize the administrator to determine the efficacy of a drug. It authorizes him to hold a hearing where the evidence of the best informed experts in the country would be received. On the basis of this testimony he would then determine *not whether the drug is efficacious, but whether or not a layman can use the drug effectively without the diagnosis or supervision of a physician.*

---

[2] The following is excerpted from H. R. 3298 as introduced by Congressman Durham.

"If the drug is intended for use by man and—

* * *

(2) has been found by the Administrator, after investigation and opportunity for public hearing, to be unsafe or ineffective for use without the professional diagnosis or supervision of a practitioner licensed by law;

* * *

A drug which is subject to clause (1), (2), or (3) of this subsection shall be deemed to be misbranded if at any time prior to dispensing its label fails to bear the statement 'Caution: Federal law prohibits sale or dispensing without prescription.'"

We submit that it is just as important that a drug be effective in the hands of the person who acts as his own physician as that it be safe in the sense that it will not poison him. (House Hearings, Page 94; emphasis supplied.)

Having the explanation of the use of the term "effectiveness" in the bill before it, the Congress specifically eliminated those terms from the bill that was passed and eventually became law. Congress evidently felt that the position as stated by FDA witnesses would have interfered with the distribution of safe proprietary medicines and that such restriction was inappropriate.

Opinions of the Courts

Not to be denied, FDA continued its quest for the inclusion of the concept of effectiveness in the determination of the prescription status of drugs. A recent example of the FDA attempts to gain, through regulatory actions, what it could not obtain from Congress, was the *Decholin* case.[3]

Subsequent to the enactment of the 1938 Federal, Food, Drug and Cosmetic Act, the FDA initiated a series of seizures and criminal cases, based on the premise that Section 502(f) was violated because adequate directions for use of the drug were not, and could not be, written for a particular drug.[4] This theory seemed to have some merit and was rather readily accepted by the courts where the questioned drug was offered for serious or life-threatening conditions. However, the situation took on a different aspect when FDA attempted to apply the same theory to drugs offered for less serious, if not minor, conditions. This expansion of the FDA theory required a more subtle approach. FDA, in support of its theory, developed the following syllogism:

1. The conditions or symptoms for which the drug was offered, however innocuous, could be caused by a variety of circumstances, some of which are serious or life-threatening;

2. The lay person is unable to diagnose the underlying cause of his condition or symptoms;

[3] *U. S. v. Article of Drug Labeled . . . Decholin*, CCH Food Drug Cosmetic Law Reports ¶ 80,163, 264 F. Supp. 473 (DC Mich. 1967).

[4] See, for example *United States v. Kordel*, 164 F. 2d 913 (CA-7 1947); *Drown v. United States*, 198 F. 2d 999 (CA-9 1952); *U. S. v. Vitasafe Formula M*, 226 F. Supp. 266 (DC N. J. 1964).

3. Therefore, adequate directions cannot be written to the lay person for him to properly determine whether to use the drug or seek medical assistance as an alternative;

4. Therefore, the drug is unsafe because the lay person might delay medical diagnosis of his problem while attempting self-help.

At the heart of the government's case against Decholin, was the theory that the drug was unsafe for unsupervised lay use because the lay person was unable to determine when the drug would be effective. Since the rather general symptoms for which the drug was offered could be caused by many conditions, the government further alleged that the lay person might be put in jeopardy by choosing to use Decholin while his condition continued unattended. Necessarily included within the scope of the government's theory is the corollary that *any drug* offered for the relief of symptoms, which symptoms might, however infrequently, be associated with a disease, which would in no way be relieved or treated by the use of the drug, must be dispensed only under the supervision of a physician.

It is immediately clear that this concept could serve to eliminate all forms of self-medication and any attempt at relief of minor symptoms. Such a theory is contrary to historical public health policies in this country and the expressed intent of Congress. This was apparently recognized by the Court in the *Decholin* decision. The Court found that the terms of the Durham-Humphrey amendment were intended to cover a situation where the supervision of a physician was necessary to enable a person to use a medication *safely*.

The test described by the statute is clearly not satisfied by merely postulating that in some patients the drug may not be effective and, therefore, the supervision of a physician is required to determine whether or not the drug will be effective for each particular person. The Court found that, were that the law, self-medication would cease to exist and the expressed intent of Congress in that regard would be completely thwarted.[5]

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[5] See footnote 3, at 482.

"Furthermore, it is worth noting that the draft bill recommended by the House Committee contained a proposal for the Federal Security Administrator to make a binding determination concerning which drugs were not safe for self-medication, subject only to limited judicial review.

The House deleted this authorization from the version that finally passed, and the record of the debate before this change was made indicates that the primary reason for its action was the fact that some lawmakers felt that the Administrator would see the provision as his mandate for placing an

(Continued on next page.)

In discussing the legislative history of the 1951 amendment, the Court stated that such legislative history "showed that Congress did not desire to proscribe self-medication with a product just because, under some set of circumstances—and especially hypothetical conditions—the drug may be harmful if taken without professional supervision." After citing certain portions of the legislative history the Court continued as follows, at p. 479:

> In fact, throughout the entire House debate runs the theme that "common household remedies" were not meant to be taken off the over-the-counter market. Since the Court is unwilling to presume that the lawmakers were merely engaging in an afternoon of question-begging disputation, it feels that there are some drugs which rather easily fall into this category. They must be the thousand and one articles which most physicians would consider perfectly harmless when taken in the normal course of events by a person with a modicum of common sense. Nevertheless, it is hard to imagine that under no circumstances could any of these drugs do serious harm to an individual who does not appreciate the nature of the cause which lies at the root of his symptoms.

The Court had more to say when discussing the requirements for reasonableness in determining whether a potential hazard of a product is significant enough to place the product on prescription:

> On the basis of this passage, it seems evident that the Committee thought that it was recommending passage of a bill which would take a drug out of unrestricted distribution only if it is hazardous for the reason that there is more than a remote possibility that it will cause harm when used in a reasonable manner. If, in attempting to evaluate a drug, a court were to consider every contingency and take account of the immaturity or stupidity of every potential user, it would not be paying heed to the Committee's desire that it give to the word "safe" the ordinary meaning. Similarly, it seems that the Government, in order to prevail in this case, must establish that Decholin has a potentiality for causing consequences for an unadvised layman which can actually be called harmful; for in common usage the term "safe" is not inapplicable to an article merely because the product may give rise to some effects which are uncomfortable or cause inconvenience. [At 480.]

While the Court did not make a final disposition of the case in ruling on motions for summary judgment, it clearly outlined what it expected the government and the claimant to prove in presenting their respective positions. After carefully considering the Court's

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(Footnote 5 continued.)
excessive number of medicines, traditionally considered harmless, into the 'prescription only' category. 97 Cong. Rec. 9538-9, 9548. If the Court accepted the rule urged by the Government, it would to a great extent be undoing Congress' precautions. If merely establishing that the easy availability of a medicine has the tendency to postpone a differential diagnosis in a case in which the drug alone cannot provide a cure were enough to compel the removal of the product from a druggist's public shelves, there would be few drugs left on the over-the-counter market once the Government saw fit to wage a full-scale assault on self-medication." (Footnote omitted.)

opinion and reassessing the nature and quality of its proofs, the government moved to dismiss the matter with prejudice against itself, just prior to the scheduled trial several months later. Since the government had withdrawn from the arena, the Court was left with no alternative other than to dismiss the case according to the motion.

Another example in the litany of attempts by FDA to limit the ability of the individual to engage in self-help is the proposed vitamin D regulations which FDA issued in August 1965.[6] Through these regulations FDA would have banned all vitamin D therapeutic preparations from the over-the-counter (OTC) market. Even vitamin D as a food supplement, over a specified minimum amount, would have been considered a prescription drug. The therapeutic preparations, that is, drugs offered for the treatment of vitamin D deficiency, would be placed on prescription because of the FDA determination that "adequate directions for safe and effective use for the self-treatment of vitamin D deficiency by the laity without medical supervision cannot be written."

