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Food Drug Cosmetic Law JOURNAL

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

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TO THE READER

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The Packaging Industry Looks at the Model Law and Regulation.—Commencing on page 396, *George M. Burditt,* a member of the Illinois House of Representatives, considers the model law and regulation from the standpoint of those firms which are packaging commodities subject to the models and suggests possible amendments to the Model Weights and Measures Law and Model Regulation. The importance of uniformity in state and federal packaging laws is stressed throughout Mr. Burditt's article, which was presented at the 51st National Conference on Weights and Measures in Denver, Colorado, on July 12, 1966.

Latin-American Food Code.—Beginning on page 404, Chapter XVIII of the Latin-American Food Code is reproduced. Definitions and regulations concerning foods for regimens are discussed in this chapter. Chapters I-V, VII, X, XII, XIII and XVII appeared in previous issues of this JOURNAL. The translation is by *Ann M. Wolf* of New York City.

Physician Owned Pharmaceutical Companies—A Wrong Without a Remedy.—*Dr. Robert W. Hammel* is Associate Professor of Pharmacy Administration at the University of Wisconsin. His co-author, *Dr. Maven J. Myers,* is Instructor in Pharmacy Administration at the Philadelphia College of Pharmacy and Science. This paper, starting on page 412, is the product of their combined research. The authors cite certain abuses that may arise when a practicing physician is in the position to prescribe a product in which he has a financial interest: patients may be exploited and fair competition obstructed. They examine both the legality of such practices on the part of doctors, and the constitutionality of measures taken to curb these practices. Existing laws governing the practice of medicine are shown to be neither specific nor uniform enough for the just treatment of this problem. On this basis, the authors criticize the recent "Medical Restraint of Trade Act," hopeful that minor changes in wording will render it an effective weapon against the physician ownership of pharmaceutical companies.

Rendezvous with Destiny.—*James F. Hoge,* General Counsel of the Proprietary Association and a member of the New York Bar, presented this article at the Second Session of the 85th Annual Meeting of the Proprietary Association, on May 18, 1966. In this article, beginning on page 431, Mr. Hoge concerns himself with the possibility of increased federal regulation of the proprietary drug industry inherent in recent legislation.

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Food·Drug·Cosmetic Law Journal

Food Package Labeling— Legal Requirements and Commercial Practices

By HARVEY L. HENSEL

The Following Article Was Presented at the 51st National Conference on Weights and Measures in Denver, Colorado, on July 12, 1966. Mr. Hensel Is a Member of the Law Department of Swift & Co.

AS A STARTING POINT, on the subject of legal requirements, let us consider a list of some of the laws with which the food industry must comply in order for the labels on its packages to be legally correct. Such a list would include:

(a) The Federal Food, Drug and Cosmetic Act;

(b) The Federal Meat Inspection Act;

(c) The Federal Poultry Products Inspection Act;

(d) Federal acts dealing with particular foods such as margarine, butter, etc.;

(e) State Weights and Measures Acts;

(f) State Food, Drug and Cosmetic Acts;

(g) State Acts governing meat and meat products;

(h) Special state acts governing particular foods such as frozen desserts, margarine, etc.

Requirements for Labeling Food Products

All of these laws have requirements concerning the labeling of food products. The general types of requirements covered fall into the following categories:

1. Giving the common or usual name of the product.

2. Listing the name and address of the manufacturer, packer or distributor.

3. Listing the ingredients.

4. Stating the net quantity.

5. Showing the inspection legend if there is government inspection of the product.

6. Showing all the above information at the proper location on the package.

7. Stating all required facts in a conspicuous manner.

8. Giving all required statements for dietary products.

9. Giving all required statements for special ingredients such as artificial coloring, artificial flavoring, preservatives, etc.

Many of the above labeling requirements are set forth in more than one law. For example, net quantity requirements are found in state weights and measures laws, state food and drug acts, the Federal Food, Drug and Cosmetic Act, the Federal Meat Inspection Act, the Federal Poultry Products Inspection Act, state laws governing meat and meat products, and state and federal laws concerning special foods, such as oleomargarine.

As a final dimension to the measurement of food packaging legal requirements, it should be remembered that most food manufacturers distribute their products nationwide. This means that food manufacturers must comply with all federal laws governing their products, while at the same time they must comply with the laws of fifty states.

The above comments briefly summarize the legal requirements for labeling food packages. Although it would seem that these requirements are more than ample to protect the consumer, additional federal legislation on this subject is now pending in Congress.