It is beyond argument that additional intake of vitamin D will benefit a person suffering from a deficiency of that substance. It was stated in comments submitted to FDA that it is irrelevant that a physician's diagnosis may be helpful for exact diagnosis or proper setting of dosage levels. In fact, it was pointed out that mild vitamin D deficiency may not even be diagnosible by a physician. Congress' views on the rights of the public to self-medicate were squarely presented to FDA in such objections. The point was clearly made that, if a drug is safe, the fact that the underlying causes are such that a layman might not in all circumstances diagnose or determine his condition with preciseness and choose the exact dosage required should not deprive such a person of the right to attempt to help himself prior to consulting a physician. After considering these objections for some time, FDA officially withdrew the proposed regulation just a few weeks ago.

Quite recently, the same issue was presented to a Baltimore federal court in an FDA seizure case. *U. S. v. Articles of Drug Labeled . . . "Quick-O-Ver."*[7] The *Quick-O-Ver* case concerned an O-T-C hangover remedy, which was charged as being a new drug for which no new drug application was in effect. The case involved four variations

[6] 30 Fed. Reg. 11140 (August 28, 1965).

[7] CCH Food Drug Cosmetic Law Reports ¶ 80,184, 274 F. Supp. 443 (DC Md. 1967).

of essentially the same preparation, three of which were found to be new drugs for various reasons not essential to this discussion. The labeling offered the drug for the relief of headache, nausea, upset stomach and lack of alertness. One variation of the drug was found to be generally recognized as *safe* and *effective* for the conditions of use directed.

In considering the safety of the preparation, the court, at p. 449, stated as follows:

> With respect to safety, the government does not contend that the ingredients of variation #4 are dangerous separately or in combination. Its only argument on this point is that since the drug may relieve headache, nausea and upset stomach, and help restore some measure of alertness, it may prevent persons from consulting a doctor even though they have serious aftereffects as a result of alcoholism or prolonged excessive drinking. The same argument could be made against any over-the-counter remedy which relieves pain or a cough, but does not undertake to cure the cause of such pain or cough. It is not a ground for finding such a drug as this unsafe . . .

As the Court in the *Decholin* case confirmed and as the Congress has expressed again and again when given the chance, there is a public need for and right to engage in self-medication. Nevertheless government physicians, lawyers and other regulatory officials, however well intentioned, continue to press the attack on this need and right. When one reviews the many actions brought by the FTC and the FDA which restrict the physician's use of drug products and, as some contend, which tend to interfere with the responsible practice of medicine, one can better appreciate these agencies' actions regarding self-medication. If they are moved to so restrict the physician in his practice, much greater must be their motivation toward restricting the layman from assisting himself.

The Philosophy of the FTC Reflected in Recent Cases

At this point we should examine the current philosophy of the FTC on the issue discussed above. A suitable example of that philosophy is found in a recent case. *J. B. Williams Co. v. Federal Trade Commission.*[8] This is a case which has been discussed at earlier proceedings of this group and which concerns the advertising for Geritol.

The Commission's *J. B. Williams* Order (In the Matter of The J. B. Williams Co., Inc., et al., D. 8547) was one of the final steps in a series of regulatory actions which required various affirmative disclosures and limitations in drug advertising. The ultimate in such

[8] 381 F. 2d 884 (CA-6 1967).

limitations was proposed by FTC in that Order.[9] Fortunately the Court of Appeals in the Sixth Circuit, acknowledging the expressed intent of Congress, recognized that the agency had gone too far and struck down the unwarranted prohibition.[10] Concerning this prohibition, the court found that the danger which was being attempted to be remedied was adequately covered by other requirements of the Order. The court concluded its consideration of this issue as follows: (at 891)

> We can find no Congressional policy against self-medication on a trial and error basis where the consumer is fully informed and the product is safe as Geritol is conceded to be. In fact, Congressional policy is to encourage such self-help. In effect the Commission's Order 1 (f) tends to place Geritol in the prescription field. We do not consider it within the power of the Federal Trade Commission to remove Geritol from the area of proprietary drugs and place it in the area of prescription drugs.

In *J. B. Williams,* the Commission made a finding of fact that the Geritol advertising implied that a person can determine the presence of iron deficiency anemia from his tiredness symptoms.[11] The Commission further determined that a person cannot rely on the tiredness symptom as an indication of such condition. This was the basis for the "self-diagnosis" prohibition.

The Circuit Court, while refusing to sustain the Commission's prohibition, did sustain the above finding of a fact. The court stated at 887: "The Commission's finding that the Geritol advertisements create a false and misleading impression on the public by taking common or universal symptoms and representing the symptoms as generally reliable indications of iron deficiency or iron deficiency anemia, is supported by substantial evidence."

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[9] ". . . cease and desist from . . .

"1. Disseminating or causing to be disseminated . . . in commerce . . . any advertisement:

* * *

"(f) which represents directly or by implication that the presence of iron deficiency or iron deficiency anemia can be self diagnosed or that either can generally be determined without a medical test conducted by or under the supervision of a physician . . ."

[10] See footnote 8.

[11] "In substance, these people are told that 'the reason' they feel tired and worn-out 'may be iron poor blood,' and that Geritol 'can help' them regain their strength and energy. This is an obvious invitation to any person with tiredness symptoms to self-diagnose his trouble as a deficiency of iron—and take Geritol. In other words, respondents, by constantly telling all tired people that their trouble may be iron deficiency, thereby imply that iron deficiency is a common affliction, such as a cold or headache, and that their tiredness generally indicates this condition." (Commission opinion in *J. B. Williams Company, Inc.*, Page 19, September 28, 1965.)

Therefore, although the Geritol advertising was found to be misleading on this question, the FTC attempt to correct the matter was judged to be excessive and contrary to Congressional policy.

As clear as the Sixth Circuit was in its *J. B. Williams* opinion, apparently FTC did not get the message. In an Order dated June 26, 1968, the Commission set down even broader prohibitions on the "self-diagnosis" issue.[12]

Even more astonishing is the opinion supporting the *S. S. S.* Order. The Commission cites the portion of the *J. B. Williams* case noted above.[13] In an attempt to avoid the obvious admonition of the Court of Appeals, the Commission finds it "necessary to distinguish between self-diagnosis and self-medication." Having found that iron deficiency cannot be self-diagnosed, the Commission contends that representations to the contrary cannot be condoned merely because Congressional policy favors self-medication on a trial-and-error basis. It therefore concludes that in order for its Order to be effective in requiring future S. S. S. advertising to be fully informative, the "self-diagnosis" prohibitions are essential.

The potential impact of this decision may be gauged from consideration of the portion of the opinion supporting the disclosure provisions of the order.[14] The Commission may be embarking on a

[12] *In the Matter of S. S. S. Company*, D. 8646. The Commission's Order prohibits:

"1. Disseminating . . . any advertisement which represents . . . that:

(a) The use of such preparations will be of benefit in the prevention, relief or treatment of tiredness, lack of pep, energy or strength, weakness, listlessness, run-down feeling or nervousness, or any other symptom . . . unless such advertisement also discloses clearly and conspicuously, in immediate or close proximity, and with equal prominence, to any such representations:

* * *

(2) that the presence of iron deficiency anemia or iron deficiency of any degree cannot be self-diagnosed and can be determined only by means of medical or laboratory tests conducted by or under the supervision of a physician; and

(3) that the presence of a deficiency of the B vitamins, or of any vitamin, cannot be self-diagnosed and can be determined only by means of medical or laboratory tests conducted by or under the supervision of a physician.

* * *

(c) The presence of iron deficiency anemia or iron deficiency of any degree can be self-diagnosed.

(d) The presence of iron deficiency anemia or iron deficiency of any degree can generally be determined without medical or laboratory tests conducted by or under the supervision of a physician.

(f) The presence of a deficiency of the B vitamins, or of any vitamin, can generally be determined without medical tests conducted by or under the supervision of a physician."

[13] See footnote 8.

[14] Opinion, pages 15, 16. "The purpose of the disclosure provisions in this order, as in the *J. B. Williams* order, is to insure that the consumer is in fact fully informed. Respondents' advertise-

(Continued on next page.)

new crusade toward an old objective. Whether the Commission is confused or trying to confuse the situation remains to be seen. In any event, the attempt to impose the concept of self-diagnosis on the right to self-medication is not novel.