The next question is, what is the commercial practice of the food industry concerning compliance with these requirements? Difficult though it may be, the rules are very simple. If at all possible, one uniform label is designed that complies with all the requirements that affect that particular product in the jurisdictions where it will be sold. If this cannot be done on a uniform basis, non-uniform labels and procedures must be adopted. Sometimes this has meant designing a package for sale only in a given state. Sometimes it has meant that a given label which is going to be used in, for example, six states will contain information which is really only required in one of the six states. In a few cases it has meant that, because of non-uniform labeling requirements, a particular product is not sold in a given state.

Steps Toward Increased Uniformity

Because of the complexity of the task of designing a uniform label, and the problems that arise when a uniform label cannot be

used, I would like to discuss with you what is being done to increase uniformity in the area of package labeling, and secondly, how you can help with this problem.

In the field of weights and measures, the most important step toward uniform laws has been the adoption, by a number of states, of the Model Weights and Measures Law. At the present time, 21 states have passed the Model Weights and Measures Law and approximately the same number have adopted the Model Regulations pertaining to packages. Each year this number increases.

One of the best examples of preserving uniformity, when a serious lack of uniformity was threatened, was the adoption of a model regulation on prominence and placement by your national conference. This experience is being cited time and time again as an outstanding example of how state officials, federal officials, and industry representatives can work together and achieve both a desired objective and uniformity.

Formation of Industry Committee

As a result of the cooperative work of industry with your conference on the subject of prominence and placement of the net quantity legend, industry has formed a permanent committee of those companies and trade associations concerned about weights and measures problems. Frank Dierson, of the Grocery Manufacturers of America (GMA), is Chairman of the Industry Committee on Weights and Measures, John Speer, of the Ice Cream Association, is Secretary, and I am Vice-Chairman. Two of the main purposes of this committee are (1) to keep industry advised concerning any proposed non-uniform weights and measures laws, regulations or interpretations which affect labeling, and (2) to work with state officials and officials of the Bureau of Standards toward more uniform labeling laws, regulations and interpretations. This industry group has been very effective in helping to achieve these goals during the few years of its existence, and I believe it will continue to advance uniformity in the future.

Other steps towards uniformity have been taken in connection with food and drug laws. As of now, 33 states have adopted the Model Food and Drug Act. Also, steps are being taken to draft a uniform meat product law which could then be adopted as a model law by the states.

In addition to the above steps that are being taken, I would like to suggest at least two ways in which enforcement officials can help achieve the goal of uniformity. If any matter comes to their attention for decision, and there is a known *uniform* law, regulation or interpretation, please follow the uniform law, regulation or interpretation. If

the matter needs further clarification, it should be referred to Mr. Jensen, of the Bureau of Standards, or to the Laws and Regulations Committee and be guided by their recommendations. Problems concerning how to express the net quantity statement have arisen in the past and have been successfully and uniformly handled in this very manner. In this regard, enforcement officials must remember that the smallest change from uniformity, such as how a word may be abbreviated, can change millions of acceptable uniform labels into unusable labels.

Secondly, I would urge enforcement officials to restrict their enforcement activities in the field of package labeling to the net quantity legend on the package, leaving other labeling requirements to more appropriate enforcement officials. As an example of this point, it is my opinion that references on a label concerning the price to be paid for an item should not be regulated by weights and measures officials.

Official Cooperation with Industry

Appropriately enough, I have saved for the last my most important comment. It concerns the cooperation of enforcement officials with industry. With this cooperation, the food industry can operate on a nationwide basis even under non-uniform laws—without this cooperation, such an operation would be almost impossible. I would like to describe several areas where this cooperation has been needed and has been fully given:

1. Although many enforcement officials are from states that have not yet adopted the Model Law and Regulations, their interpretation of the law and regulations has been substantially the equivalent of that given to the Model Law and Regulations.

2. If a label is brought to their attention which appears not to be in compliance with the law, an informal notice of this fact is generally given so there is opportunity to correct any error that may exist.

3. Where changes in labels are necessary, a reasonable time is usually allowed for using up old labels.

4. Where honest differences of opinion have occurred, they have been resolved on a reasonable, practical basis. I cannot overemphasize the appreciation of industry for this attitude on their part.

We have had enforcement officials' 100 percent cooperation in the past. We very much need it in the future. Since cooperation is only successful as a two-way proposition, I want to assure them that the food industry will do its part to make our relationship both effective and congenial.

[The End]

The Packaging Industry Looks at the Model Law and Regulation

By GEORGE M. BURDITT

Mr. Burditt Is a Member of the Illinois House of Representatives, and a Partner in Chadwell, Keck, Ruggles & McLaren. This Article Was Delivered at the Fifty-First National Conference on Weights and Measures, on July 12, 1966, Denver, Colorado.

THE MODEL LAW AND MODEL REGULATION [Model Weights and Measures Law] are virtually sacrosanct documents. They constitute a subject which is important to enforcement officials, industry and consumers. As more and more state legislatures adopt the model law, and more and more officials promulgate the model regulation, uniformity is increased and, as Mr. Hensel has said, uniformity is especially important to all of us. *Consumers* benefit, since they can be assured of uniform manufacturing procedures, quantity control and labeling requirements regardless of where the product is manufactured or sold. *Enforcement officials* benefit, since uniformity promotes compliance, and since a substantial body of judicial and administrative interpretations is quickly built up. And *industry* benefits, since a package legal in one state is legal in others. So I join Mr. Hensel in thanking and congratulating those responsible, including, of course, Mr. Jensen, his predecessor Mr. Bussey, and the other members of the staff of the National Bureau of Standards, for their work in drafting the model law and regulation and securing their adoption in so many states.

My assignment is to consider the model law and regulation from the standpoint of those firms which are packaging commodities subject to the models, and to suggest possible amendments for consideration. My first comment, from industry's viewpoint, must necessarily be, however, that uniformity is the most important single factor to be kept in the forefront of any discussion of the model law and regulation.

But uniformity is not necessarily promoted by rigid adherence to the status quo. Any law or regulation governing industries as dynamic as are those which sell consumer commodities, must itself be dynamic rather than static, if it is to serve the public properly. If the model law and regulation are not dynamic, they will soon become models in name only. Therefore, it behooves the National Conference, as it has always done, to review the models frequently and systematically to make certain that they are accomplishing the purpose set forth on the cover of both documents: "uniformity in weights and measures laws and methods of inspection."

So let me make a few suggestions which are intended to promote *future* uniformity by keeping the model law and regulation vital and viable. I should, of course, emphasize that all views expressed herein are those of the author, and not necessarily those of the sponsor or anyone else!

Remedies

First a few words about two sections of the model law which set forth the remedies available to the enforcement official. Section 14 authorizes the director to issue:

> . . . stop-use orders, stop-removal orders, and removal orders . . . whenever . . . he deems it necessary or *expedient* to issue such orders. . . . (Emphasis added by author.)

I, personally, am not aware of any instance in which a weights and measures official has based a stop-use or similar order merely on "expediency" as is authorized by the Model Weights and Measures Law. Nevertheless, expediency is one of the tests provided by Section 14. It seems to me that both industry and enforcement officials would be better served by a statute which at least required the enforcement official to make a finding that public interest necessitated the issuance of the order. Indeed, an order not based on the public interest, but merely on expediency, might well be unconstitutional, and, at the very least, give a possible defense to such an order in cases which should not be defensible on procedural grounds which are irrelevant to the substantive issues involved.

Section 16 of the Model Weights and Measures Law authorizes the director:

> . . . to arrest, without formal warrant, any violator . . .

This same section authorizes seizure of packages without formal warrant, which, itself, is a broad power, but one which is probably justified, since the action is against goods, rather than against a per-

son. But the provision in the section which authorizes *arrest* without formal warrant is, it seems to me, too broad to justify leaving it in the model. Again, I am not aware of any instance in which this section has been used or abused, which perhaps illustrates that enforcement officials, or perhaps attorneys general, also view this section as being too extreme.

I make these comments on Sections 14 and 16 only after serious consideration and reflection. As a member of the Illinois Legislature, I have tried to vote consistently against what I like to call "molly-coddling" bills: those which make it easier for the criminal, the delinquent, the draft card burner or the cheat to get along in our society. I feel very strongly that this type of legislation, which has friends not only in legislative bodies but also in our court system, runs counter to our American tradition. So do statutes which authorize action based on expediency, or on arrest and deprivation of liberty without a formal warrant. So I commend for consideration a review of Sections 14 and 16, since extremism, even in the defense of honest weights and measures, is probably not justifiable.

Qualifying Terms

The next subject which I should like to discuss is the use of qualifying terms. Section 26 of the Model Weights and Measures Law and Section 3.9 of the Model Regulation prohibit the use of any term:

> such as "Jumbo," "Giant," "Full," or the like that tends to exaggerate the amount of commodity.

Now I can understand how a word like "Jumbo" or "Giant" might be misleading, although I would like to see a thorough consumer survey on this point before I am completely convinced. But the word "Full" does not seem to me to belong in this list of prohibited terms. Let me give you a specific example. Two or three years ago, several food companies began marketing a liquid food product in exotic shaped jars and bottles which contained slightly less than a pint, some 15 fluid ozs., some 14 fluid ozs., and some as low as 13 fluid ozs. The exotic shape of the bottles precluded consumers from telling at a glance which of the jars were larger in volume. Indeed it was virtually impossible to differentiate the quantity in these jars from the full pint contained in competitors' jars. Accordingly, reputable firms who wished to hold the line at one pint, which was the size to which consumers had become accustomed, began marketing their jars with a flag which bore the words "Full