A Significant Distinction

As stated above,[15] the original Durham-Humphrey bill defined a prescription drug as "safe and efficacious for use only after *professional diagnosis* by or under the supervision of a practitioner . . ." (emphasis supplied). Congress deleted the term "diagnosis" as well as "efficacious" in floor debate.

The Minority Report from the House Committee by the members sponsoring the floor amendment specifically attacked the inclusion of drugs, safe only after medical diagnosis, and implied that the layman should be able to self-medicate even though he may not be able to make a diagnosis:

> For further illustration, attention may be drawn to the word diagnosis. Drugs which the Administrator determines are not safe or efficacious until after professional diagnosis are to be restricted to prescription sale. It is well known that there are some experts who entertain the view that hardly any drug is either safe or efficacious without professional diagnosis; that the layman is not competent to diagnose his ailments and that, without being able to diagnose, he is all the more unable to prescribe for himself.[16]

The Minority House Report should be of principal significance in determining legislative intent, because the Minority bill succeeded.

The difference in scope between requiring prescription dispensing where medical *supervision* is necessary to effective use, and requiring such dispensing when medical *diagnosis* is necessary to effective use, is

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(Footnote 14 continued.)
ments create the false impression that tiredness is generally or frequently attributable to iron deficiency or iron deficiency anemia. In effect, when the reader is asked to draw the conclusion that his tiredness is attributable to iron deficiency, he is being asked to engage in self-diagnosis. We do not hold in this case that such an invitation to self-diagnosis is prohibited. However, we agree with the court in the *J. B. Williams* case that where an advertisement for a proprietary drug seeks to sell the product on the basis of such self-diagnosis, the consumer must be fully and honestly informed of the material facts.

If self-medication is to be encouraged, it is important that there not be a wrong diagnosis. If each of us is invited to become his own doctor and to choose among the various remedies offered for sale to the public, a clear obligation rests on the seller to disclose all the relevant facts concerning his product, including its dangers, if any, and the limits of its efficacy."

[15] See footnote 3.

[16] H. R. Rept. No. 700 (82nd Cong., 1st Sess.) 30 (1951)

quite substantial. The considerations are identical whether the matter is being viewed in terms of the FTC Act or the Federal Food, Drug and Cosmetic Act.

A significant distinction can be made between the need for knowledge of one's own condition for purposes of self-medication and the need for medical administration of a drug for purposes of setting the dosage or varying the dosage or examining for side effects. When weighing the cost and inconvenience of prescription drugs against possible harm from self-medication, Congress apparently concluded that a person's knowledge of his own condition could be derived in any number of ways, but that the need for medical skill in administration could be satisfied only by going to a physician in each case.

FDA has itself recognized that the lay ability to make a diagnosis is not a prerequisite to self-medication. One need only look to some of the warnings required by FDA for "switch list" drugs (21 C. F. R. § 130.102), or those recommended for OTC Drugs (21 C. F. R. § 131.15). Scopolamine may be sold OTC if the label warns against use by persons with glaucoma; ephedrine, if there is a warning against use by persons with high blood pressure, heart disease, diabetes, or thyroid disease; methylresaniline chloride if there is a warning against use by persons with heart, kidney, liver disease or intestinal disorders.

These conditions cannot be diagnosed by a layman. The warnings are effective only after medical diagnosis and the respective drugs are *absolutely safe* only after medical diagnosis. Yet they remain approved OTC drugs because medical supervision is unnecessary for their safe use in the conditions and for the symptoms indicated on the label.

Conclusion

Recited above are a few specific instances where an individual company or a group of individuals or organizations opposed the actions of FDA and FTC, when it was felt that these agencies had misconstrued the direction of Congress. In the *Decholin* case and the Vitamin D regulation, the government agency withdrew from its position. In the *Decholin, J. B. Williams* and *Quick-O-Ver* cases, the courts determined that the government theories were not appropriate in light of the basic statute and Congressional policy. However, since these regulatory agencies have been pursuing this theory for so many years, it is obvious that they have successfully forced their policies on other individuals or companies. Too frequently it is more expedient

to accede to a demand for re-labeling, or default on a seizure, rather than to face litigation. An individual product is quite often considered not worth the price of litigation. Furthermore, when contesting with a government agency on matters of health, there is always an additional burden on the defending party.

Even in the light of the set-backs discussed above, it is unlikely that FDA and FTC will abandon the described policy immediately. The *S. S. S.* case is immediate evidence of that conclusion. However, if more persons and firms will meet the challenge in these isolated cases as they arise, such policy might well be abandoned. As can be seen from the above discussion, the individual or firm who contests with the agency over such policy can be expected to receive fair treatment in the courts.

Furthermore, individual companies ought not wait until one of their products or their integrity is attacked. It would seem logical that through individual means or through some united effort, the public should be made aware of this attempt at unwarranted restriction of its basic right to freedom of choice. The consuming public should also be thoroughly informed of the manner in which Congress has protected that right. To complete this educational process the public should be told how to recognize when those rights are unreasonably put in jeopardy. Through such an informational program both the manufacturers of drugs and their customers can work together in assuring that safe home remedies will always be available as part of the public health program in this country. **[The End]**

PROMOTIONAL DRUG LABELING RULES STRENGTHENED

Essential prescription information in promotional drug labeling must be "the same in language and emphasis" as in the package insert, under new amendments to the drug advertising regulations adopted by the Food ad Drug Administration. The amendments as proposed on July 18 were adopted without change. Former regulations required that the language be "substantially the same."

The FDA said that the former language of the regulations was inadequate because, frequently, important prescription information was omitted in promotional labeling or was presented in a misleading manner. Reg. §§ 1.106, 130.4, 130.9, and 146.2, CCH FOOD DRUG COSMETIC LAW REPORTS ¶ 9923, 71,304, 71,309, and 74,252.

The EEC on the Way to a Common Market for Drugs: Its Meaning for Foreign Imports

By WALTER P. VON WARTBURG

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THE FIRST OF JULY 1968 is regarded as an important milestone in the history of the European Economic Community (EEC). The deadline for a total elimination of tariffs was set to bring about a natural freedom of intra-Community trade among the six Member Countries of the EEC.[1] There exists one area, however, which will not benefit from the increased elimination of trade barriers, namely the inter-Member State trade with industrially manufactured drugs, called pharmaceutical specialties.[2] Many steps have already been taken to remedy this situation,[3] the last one[4] of which merits close attention even outside the EEC and will be discussed in the following analysis.

[1] For further reference see: *Information Memorandum from the European Community Information Service, June 14, 1968.* CCH COMMON MARKET REPORTS ¶ 9239.

[2] The EEC definition of a pharmaceutical specialty, also called branded pharmaceutical, is: "Any medical preparation prepared in advance, sold under a special name and put up in a special way" Article 1 of the *"First Council Directive on the Approximation of Legislative, Regulatory and Administrative Provisions Governing Pharmaceutical Specialties,"* issued by the Council January 26, 1965. Published in the *Official Journal of the European Communities*, No. 22, (February 9) 1965, page 369. Amended by Council directive of July 28, 1966, *Official Journal of the European Communities*, No. 144, August 5, 1966, page 2658. See CCH COMMON MARKET REPORTS ¶ 3404.

[3] Besides the initially mentioned First Council Directive several other proposals for directives have been submitted to the Council by the Commission for finalization. Among these are to be cited: *"Proposed Second Directive on the Approximation of Legislative, Regulatory and Administrative Provisions Governing Pharmaceutical*

(Continued on next page.)

[4] For footnote 4, see next page.

Territorially Limited Authorizations

Pharmaceutical specialties may be put on the market in a Member State of the EEC only if it has been granted an authorization by the competent authorities of such Member State. In principle, an authorization, also called sales license, is given subsequent to a procedure similar to the U. S. New Drug Application system. But contrary to the federal order of the Food, Drug and Cosmetic Act, there still exist different systems of registering pharmaceutical specialties in the various Member States of the EEC. In Germany, every pharmaceutical specialty must be the object of an application to the Ministry of Public Health and be recorded in the register for specialties.[5] France requires that a so-called visa be obtained from the Ministry of Public Health prior to putting the specialty on the market.[6] Belgium provides for registration with the Ministry of Public Health on opinion and advice by a commission of "medicaments."[7] Luxemburg follows the same pattern.[8] Italy[9] and the Netherlands[10] provide for registration with Public Health Ministries.