Pint." The purpose of this quantity declaration was to enable consumers to see at a glance that the reputable firm's jars contained a full pint, as distinguished from an ounce or two or three less than a pint contained in the exotic shaped jars. Use of the word "Full" in this instance, it seems to me, promoted honesty and fair dealing in the interest of consumers, and should not have been absolutely prohibited by the Model Weights and Measures Law and Model Regulation. Every once in a while one of my children brings home a test with a list of words, one of which does not match the other words for some reason. The object of the test is to pick out the word which does not belong with the others on the list. It seems to me that such a test could be applied to Section 26 of the Model Weights and Measures Law and Section 3.9 of the Model Regulation, and if it is applied, the word "Full" would be deleted from these two sections. An alternative suggestion would be to permit the enforcement official to allow use of the word "Full" when in his opinion public interest was served by use of the word "Full."

Pricing

Next let me make a few comments concerning sections of the Model Weights and Measures Law which relate to pricing. Mr. Hensel listed the many laws with which a seller of consumer commodities must comply. Of course, these laws are enforced by numerous agencies. Right now, in Illinois, we have an interim legislative commission, entitled the Food, Drug, Cosmetic and Pesticide Laws Study Commission—of which Mr. Hensel, incidentally, is one of the public members—which is reviewing all of our state's laws in this area. We have found laws enforced by the Department of Public Health, the Department of Public Safety, the Department of Agriculture, the Department of Education and Registration and of course by several divisions within these departments. All of the Departments, and specifically Mr. Goforth of the Department of Agriculture, have given us their fullest cooperation. If we are to avoid overlapping jurisdiction, duplication of effort, unnecessary expense to the taxpayer, and unwarranted burdens on industry, it is important that specific lines of authority be described in our statutes and regulations.

In this regard, it seems to me that matters relating to pricing and price labeling should be assigned to state and local law enforcement officials, such as state's attorneys and attorneys general, and to state agencies analogous to the Federal Trade Commission (FTC), rather than

to weights and measures officials. By this, I do not in any way mean to de-emphasize the importance of pricing regulations; indeed I believe their importance would be emphasized by centralizing enforcement in one official and placing the burden squarely on that official to make certain that laws are complied with by everyone. I am sure you know, from your own experience, that any time two different departments or two different officials within a state are given jurisdiction over the same subject matter, enforcement tends to be either more lax or more confusing than it is when clearly defined jurisdiction is assigned to one department or to one official.

Section 27 of the Model Weights and Measures Law requires random weight packages to bear on the outside of the package:

a plain and conspicuous declaration of the price per single unit of weight, measure or count.

Section 31 of the Model Weights and Measures Law prohibits the misrepresentation of a price, prohibits representation of a price in any manner calculating or tending to mislead the purchaser, and requires fractions of a cent in price labeling to be prominently displayed. No one can argue that misrepresentations of price should be prohibited; but it does seem to me that officials other than weights and measures officials should be charged with the responsibility of enforcing these provisions.

Supplementary Declarations

Section 3.7.1 of the Model Regulation permits a supplementary declaration of weight, measure or count, provided, among other things, that:

. . . any such supplementary declaration shall be neither in larger size type or more prominently displayed than the required quantity declaration . . .

But, frequently, a consumer is far more interested in a supplementary declaration than in the primary declaration, and in such cases it is customary for industry to put the supplementary declaration in larger size type. For example, a consumer is more interested in "4 waffles" than in "6½ ounces net weight"; or in "8 slices" than in "8 ounces net weight." In such instances, it is, of course, possible that "4 waffles" or "8 slices" might be considered the primary declaration, but I would suggest that Section 3.7.1 be amended to give the enforcing official authority to permit what would normally be considered to be a supplementary declaration to be larger than the primary declaration if the public interest is thereby served.

Section 3.7.3 of the Model Regulation requires that a declaration of quantity in terms of count be supplemented by a declaration in terms of weight, measure or size:

. . . unless a declaration of count alone is fully informative to the consumer

and Section 3.7.4 requires that a declaration of weight or measure be supplemented by a declaration of count or size:

. . . unless a declaration of weight or measure alone is fully informative to the consumer.

The words "fully informative to the consumer" are perhaps not quite as clear as they might be. They are the kind of words which lead to differences of interpretation, and, to that extent, impair uniformity. One official might well take the position that a declaration of weight is "fully informative to the consumer," and therefore adhere to what he thinks is the strict meaning of those words. Another official, on the other hand, might decide that the declaration is not *"fully* informative", and that a supplementary declaration is therefore required. Here is another instance in which "public interest" might be written into the Model Regulation to the benefit of all parties.

Non-Consumer Packages

A great deal of effort has been put into the wording of Section 6.8.1 of the Model Regulation over the last few years. This is the section which relates to "industrial-type" or "non-consumer type" packages. The present wording is still perhaps not quite as clear as it could be. For example: are "free samples" exempt, as they probably should be, and if so—what packages qualify as free samples? This section is something of a Pandora's Box, but perhaps the lid could be lifted just a little for more examination of the contents without allowing anything to escape.

Shrinkage

No discussion of the model law and regulation would be complete without a few comments on the very important and very controversial subject of shrinkage. Section 8.2 of the Model Regulation permits variations from the declared weight or measure, when such variations are caused by ordinary and customary exposure to conditions that normally occur in good distribution practice, and that unavoidably result in change of weight or measure,

. . . but only after the commodity is introduced into intrastate commerce:

which is defined as:

. . . the time and the place at which the first sale and delivery of a package is made within the State, the delivery being made either (a) directly to the purchaser or to his agent, or (b) to a common carrier for shipment to the purchaser . . .

This section also requires that:

. . . so long as a shipment, delivery or lot of packages of a particular commodity remains in the possession or under the control of the packager or the person who introduces the package into intrastate commerce exposure variations shall not be permitted.

This position appears to be in conflict with the federal rule which requires that the package bear the stated quantity at the time it is introduced into interstate commerce, but permits shrinkage which unavoidably results in change of weight or measure after the product is introduced into interstate commerce.

There is no panacea for this difficult problem. A uniform federal and state rule would, however, be most desirable and I sincerely urge incorporation of the federal rule into the Model Regulation.

One method of alleviating this difficult problem, for at least some parts of the food industry, has recently been suggested. A number of viscous or semi-solid products have customarily been sold by liquid measure. These products may shrink through loss of air or for other reasons, but they do not lose weight. Therefore, it seems to be becoming more and more prevalent to label such products by weight rather than by liquid measure. This change in the method of sale is probably authorized by Section 25 of the Model Law and Section 3.2 of the Model Regulation, particularly if state officials are sympathetic to the difficult problem which faces industry.

Prescribed Units and Fractions

Section 3.5 of the Model Regulation requires that a declaration of quantity be expressed in terms of the largest whole unit of weight or measure. I believe an alternative to this requirement has been suggested by Mr. D. W. Leeper of H. J. Heinz Company. Mr. Leeper suggests that weight declarations of ten pounds or less, or one gallon or less, be in ounces and fractions or decimal parts of an ounce unless the quantity declaration is accompanied by a declaration of both the price per unit of quantity and the total price. This "All Ounce" system has the advantage of facilitating price comparisons, and is included in S. 985 which was recently passed by the United States Senate.

One other suggestion concerning the declaration of quantity should be made in regard to the binary submultiple system—a term which Mr. C. D. Baucom introduced me to about ten years ago. Section 3.6 of the Model Regulation provides that:

Declarations of quantity may employ common fractions or decimal fractions

and requires that a common fraction be in terms of halves, quarters, eighths, sixteenths or thirty-seconds and be reduced to its lowest terms. Frequently a manufacturer finds it necessary or desirable—for example, because of the size of servings, or for recipes or for various dietary reasons—to package a food in fractions of an ounce which are not part of the binary submultiple system. In such instances, the manufacturer is forced to show on his label for example, "6.33 ounces" rather than "6⅓ ounces," even though the latter may be more meaningful to most consumers. I realize that the binary submultiple system had valid and justifiable reasons for its original inclusion in the law, but those reasons are no longer valid; this is evidenced by the provision authorizing use of the decimal equivalent of fractions which are not binary submultiples. So, even though it was historically sound, and even though I love to say "binary submultiple", it seems to me that public interest in the simplification of quantity statements should lead you to consider amending Section 3.6 to relegate the binary submultiple requirement to the archives and to permit declarations at least in thirds of an ounce.

Prominence and Placement

Finally, I should mention prominence and placement, which are so thoroughly covered by Section 26 of the Model Weights and Measures Law and, particularly, by Section 6 of the Model Regulation. I have no suggestions for amendments. Section 6 is a perfect example of the way in which consumers benefit when enforcement officials and industry cooperate to reach a desired goal. The Committee on Laws and Regulations of the National Conference—Mr. Barker, Mr. Littlefield, and Mr. Lewis as Chairmen, and Mr. Goforth, Mr. Gustafson, Mr. Jennings, Mr. Lyles, Mr. Turrell, and, very importantly, Mr. Bussey and Mr. Jensen—have made a great contribution in their work on Section 6. The Industry Committee on Weights and Measures, under the able chairmanship of Mr. Frank Dierson, with Mr. James Bell and Mr. Harvey Hensel as vice chairmen and Mr. John Speer as secretary, also deserves our deep appreciation. If there is any way in which the Industry Committee can be helpful—or any way in which I, personally, can be helpful as a state legislator who has had the experience of shepherding a model food bill through the legislature—we are ready to do all that we can. The reciprocal cooperation of the Industry Committee and the National Conference, as Mr. Hensel has said, will inevitably keep the Model Weights and Measures Law and Model Regulation vital and viable in our mutual endeavor to serve consumers. **[The End]**