(Footnote 3 continued.)
Specialties," proposal submitted to the Council by the Commission on February 19, 1964, *Official Journal of the European Communities*, No. 107, June 19, 1965, page 1825. See CCH COMMON MARKET REPORTS ¶ 3431. *"Proposed Third Directive on Approximation of Member State Legislation Concerning Pharmaceutical Specialties,"* proposal submitted to the Council by the Commission on December 7, 1967, *Official Journal of the European Communities*, No. C14, February 24, 1968, page 4. See CCH Common Market Reports ¶ 3433. *"Proposed Directive on the Approximation of Member State Legislation on Materials That May Be Added to Pharmaceutical Specialties for Coloring,"* proposal submitted to the Council by the Commission on June 9, 1966, *Official Journal of the European Communities*, No. 17, January 28, 1967, page 265. See CCH COMMON MARKET REPORTS ¶ 3435. *"Proposed Directive on the Approximation of Member State Legislation Relating to the Advertising of Pharmaceutical Specialties and to the Package Leaflet,"* proposal submitted to the Council by the Commission on June 7, 1967, *Official Journal of the European Communities*, No. 248, October 13, 1967, page 18. See CCH COMMON MARKET REPORTS ¶ 3437.

[4] *"Proposed Third Directive on Approximation of Member State Legislation Concerning Pharmaceutical Specialties,"* proposal submitted to the Council by the Commission on December 7, 1967, *Official Journal of the European Communities*, No. C14, February 24, 1968, page 4. See CCH COMMON MARKET REPORTS ¶ 3433.

[5] *"Gesetz über den Verkehr mit Arzneimitteln"* of May 16, 1961, Art. 21.

[6] *"Code de la Santé Publique"* as amended in the French *Journal Officiel* of February 8, 1959, and April 7, 1966, Art. L 601.

[7] *"Arrêté Royal"* of June 6, 1960 and *"Wet op de Geneesmiddelen"* of March 25, 1964, Article 33, 36.

[8] *"Loi portant réglementation générale de la vente, du débit et de la publicité des spécialités pharmaceutiques dans le Grand-Duché de Luxembourg"* of May 23, 1958.

[9] *"Regolamente contenente norme per la produzione ed il commercio delle specialità medicinali, R.D."* of March 3, 1927 and Law of May 1, 1941, No. 422.

[10] *"Wet op de Geneesmiddelen voorziening"* of July 28, 1958 and Decree of July 16, 1963, Art. 4.

In accordance with the commonly accepted principle of the territorially limited legal effects of administrative decisions issued by a domestic authority, a sales license obtained in one country has no validity in the territory of another nation.

As a result of the existing legal varieties in the EEC, a drug manufacturer who wants to introduce a new pharmaceutical specialty in the entire European Common Market is forced to go through a complicated system of drug registration in every one of the six Member States. He has to prepare six times all pertinent scientific data for submission of the required new drug applications, he has to perform clinical studies in various places, and he is obliged to follow separate registration procedures in all of the EEC Member States.[11]

Furthermore, even if a manufacturer has registered a given pharmaceutical specialty with all competent public health authorities and, accordingly, has obtained a sales license in each of the six Member States, a free interstate trade within the EEC is not possible. The six national markets remain separate.[12] Due to a puzzling variety of different national provisions with regard to the manufacture, advertising and dispensing of pharmaceutical specialties and due to divergent national systems of protection of the public, a pharmaceutical specialty—even though registered in all Member States—cannot circulate freely within the EEC.[13] For pharmaceutical specialties there exists no Common Market as yet.

Mutual Recognition of Sales Licenses

The drug control legislations of each EEC Member State are an expression of the public policy according to which each of the authorities intends to safeguard the interests of public health within its territory when deciding on the admission of new pharmaceutical specialties. Given the obvious natural diversities in the different countries forming the EEC it is quite obvious that the rules and provisions in the public health

[11] For details see, for example, Coustou, Auby, Bernay, Hauser *Droit pharmaceutique* (1963).

So'di, *"Produzione e Controllo delle specialità medicinali in Italia"* in *Cronache Farmaceutiche* June 1968, No. 3, page 140.

Treillard, *"La pharmacie allemande"* in *Droit et Pharmacie*, 1962.

Auby *"La pharmacie belge"* in *Droit et Pharmacie*, 1963.

Duprat *"La réglementation des spécialités pharmaceutiques dans la CEE"* in *Revue du Marché Commun* 1965, page 296.

[12] See Campet *"Die Errichtung eines Gemeinsamen Marktes für Arzneispezialitäten"* in *Die Pharmazeutische Industrie* June 1968, page 360.

[13] See Schoenbaum *"Harmonization of Laws Concerning Pharmaceuticals in the European Economic Community"* in *The American Journal of Comparative Law* Vol. 15, 1967, page 525.

area vary to a considerable extent in the six Member States.[14] It is conceivable that the existing disparities may even lead to different decisions by national authorities on the same or similar issues relating to the registration of a pharmaceutical specialty.

For many years now the Commission of the EEC has been desperately trying to harmonize the various national drug control laws on the basis of article 100 of the Rome Treaty.[15] To this purpose the Commission has submitted a great number of proposals for directives to the Council of Ministers.[16] However, the harmonization process being a very difficult one, it may not be surprising that, as of today, only one directive has been put into force by the Council of Ministers.[17] And even this First Directive has not yet been fully implemented into the national laws of the Member States.[18]

Faced with the actual deadlock in the harmonization procedure caused by the Council of Ministers—which for political and practical reasons has not promulgated any further directives over the last four years—the EEC Commission has put forward a proposal for a direc-

[14] Duprat, page 298. See footnote 11.

[15] According to the provisions of Art. 100 of the Treaty establishing the European Economic Community the Council, acting by means of an unanimous vote on a proposal of the Commission, shall issue directives for the approximation of such legislative and administrative provisions of the Member States as have a direct incidence on the establishment or functioning of the Common Market. For further reference see, for example, Stein, *"Assimilation of National Laws as a Function of European Integration"* in *American Journal of International Law*, Vol. 58, 1964, page 1. Monaco, *"Comparaison et rapprochement des législations dans le Marché Commun Européen"* in *Revue Internationale de Droit Comparé*, Vol. 12, 1960, page 61. Schwartz, *"Zur Konzeption der Rechtsangleichung in der Europäischen Wirtschaftsgemeinschaft"* in *Probleme des Europäischen Rechts*, Festschrift für W. Hallstein, 1966, page 474. Malintoppi *"Il ravvicinamento delle legislazioni come problema di diritto internazionale"* in *Rivista di diritto internazionale* Vol. 42, 1959, page 239.

[16] See footnote 3. Additionally there are quite a number of proposals for directives under consideration within the competent services of the Commission relating mainly to the approximation of national legislations with regard to freedom of establishment in the pharmaceutical sector.

[17] *"First Council Directive on the Approximation of Legislative, Regulatory and Administrative Provisions Governing Pharmaceutical Specialties,"* issued by the Council January 26, 1965. Published in the *Official Journal of the European Communities*, No. 22, February 9, 1965, page 369. Amended by Council Directive of July 28, 1966, *Official Journal of the European Communities*, No. 144, August 5, 1966, page 2658. See CCH COMMON MARKET REPORTS, ¶ 3404.

[18] Only Belgium, France and Italy have thus far taken the necessary steps for the implementation of the provisions of the First Council Directive into their public health legislations. Belgium: *"Moniteur belge"* of November 11, 1966, page 11.362. France: *"Ordonnance Française No. 67-827"* of September 23, 1967. Italy: *"Circolare 54 bis"* of March 30, 1967.

tive stating the principle of mutual recognition of sales licenses among all the authorities of the six Member States.[19] It is evident that the Commission by proposing this principle is trying to reactivate the harmonization process, and intends to show a way out of the impasse.