Latin-American Food Code 1964 Edition

In August, 1964, the Latin-American Food Code Council Published the Second Edition of the Latin-American Food Code. Information Concerning the Code and the Table of Contents of the New Edition Appeared in the April 1965 Issue of the *Food Drug Cosmetic Law Journal* (Vol. 20, page 238). The First Five Chapters Were Published in the September 1965 Issue; Chapters XII and XIII in the October 1965 issue; Chapter XVII in the November 1965 Issue; Chapter X in the December 1965 Issue; and Chapter VII in the June 1966 Issue. Chapter XVIII Appears Below. The Translation Is by Ann M. Wolf of New York City.

Chapter XVIII: Foods For Regimens

Article 701.—The term "foods for regimens" ("dietetic products") means any foods and beverages which distinguish themselves from the products ordinarily and currently found on the market either by their special composition or because they have during processing undergone a biological, chemical or physical change which makes them especially suitable for the diets of children, the aged, the sick (diabetics, obese, persons with kidney and liver ailments, etc.) and the convalescent.

When foods for regimens (dietetic products) contain eggs, salt and/or sugar, a statement to that effect must be included in the text of the principal label.

Dietetic products to which medicinal substances have been added shall be considered "medicinal specialties" and as such shall be subject to the special regulations issued thereon by the health authorities.

Article 702.—Any establishments, or sections of establishments, at which foods for regimens (dietetic products) are prepared shall meet the general standards and, in addition, comply with the following requirements:

a. The rooms in which raw materials and finished products are stored and the rooms in which the products are prepared and packed shall have flat ceilings, waterproof floors and waterproof wainscots 1.80 m. in height.

b. They shall have the necessary equipment, maintained in a state of good preservation and cleanliness, and a quality control laboratory at which to check the raw materials and finished products. This laboratory shall be headed by a professional who shall be a food technician, chemist, biochemist, pharmacist, physician, veterinarian, or

agronomist, or shall hold a university degree in one of these professions and who, jointly with the business firm, shall be liable for the quality of the dietetic products prepared.

c. Dietetic products shall be packed in hermetically sealed containers which, whenever necessary, shall be subjected to sterilization. They are not permitted to have in their labeling or in leaflets or tags attached to them any medical indications or legends which imply a therapeutic treatment, unless they circulate as medicinal products subject to the official treatment as such.

d. In addition to the other regulatory declarations, the labeling of dietetic products shall indicate the manner of administration and the thermogenetic value of 100 grams of the product. Whenever advisable, or when so required by the competent authority, their percentage content in proteins, fats and sugars and their content in vitamins and mineral salts shall be stated, as well as any other component or property which characterizes or distinguishes the product.

e. Only official analysis results may be reproduced in the labeling of dietetic products, and in cases in which the total glycogenic value of the product is stated, hydrocarbons shall be considered as having a glycogenic value of 100 percent, proteins of 58 percent and fats of 10 percent.

Article 703.—The term "baby food" ("Alimentos para lactantes") means any foods intended for children of up to two years of age. The labeling of acid or alkaline foods shall, in addition to the data required under this Code, include a declaration of their acid or alkali content, expressed as lactic acid or potassium bicarbonate.

In addition, any baby food must have a label with the legend: "Always consult your doctor."

Article 704.—Dietetic sugars include monosaccharides, such as dextrose (see Article 343), levulose or fructose, and disaccharides, such as lactose (see Article 344) and maltose. The sweetening power attributed to sucrose is 100, that of levulose 150, that of invert sugar 85, that of maltose 60, that of dextrose 52 and that of lactose 28. Certain commercial products have a base of dextrose or levulose; others contain maltose and dextrin, and others consist of mixtures of said sugars.

Article 705.—As a general rule, the term "dietetic flour" means flours intended for children which consist of cereal, vegetable or banana flour. Such flours may have undergone different treatments to render them more easily digestible or soluble;

other starchy substances, starch derivatives and other products, such as milk powder, malt extracts, glucides, egg powder, mineral salts, vitamins and aromatics may be added to them.

Article 706.—The name "milk flour" means a product obtained by mixing condensed milk or milk powder with crackers made of wheat, cereal or leguminous flours to which dextrin has been added. Its moisture content may not be more than 6 percent and it must contain butter fat in a proportion of not less than 3 percent, lactose in a proportion of not less than 10 percent, and only traces of cellulose.

Article 707.—The term "cereal mixture" means any triturated or untriturated cereal mixtures sold for the preparation of decoctions or broths and consisting in general of wheat, rice, corn, malt, oat or rye grains. The same mixtures, finely ground, constitute the so-called "cereal flours." When part of the starch has been converted into dextrin and maltose, they are called "dextri-malted flours." Those prepared by pulverizing malted wheat crackers are named "dextrin flours." Sodium chloride and potassium bicarbonate are usually added to them.

Article 708.—The adjectives "enriched, activated or fortified" added to the name of a food mean that vitamins, mineral salts and/or essential aminoacids have been added to it. A qualitative declaration of the substance added must be included in the labeling used on the container.

A food product may be named "enriched, activated or fortified" only if the proportion of added elements (vitamins, essential aminoacids, mineral salts) is large enough for the amount of enriched food normally consumed to supply the body with not less than 80 percent of the total daily requirement of the element added. Larger additions are considered therapeutical and lend the enriched product the character of a medicine which, as such, is liable to the provisions on drugs.

Except in cases in which foods are enriched by official order in accordance with special formulae prescribed by the health authority to correct in certain areas a general deficiency in basic consumer foods (milk, cereals, flour, fats, bread, noodles, etc.), enriched products must comply with the following requisites:

1. Fortified, activated or enriched flours: Cereal flours, as well as food powders, with or without the addition of cacao or similar products, may be labeled "enriched" or "fortified" only when the enriching agent has been added in the following minimal proportions: Thiamine (Vitamin B_1) 4 p.p.m.; Riboflavin (Vitamin B_2) 2.6 p.p.m.;

Niacin (Vitamin Pp) 35 p.p.m.; Iron (Fe) 28 p.p.m. The addition of the following elements is optional:

Calcium (Ca)	150 p.p.m.
Calcium carbonate ($CaCO_3$)	400 p.p.m.
Monocalcium phosphate (CaH_4 (PO_4)2)	1,000 p.p.m.
Vitamin A	150 I.U. per 100 g.
Vitamin D_2	5 I.U. per 100 g.
Wheat germ	not more than 5 percent

Bakery, macaroni and confectionery products prepared with such flours shall be named: enriched, activated, or fortified.

2. Enriched or fortified margarine and butter: These are the products defined in Articles 177 and 204 of this Code, to which 30,000 I.U. of Vitamin A and 1,500 I.U. of Vitamin D_2 have been added per kilo.

Products enriched as specified in this article are not considered medicinal specialties.

Article 709.—"Gluten powder" or "gluten flour" is a product obtained from wheat flour from which practically all the starch has been subtracted. It may not contain more than 10 percent of moisture and 7 percent of starch.

Article 710.—Products may be sold as "gluten" products (bread, noodles, biscuits, etc.) only if they are made from a mixture of gluten flour and other flours in such proportions that the protein content of the finished product amounts to not less than 15 percent and their starch content to not more than 45 percent.

Article 711.—Foods for regimens (dietetic products) intended for obese persons and diabetics which have a base of cacao, chocolate, coffee, tea, mate, guaraná or kola, such as ices, soft drinks, desserts, etc., may be prepared by replacing the sugar by sodium or calcium cyclamate, saccharine, or another authorized safe artificial sweetener. Such products shall not only comply with Article 584, but shall also have the statement: "Contains artificial sweetener" in their labeling.

The proportion of saccharine may not exceed 0.15 grams per 100 grams of food or beverage, and the proportion of cyclamate may not exceed 2 grams per centum, expressed as cyclamic acid (cyclohexylsulfamic acid).

Article 712.—The terms "dietetic salt," "sodium-free salt" and similar names apply to table salts consisting of mixtures of potassium and ammonium chlorides with formiates, glutamates, phosphates or citrates of potassium, ammonium or cal-

cium, with or without the addition of vegetable condiments, which are intended to replace table salt in salt-free diets.

Article 713.—The term "malt extract" means a product of syrupy, pasty or dry consistency obtained from barley malt which has been subjected to special treatments (maceration, digestion, concentration, etc.). It may not contain alcohol in an amount detectable by official analysis methods; its dry residue, calculated by weight, shall not be less than 65 percent. Malt extracts may be non-diastatic or diastatic. The latter shall have a diastatic power, calculated on 100 grams of dry residue, capable at 55° C. of converting its own starch weight into sugar in less than 10 minutes.

Article 714.—The names "some," "neosome" and similar names distinguish dietetic beverages prepared from different fruit juices, sugar cane or agave juice, mate and tea extracts, roasted cereals, etc. which have been fermented with bacteria of the type Termobacterium mobile, not with yeasts which produce fusel oil. They are in general sold unfiltered and turbid in order to keep their bacteria live.