It would have been much more logical to first complete the harmonization and co-ordination of the existing drug control laws in the various Member States before attempting to establish a system of mutual recognition of sales licenses.[20] But, since an overall harmonization of pharmaceutical provisions within a reasonable time period seemed unlikely, it is now suggested to the Council of Ministers that, by issuing the proposed directive, each Member State of the EEC should be obliged to accept as valid, for its own territory, a sales license for a pharmaceutical specialty issued in any one of the EEC countries.

Contents of Third Directive

The proposed Third Directive very rightly states as a reason for its being submitted to the Council that the existing necessity of having to register a pharmaceutical specialty in each one of the six Member States represents a serious obstacle to the envisaged establishment of a Common Market because it favors the separation of the individual national markets.[21] It suggests that a system of mutual recognition of sales licenses by the public health authorities be introduced with a view to enabling the marketing of a new drug, after a minimum amount of time, in the entire territory of the EEC.[22] Based on such a system, the inter-Member State trade in pharmaceutical specialties would be facilitated and the idea of a common market for drugs within the EEC could eventually be realized.[23]

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[19] *"Proposed Third Directive on Approximation of Member State Legislation Concerning Pharmaceutical Specialties."* proposal submitted to the Council by the Commission on December 7, 1967, *Official Journal of the European Communities*, No. C14, February 24, 1968, page 4. See CCH COMMON MARKET REPORTS ¶ 3433.

[20] For further reference see von Wartburg, *"Die Rechtsangleichung des Arzneimittelrechts in der Europäischen Wirtschaftsgemeinschaft"* in *Aussenwirtschaftsdienst des Betriebs-Beraters*, 1967, page 293.

[21] Third Considering: See CCH COMMON MARKET REPORTS ¶ 3433. The comments of the European Parliament given to the Commission's proposal also recognize this situation. See *Europäisches Parlament, Sitzungsdokumente 1968-1969*, Dokument 55 of June 26, 1968, page 13.

[22] Fourth Considering: See CCH COMMON MARKET REPORTS ¶ 3433.

[23] The intentions of the EEC as expressed in the Rome Treaty are twofold: (a) Unification of the national markets by means of assuring free inter-Member State trade and (b) Creation of an un-

(Continued on next page.)

After having laid down the principle of mutual recognition,[24] the text of the proposed Third Directive states that the national authority which has granted a sales license is obliged to send tc every Member State indicated by the person responsible for the marketing a copy of such license together with a translation of all relevant documents and information.[25] A Member State that has been duly notified of the granting of a sales license for a given pharmaceutical specialty in another Member State shall publish the name of such specialty in its official government publication within a period of not more than thirty days following receipt of such notification.[26] The legal effect of such publication would be the recognition of the validity of a sales license for the territory of the Member State which had received the notification.[27] A refusal to recognize the sales license of one EEC country by the authority of another Member State would only be possible under few and specifically defined circumstances.[28] In the event of a difference of opinion among the Member States, and in case the individual authorities fail to arrive at a common agreement, the Commission of the European Communities shall be promptly informed. The Commission shall then call in experts designated by the Member States who will be empowered to make appropriate recommendations.[29] A transitional provision adds the obligation that, pending the co-ordination of the laws on the manufacture of medicinal preparations, the Member States shall take all appropriate measures to ensure that the pharmaceutical specialties are manufactured and checked under the direction of a pharmacist or of a person who, in addition to a certificate of qualification, has at least three years experience in the manufacture and control of pharmaceutical specialties.[30]

(Footnote 23 continued.)
distorted system of inter-Member State competition by means of harmonizing the various national elements of competition. For further reference see, for example, von der Groeben *"Die Aufgaben der Wettbewerbspolitik in Gemeinsamen Markt und in der Atlantischen Partnerschaft"* in *Wirtschaft und Wettbewerb*, 1964, page 1001; Guenther *"Wege zur Europäischen Wettbewerbsordnung"* in *Schriftenreihe zum Handbuch für Europäische Wirtschaft*. With special regard to pharmaceutical specialties see: Duprat, see footnote 11, page 304; and von Wartburg, see footnote 20, page 294/295.

[24] Article 1: See CCH COMMON MARKET REPORTS, ¶ 3433A.

[25] Article 2: See CCH COMMON MARKET REPORTS, ¶ 3433B.

[26] Article 3: See CCH COMMON MARKET REPORTS, ¶ 3433C.

[27] Article 4: See CCH COMMON MARKET REPORTS, ¶ 3433D.

[28] Article 6: See CCH COMMON MARKET REPORTS, ¶ 3433F.

[29] Article 7: See CCH COMMON MARKET REPORTS, ¶ 3433G.

[30] Article 8: See CCH COMMON MARKET REPORTS, ¶ 3433H. The question as to what kind of qualification a person in charge of controlling the manufacture of pharmaceutical specialties should have has given rise to non-ending discussions provoked mainly by national associations of pharmacists. This transitional provision intends to compromise the absolute demand that only pharmacists be qualified for such positions.

Observations on the Third Directive

The ultimate goal of the envisaged Common Market for drugs in the EEC, namely the granting of European sales licenses valid throughout the entire EEC, may well be regarded as having come a considerable step closer.[31] This is manifested also in one of the provisions of the proposed Third Directive requesting the Commission to determine, on the basis of the experience acquired in the first three years of application, whether European sales licenses valid throughout the entire Community may be substituted for the proposed principle of validation through mutual recognition.[32]

Despite this positive move towards a more liberal system for putting pharmaceutical specialties on the market of the EEC, some doubts concerning the adequacy of the approach and the methods must not be overlooked. The fact that the Member States of the EEC have not been able, as of today, to reach a common understanding with regard to the contents and principles of a harmonized and co-ordinated procedure for registering pharmaceutical specialties in their respective territories is deplorable, but it remains, nevertheless, the reality of the actual situation.[33] If it is true that a common agreement on the adequate material and procedural rules for registration of pharmaceutical specialties with a view to granting sales licenses is far from being reached among the EEC countries, one cannot help wondering why there should be a common acceptance of the proposed principle of mutual recognition of sales licenses. A prior approximation of the pertinent national drug control legislations seems almost to be a *conditio sine qua non* for the possibility that a license granted in one country should become valid in the territory of another one.

Be that as it may, the intention of the Commission to promote the principle of mutual recognition of sales licenses in the interest of a ready availability of new drugs within the entire EEC nevertheless merits interest and consideration. It shows its willingness to ask for an advanced integration of the national drug markets. At the same time, it proves the determination to further inter-Member State competition in the pharmaceutical sector, even though the various public health laws are not yet harmonized, and despite the diversity of the factors determining

[31] Given the overall situation of the EEC at the present time, it is, however, uncertain whether or not the Council of Ministers is going to decide positively—a unanimous vote is needed—on the Commission's proposal.

[32] Article 11. See CCH COMMON MARKET REPORTS, ¶ 3433L.

[33] Campet, see footnote 12, page 362.

intra-State competition in the different Member States.[34] Such an approach shows that primary importance is being given to the interests of the medical profession and the public in benefits available from new discoveries of the research-based drug industry at the earliest possible moment throughout the EEC. Possible distortions of inter-Member State trade which are likely to be the result of a system of mutual recognition of sales licenses might therefore be tolerated.

This aspect will be relevant in the following search for an objective answer to the question of whether or not pharmaceutical specialties which are imported from third countries should also benefit from the system of mutual recognition of sales licenses within the EEC.

The Third Directive and Non-Member States

The proposed Third Directive mentions in one of the preliminary considerations[35] that "...the new provisions that will govern the introduction of pharmaceutical specialties on the market in a similar manner in all the Member States cannot be applied fully to pharmaceutical specialties which are produced in third countries, and that as a result such pharmaceutical specialties cannot, for the time being, be included in the system of mutual recognition of sales licenses." In other words, pharmaceutical specialties which are manufactured in a non-Member State of the EEC to be imported into the Common Market for distribution have to be registered, as before, according to separate procedures with each one of the national public health authorities concerned. It is obvious that this implies a considerable competitive disadvantage for foreign drug manufacturers which will hardly be understood. As a general principle, the granting of a sales license is based on the evaluation of all the submitted documents required for an application. The result of such evaluation is either positive or negative. If it is positive, the sales license will be granted without regard as to where the specialty is being manufactured.

No doubt, certain protectionist measures are part of the very reason for the creation of an economic union. However, one might fairly argue that their adequacy appears to be somewhat less apparent in the light

[34] Differing provisions with regard to freedom of establishment of pharmaceutical firms, advertising of drugs to the medical or lay profession, granting of pharmaceutical patents, price control measures and social security systems in the individual Member States will no doubt arbitrarily affect the free flowing of interstate trade with pharmaceutical specialties. For further reference, see von Wartburg (see footnote 20), page 296.

[35] Fifth Considering: See CCH COMMON MARKET REPORTS, ¶ 3433.

of the manifold public health aspects which are at stake. Therefore, the question whether the economic or the health interests ought to be given preference cannot readily be answered under the given circumstances. It is particularly interesting to note that the Commission of the European Communities is apparently prepared to let the interest of public health, namely the advantage of an early availability of a new pharmaceutical specialty throughout the entire Common Market, prevail over the economic improvement of a balanced and undistorted inter-Member State trade among the various EEC countries. This is evidenced by its described intention to arrive in practice at a system of mutual recognition of sales licenses, despite the existing discrepancies of the different public health laws, and even though the competitive situations in the various countries are far from being equalized. It appears therefore, that the Commission greatly favors the idea of a Common Market for pharmaceutical specialties, and is not too much worried by possible inter-Member State trade distortions as long as a less hampered marketing of new drugs within the whole EEC area is to be expected.[36]

In view of the reasonable approach of the Commission in weighing economic versus public health interests, it is difficult to understand why pharmaceutical specialties manufactured outside the EEC should be banned from the benefit of the envisaged system of mutual recognition of sales licenses. If a pharmaceutical specialty is registered in one of the EEC Member States on the basis of the submitted scientific data and if the registering public health authority has issued a sales license for said specialty, one ought to assume that such sales license should, upon request, be equally notifiable to the authorities of other Member States for recognition. Considerations as to whether or not the specialty is manufactured inside the EEC should not be a deciding factor.

The discrimination to be expected in the field of registration of pharmaceutical specialties manufactured outside the EEC for use within the Common Market is especially difficult to understand if pharmaceutical specialties to be imported into the EEC area are produced in countries which have enacted legislation for the control of the manufacture of

[36] The European Parliament having been consulted by the Commission in accordance with the procedure of Art. 100 of the Rome Treaty expressed a similar view by saying: "The European Parliament... expresses the wish that [with regard to sales licenses for pharmaceutical specialties] a true Community-solution be found which promotes the basic goal of a public health policy, namely to attain better and easier ways and means guaranteeing a quick supplying of the public with new highly potent pharmaceutical specialties...." See *Europäisches Parlament, Sitzungsdokumente 1968-1969*, Dokument 56 of June 25, 1968, page 3.

pharmaceutical products which is at least as effective as the one practiced in the Member States of the EEC. The United States' system of good manufacturing practice control and the very extensive rules and regulations ensuring the safety, efficacy and quality of drugs have often been called the world's most stringent public health legislation in the drug area.[37]

Conclusion

The future will show whether or not the Common Market will uphold its theory of putting pharmaceutical specialties produced outside the EEC area at a disadvantage even if they are to be regarded as truly equivalent in all relevant respects to products manufactured inside. In the affirmative, this would mean that obstacles to the inter-Member States trade would in fact remain for certain products, thereby perpetuating a situation which is, in its nature, contrary to the basic objectives of a Common Market.[38] **[The End]**

SUPREME COURT REFUSES TO REVIEW LIGATURE CASE

A decision by the Court of Appeals for the Second Circuit holding that surgical ligatures were new drugs *(AMP, Inc. v. Gardner,* CCH FOOD DRUG COSMETIC LAW REPORTS ¶ 80,192) will stand as a result of the U. S. Supreme Court's refusal to review the case. The surgical ligatures are new nylon devices that surgeons can use to loop around severed blood vessels and lock to constrict blood flow. The Court's refusal to review means that the Food and Drug Administration can require premarketing clearance of such articles as surgical ligatures. Under the Federal Food, Drug and Cosmetic Act, new drugs must be approved by the FDA before marketing, but devices are not subject to prior approval.

For a discussion of the treatment of surgical devices in a manner similar to that provided for new drugs, including comment on the *Amp, Inc.* case, see "Surgical Implants: Drugs or Devices, and New Device Legislation" on the following pages.

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[37] See, for example, Dunlop *"The assessment of the safety of drugs and the role of government in their control,"* Honor Lecture, 1967.

[38] See, for example, Mestmaecker *"Offene Märkte im System unverfälschten Wettbewerbs in der Europäischen Wirtschaftsgemeinschaft"* in *Wirtschaftsordnung und Rechtsordnung,* 1965, page 345.

Surgical Implants: Drugs or Devices, and New Device Legislation

By VINCENT A. KLEINFELD

The Following Article Was Presented at the Denver Research Institute Conference on Biomedical Materials Held at the University of Denver, Denver, Colorado on July 15-20, 1968. Mr. Kleinfeld Is a Member of the District of Columbia Bar.

IN DISCUSSING LEGISLATION designed to afford greater protection in connection with implants and therapeutic devices, it is interesting to realize how our philosophy with regard to the protection of the public in the fields of foods, drugs and devices has continued to expand.

Since a government sponsored device bill follows, to a considerable extent, the pattern of the new drug provisions of the Federal Food, Drug and Cosmetic Act, it is helpful, I think, to discuss very briefly existing law in connection with new drugs.

Under the original Food and Drugs Act of 1906, new drugs were not required to be cleared to the satisfaction of the Food and Drug Administration (FDA) before they were put into the channels of commerce. Devices were not controlled in any respect. In the several decades after the passage of the 1906 Act, it became clear that various weaknesses had to be met, and among the changes put into effect by the Federal Food, Drug and Cosmetic Act of 1938 was a provision placing therapeutic devices under the coverage of the statute. There was and is no provision, however, providing that the safety or effectiveness of a new device must be demonstrated to the satisfaction of the FDA before it is marketed, nor one dealing specifically with transplants.

A tragic incident occurred during consideration of the 1938 Act. An untested solvent which had been used for a sulfanilamide product resulted in the deaths of over 100 persons. It was this tragedy which led to the incorporation in the 1938 Act of a provision that no new drug might be marketed without prior clearance by the FDA as to its safety. Effectiveness, however, did not have to be demonstrated, although the FDA took the position with respect to any drug offered for treatment of a serious condition that lack of effectiveness would, in fact, make the product an unsafe one. The term "new drug" was defined in the 1938 Act as any drug which was not generally recognized by qualified scientific experts as safe for use under the conditions specified in the drug's labeling. If a new drug was put on the market without prior clearance by the FDA, the product could be seized and its manufacturer criminally prosecuted.

Just as weaknesses became apparent in the original 1906 Act, it was discovered, years after the passage of the present 1938 Act, that the 1938 Act did not afford the consumer sufficient protection in the vital area of drugs. It was these weaknesses and another tragedy, caused by the use of thalidomide, and the horrible consequences which ensued to hundreds of infants in Europe, that led to the passage of the Drug Amendments of 1962. One of the amendments changed the new drug section so that the manufacturer of a new drug had to demonstrate to the FDA that his product was effective as well as safe. The burden of proof is on the manufacturer, and from both a scientific and legal viewpoint this is extremely important. But as indicated, a therapeutic device may now be marketed without prior clearance by the government. If a device is marketed and harm results, or if false and misleading claims are made for the device, the product may be seized and condemned and the manufacturer may be criminally prosecuted. The burden of demonstrating hazardousness or ineffectiveness, however, is on the government.

The government has stressed the importance of the preclearance of devices employed by physicians. The basis for this is questionable. There is no question but that there is a problem. Whether it is a really important one, of sufficient importance to warrant the passage of a complicated law, with the consequent delays and expense, is questionable in my opinion. As I see the general situation, existing law can cover the problem, particularly if certain recommendations which I will make are followed.

Application for Clearance

The general pattern of the Administration device bill is not dissimilar from that in existence with respect to new drugs. Under Title 2, not only any device, but also any component, part or accessory of a device, is deemed unsafe, unreliable or ineffective unless its manufacturer has first obtained clearance from the FDA. A device which is intended to be secured or placed within the human body or into a body cavity or in such contact for a substantial period, or one which is intended to be used for subjecting the body to ionizing, radiation, electromagnetic, electric or magnetic energy, heat, cold, physical or ultra-sonic energy and the like, is deemed to be unsafe, unreliable or ineffective if it is not generally recognized by qualified experts to be safe, reliable and effective for the conditions specified in its labeling.

There is a further important provision: The bill provides that, if the Secretary finds that there is probable cause to believe that any other device is not effective for its use or is not safe or reliable, he may declare the device to be a new device requiring the submission of a new device application. It is not clear whether this may be extended to a device complying with a standard. There is no provision for judicial review of such a finding; such a provision would be helpful.

The manufacturer of a device of the kinds specified must file with the Secretary an application for clearance of the device unless the device "is solely for diagnostic use" or is exempt under certain specified circumstances. It is not entirely clear what the situation is with respect to a device which is offered both for diagnostic and other uses; that is, for use in the cure, mitigation, treatment or prevention of disease as well as diagnosis, or to affect the structure or any function of the body. I might say, parenthetically, that this is an extremely broad definition and the problem is often one of semantics. Thus, many implements not ordinarily considered as therapeutic devices have been classified in that manner; for example, vacuum sweepers and phonograph records.

In the application to be filed with the Secretary, data must be submitted similar to that which must be submitted in connection with a new drug; that is, essentially all information designed to establish the safety and effectiveness of the product. The bill provides that among this material there must be included "an identifying reference to any standard, applicable to such device, which is in effect," and although it is my understanding that the bill is not designed to require that the manufacturer of a device which has

been standardized must submit an application for clearance and be cleared before it may be marketed, it would appear that if this is so it should be specifically stated.

A provision not present in the new drug section is contained in the bill to the effect that the Secretary shall promulgate and keep current a list of devices which he finds are generally recognized by qualified experts as being safe, reliable and effective. This would seem at first glance to be helpful to industry and the medical profession, but a problem may arise with respect to devices which are, in fact, not new devices requiring preclearance and yet which might not, for one reason or another, have been placed on such a list.

The Administration bill further provides (similar to existing provisions dealing with new drugs) that within 180 days after the filing of a new drug application, the Secretary shall either approve the application or give the applicant notice of an opportunity for a hearing. It is to be noted that there is no automatic clearance of the device if the Secretary does not comply with those provisions within 180 days. Further, the Food and Drug Administration may choose to utilize the procedure employed in the past with respect to new drug applications—at any time within the 180 days, advise the applicant that the application is "incomplete" because of insufficient data. It is to be borne in mind, therefore, that the 180 days specified is subsequent to the filing of the application and not subsequent to its receipt by the FDA.

If a new device application is turned down by the Secretary, the applicant, if he so desires, may have a hearing before a trial examiner and attempt to demonstrate that his application should be approved because it is, in fact, safe and reliable and that there is substantial authoritative evidence as to its effectiveness. There is a specific rather ambiguous provision that when a device is intended for use by a physician, surgeon or other person licensed or otherwise specially qualified therefor, its safety, reliability, and effectiveness shall be determined in the light of such intended use. A possible further ambiguity can be eliminated by providing that when a device is intended for use by a person licensed or otherwise specially qualified therefor, or by a physician or surgeon, its safety, reliability or effectiveness shall be determined in the light of such use. Otherwise, lists of physicians and surgeons deemed to be qualified might be required.

As in the case of new drugs, approval of a new device application may be withdrawn if new evidence, linked with the original

data, reveals that the product is not, in fact, safe or reliable, or that there is a lack of substantial evidence as to effectiveness. Here, as in the case of a denial by the Secretary of clearance for a new device application, judicial review may be had in a United States Court of Appeals. Before seeking judicial review, however, an applicant, in connection with an order of the Secretary denying or withdrawing approval of a new device application, may request a referral of the problem to an independent Advisory Committee appointed by the Secretary, for a report and recommendations.

The bill provides for exemptions of new devices for investigational use. A new device may be introduced into interstate commerce if it is intended solely for investigational use in a hospital, laboratory, clinic, or other appropriate scientific environment by qualified experts. The Secretary is authorized to promulgate regulations relating to the application of this exemption to any device that is intended for use in clinical testing upon humans by separate groups of investigators under essentially the same protocol followed in developing data required to support a new device application. As in the case of investigational new drugs, the Secretary may and undoubtedly will provide for rigorous safeguards in any investigational testing. Whenever the Secretary determines that a device which is being shipped in interstate commerce for investigational testing upon humans does not meet the conditions pursuant to which the product may be shipped for such investigational use, he may terminate the exemption so that the product may not be used investigationally. The bill does not provide for any hearing on a termination of an exemption or for judicial review.

The Administration bill further provides that the Secretary shall exempt a device that conforms to a standard which has been placed in effect by the Secretary, "to the extent that the Secretary finds that the standard provides assurance that the device will be safe, reliable and effective for such use." The requirements with respect to a device which has been standardized are not free from ambiguity as far as any particular manufacturer is concerned. In other words, it is not entirely clear that preclearance is not required.

Mandatory Standards

The second main class of devices covered by the Administration bill would be composed of devices subject to mandatory standards relating to the "composition, properties or performance of the device."

Diagnostic devices are specifically exempted. Any device of the type for which a standard is in effect will be deemed to be "adulterated" unless it conforms to the standards.

The statutory authority to the Secretary to set mandatory standards is couched in broad and vague language—"whenever in [his] judgment such action will protect the public health and safety." The FDA is directed to consult with and give "appropriate weight" to standards published by other Federal and international agencies, and to invite participation by the scientific and industrial community. Anyone adversely affected has the right to have the Secretary's action referred to an advisory committee. The Act also confers upon an aggrieved applicant the right to an administrative hearing and judicial review.

The FDA has set forth the many types of devices which may be standardized. These include oxygen tents, resuscitators and defibrillators, anesthetic equipment, ultra-sound devices, diathermy machines, electrosurgical units and accessories, low volt generators, oscillograph recorders, thoracic brain and eye instruments, ear, nose and throat and genito-urinary instruments, cardiac catheters, metal prosthesis and implant materials.

Neither the clearance nor standard authority would be imposed on devices generally recognized by experts as safe and effective and accepted in medical practice. This is such a vague term that, although it would be legally possible, it would be hazardous for a manufacturer to make this determination without clearance from the FDA. And a question of this character almost inevitably results in a reply that the product must get prior clearance. Devices used by investigators in research and development in early, nonremunerative steps would not be required by the bill to obtain preclearance.

The bill further provides that any device, made to the order or in accordance with specifications of a practitioner licensed by law to use or prescribe the device, is exempted from the requirements of the bill if a device meeting the specifications is not generally available in finished form for purchase or dispensing upon prescription, is not stocked or offered through a catalogue or other commercial channels and is either intended for use by a patient named in such order by the practitioner or solely by the practitioner or by persons under his supervision in the course of his professional practice.

Again, as in the case of new drugs, every person manufacturing, processing or distributing a device which is subject to a standard

or which has received approval of a new device application must establish and maintain records and make reports to the Secretary containing data bearing on the safety, reliability or effectiveness of the device, or on whether the device may be adulterated or misbranded. Officials of the FDA must be given access to—and are given the right to copy and verify—these records. Pharmacies and practitioners licensed to prescribe or administer devices and who manufacture or process them solely for use in the course of their professional practice, and those who manufacture or process devices solely for use in research or teaching, and not for sale, are not required to keep such records and make such reports.

The authority provided with respect to the inspection of establishments where devices are manufactured is extremely extensive, as is presently the situation with regard to prescription drugs.

Every person who manufactures, prepares, propagates, compounds or processes a device in any establishment must register with the Secretary his name and place of business of such establishment and the Secretary may assign to him a registration number. As I read the bill, even such persons who do not introduce their products into interstate commerce must register and their establishments are subject to inspection by the FDA.

It may be that the courts have in effect enacted legislation which will not require Congress to pass a law providing generally for the preclearance of devices, including implant materials, to the satisfaction of the FDA.

A Choice of Definitions

In a recent case, *AMP, Inc. vs. The Secretary of HEW and the Commissioner of Food and Drugs,*[1] the problem involved two types of surgical ligatures—implements for tying severed blood vessels. The first consisted of a plastic pliers-like holder (a hemostat) to which was attached a strand of nylon suture material extending in a loop beyond the hemostat. The second was a narrow hollow plastic rod to which was attached a similar strand. By manipulating the hemostat or rod, a tiny locking disc strung on the suture strand could be made to slide along the strand, reducing the aperture of the loop in much the same manner as a hangman's knot tightens a noose. In surgical procedures the loop is placed so as to encircle

[1] CCH Food Drug Cosmetic Law Reports ¶ 80,192, CA-2, 1968, aff'g 275 F. Supp. 410 (DC NY 1967). For the U. S. Supreme Court's refusal to review, see story on page 509.

a severed blood vessel and, when pulled tight, constricts the vessel, thereby stopping the flow of blood therefrom.

The United States District Court for the Southern District of New York held that the essential element of the product is the suture and that the listing of sutures in the U. S. Pharmacopeia was some evidence that sutures are a drug. More important, however, the court held that assuming that the products fall within the definitions of "drug" and "device" in the Federal Food, Drug and Cosmetic Act —

> the remedial nature of the Food, Drug and Cosmetic Act warrants a liberal construction for the protection of the public health and, thus, a finding that plaintiff's products are drugs.... The public will be better protected by classifying plaintiff's products as drugs rather than devices so that proper testing, controlled by the government, can be pursued. It would seem that where an item is capable of coming within two definitions, that definition according the public the greatest protection should be accepted.

The judgment of the District Court was affirmed by the United States Court of Appeals for the Second Circuit. The Court of Appeals was bothered by the fact that the definition of the term "drug" in the statute excludes "devices." The Court, with the same general reasoning as that used by the court below, stated that it was reluctant to construe the statute, which deals with the public health, narrowly, and declared that the exclusion of "device" in the definition of "drug" should be limited to such things as Congress expressly intended it to cover when the Act was passed, in 1938. The Court also held that since there was no general recognition of the safety and efficacy of the instruments in question, they were "new drugs" which could not be marketed legally in interstate commerce until their safety and effectiveness had first been approved by the FDA as "new drugs."

The tremendous scope of the authority granted to the FDA by this piece of judicial legislation is highlighted by a statement by the counsel for the FDA, set forth in a report in the *Washington Post* of June 8, 1968. The report stated, in part, as follows:

> The position taken by the FDA, on the advice of its counsel, William W. Goodrich, was that the products were legally "new drugs" and therefore could not be sold until their safety and efficacy had been demonstrated to the agency.
>
> It argued that any products used to diagnose, prevent or treat disease legally fell under the more stringent procedures governing "new drugs" rather than the weaker controls regulating "devices."
>
> * * *
>
> The Supreme Court's denial of AMP's request revolutionizes the situation for a great number of products, ranging from nails used in bone repair to artificial eyes.

Now, counsel Goodrich said, the agency has power to require that, like drugs, they be cleared for safety and efficacy before being sold.

In addition, he said, the FDA now will have the same powers for articles that affect any of the bodily functions. Thus, Goodrich said, the FDA will be able to regulate before sale intrauterine birth control devices, which are used by possibly 1 million women in this country and by 6 to 8 million in others.

Transplants Must Be Defined

What is the situation with respect to transplants? As I see the situation, unless certain basic problems are met by the medical and scientific disciplines, the government will enter the picture, either under existing law or, more likely, by further amendments to existing law. I have referred to the opinion which placed articles which were clearly devices under the drug and new drug provisions of the Act. The reasons advanced by the courts were not really legal ones —they merely consisted of the courts' belief that, since the public would be better protected if the products were called drugs, they should be so designated.

Certainly Congress, and the courts if Congress does not act, are going to be anxious to find some way to exercise some control with regard to transplants if safeguards and adequate procedures are not created by the medical and scientific professions. The terms "device" and "drug" are so very broad that almost anything can be encompassed within them. A drug is defined in part as an article (other than a device) intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease, articles intended to affect the structure or any function of the body and articles intended for use as a component of such articles. A device is defined to mean instruments, apparatus and contrivances, including their components, parts and accessories, intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease or to affect the structure or any function of the body of man. And a government agency is never loathe to assume greater power and jurisdiction, particularly where the agency is traditionally equated by large segments of the public, the press, the consumer groups, the Congress and the courts, with the American flag. After all, an organ taken from a cadaver for transplant can be said to be intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease or intended to affect the structure or function of the body of man. And the concept of interstate commerce has been so vastly expanded in the last 30 years as to cover most activities which were theretofore considered

to be intrastate and none of the constitutional business of the federal government. Perhaps the transplant would be held to be a component of devices (or drugs) used in transplant procedures, thus indirectly giving the federal government jurisdiction. Stranger results than these have been reached in the food and drug area.

Conclusion

What can be done to meet the problems raised by transplants? I believe much can be done by the medical and scientific groups and societies. It should not be beyond their expertise and skills to establish criteria to be utilized by the doctor and surgeon, for example, in determining whether the donor is dead. Organizations such as the National Academy of Sciences could be called upon to study the problem and establish the necessary safeguards. Presumably a particular doctor or surgeon would not make the decision. Rather, a committee would be established in every hospital where an organ is to be removed so that the decision is not a personal one. Doctors and surgeons, like lawyers and shoemakers, are human beings (although some patients have reservations about this), with the frailties and predilections of other persons. I do not believe that civilized society will tolerate, at this time, the philosophy of some eager surgeon that there is no merit in waiting for that last moment when certain death will ensue, if a removal of an organ a few minutes sooner may give the recipient of a transplant a somewhat better likelihood of survival. I am afraid, also, that civilized society, at this time, will require that the prospective donor give written consent to the removal of an organ upon his death or, if he is incapable of giving such consent, that it be obtained from his legal representatives. This, of course, would raise many legal questions, and it may be that every person entering a hospital for an operation, at least perhaps for a major operation (if such a distinction can be made), could be asked the grim and forbidding question. I can, of course, comprehend the practical difficulties.

As far as important devices used by the surgeon and the physician are concerned, again it would be extremely advisable if some prestigious scientific societies were to establish standards for them. These could be related to specifications and safety, and the tremendous delays and expense of governmental controls might be avoided. It seems to me, in conclusion, that this procedure is at least worth trying; if it does not work legislation can always be enacted. **[The End]**

INSTITUTE OF FORENSIC MEDICINE ESTABLISHED

Formation of an Institute of Forensic Medicine—the first of its kind in the United States—was announced at a celebration commemorating the founding of the Office of Chief Medical Examiner of New York City in 1918. In that year, following a widely-publicized investigation of the coroner system, the State Legislature adopted a law setting up the city-wide office and requiring that all medical examiners be doctors of medicine and trained pathologists and microscopists.

The celebration also commemorated the 35th Anniversary of the establishment of the Department of Forensic Medicine at New York University School of Medicine.

According to Dr. Milton Helpern, Chief Medical Examiner of New York City and Professor and Chairman of the Department of Forensic Medicine at N. Y. U., the main purpose of the Institute of Forensic Medicine is to strengthen teaching and research in forensic (legal) medicine and forensic pathology by formalizing the relationship that has existed for many years between the Office of Chief Medical Examiner, a municipal agency, and New York University's School of Medicine, School of Law and College of Dentistry.

Under this relationship, numerous research projects have already been carried on and undergraduate and graduate teaching programs have been conducted for medical students and physicians from various sections of the United States and many foreign countries.

Another purpose of the Institute will be to further understanding of forensic medicine on the part of physicians, attorneys, members of other professions and the general public.

The Institute will be somewhat comparable to the Institutes of Legal Medicine that are found in most European countries. These Institutes are governmental agencies but they are also part of a local university and, in addition to conducting official investigations of sudden, suspicious and violent deaths, carry on teaching and research in medicolegal questions.

Mayor John V. Lindsay recently approved the establishment of the Institute of Forensic Medicine as an important step forward in the improvement of the administration of justice and the protection and advancement of the public health.

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