Article 715.—All dietetic products derived from milk must be prepared from pasteurized or boiled milk:

a. Buttermilk: A product obtained by souring milk from which the cream has been removed by means of selected enzymes and/or the addition of an organic acid. Buttermilk may not contain lactic acid in a proportion of more than 1 percent and its fat-free dry residue shall vary between 4 and 8.5 percent. When the fat content exceeds 0.5 percent, the percentage must be stated in the labeling. It must be sold in hermetically sealed containers subjected to sterilization. Average percentage composition: water 91; protein 3; fat 0.5; assimilable carbohydrates 4; ash 0.6; lactic acid 0.6.

Powdered buttermilk is prepared by drying buttermilk, with or without the addition of carbohydrates. Average percentage composition: water 3; protein 15; fat 2.8; assimilable carbohydrates 72; ash 3.5; lactic acid 3.

b. Kefir: A product obtained by the lactic and alcoholic fermentation of the milk of ewes, goats or cows by means of the enzymes contained in kefir grains or by the addition of brewer's yeast and Bulgarian culture[1] free from proteolytic pseudo-lactic bacillae. It must contain alcohol in a proportion of not less than 0.5 and not more than 1.5 percent, and a very small amount of peptones. It must have

[1] Note of the Translator: "Bulgarian culture" is a microbial association of thermophilic Lactobacillus bulgaricus and thermophilic Streptococcus lactis which may contain other lactic bacteria in a proportion of up to 20 percent.

the appearance of a homogeneous frothy liquid of creamy consistency and a slightly alcoholic, pungent, acid flavor. Depending upon the amount of lactic acid that forms during fermentation, it shall be named "weak kefir" when its lactic acid content is not more than 0.5 percent, or "strong kefir" when its lactic acid content is more than 0.6 and less than 1 percent. Kefir shall be labeled according to type. When the kefir has been prepared from skimmed milk, this shall likewise be stated in the labeling. Average percentage composition: water 86; protein 3; fat 3; assimilable carbohydrates 2.8; ash 0.6; lactic acid 0.6.

KEFIR GRAINS: see Article 245.

c. Kumiss: A product prepared from mare's, ass's or cow's milk fermented by means of brewer's yeast and Bulgarian culture,[2] free from proteolytic pseudo-lactic bacillae. It contains almost the same amount of lactic acid as kefir, but a larger amount of alcohol and an abundance of peptones. It must have the appearance of a frothy liquid, slightly thicker than milk, but thinner than kefir, and a slightly alcoholic, acid flavor. The alcohol content shall fluctuate between 2 and 4 percent and the lactic acid content between 0.5 and 1.5 percent. Depending upon the proportion of lactic acid, a distinction shall be made between "weak kumiss" containing up to 0.5 percent, and "strong kumiss" containing between 0.6 and 1.5 percent of lactic acid.

d. Activated milk: Milk enriched by vitamins which either have been added or derive from a special feed given to the animals producing it. Its vitamin content must be stated in the labeling.

e. Concentrated milk: A baby food, with or without cream, dried or not. The following may be added to it: lactic and/or citric acid (not more than 5 grams per liter); lemon juice (not more than 60 grams per liter); sugars (glucose, fructose, maltose in a proportion of not more than 50 grams per liter, and lactose in a proportion of not more than 25 grams per liter), and honey (not more than 70 grams per liter). Ascorbic acid may be added as an antioxidant, and the following substances as stabilizers: disodium phosphate, trisodium citrate and calcium chloride which, combined or separately, may not exceed 0.2 percent in concentrated milks or 0.5 percent in milk powders. The presence of these additives need not be declared in the labeling.

f. Dietetic milk powder: A product obtained by dehydrating milk with varying fat contents, to which different carbohydrates, dextrin, lactose, sucrose or maltose may be added. Average percentage composition (milk powder with a fat content of 26 percent): water 3;

[2] See footnote 1.

protein 28; fat 26; assimilable carbohydrates 36; ash 6.5. (Separated milk powder): water 3; protein 38; fat 1; assimilable carbohydrates 50; ash 7.

g. Corrected milk: Milk in which the natural proportion of one or several components has been changed. This must be stated in the labeling.

h. Frothy or sparkling milk: Flavored whole or skimmed milk (the type shall be stated in the labeling) carbonated with carbon dioxide to which carbohydrates may have been added.

i. Enriched or fortified milk: Milk to which vitamins or mineral salts have been added, with or without the addition of essential amino-acids. The quality and quantity of the substances added must be stated in the labeling.

j. Jellied milk: A product of semi-solid consistency, prepared from whole or separated milk, jellied by the addition of permitted thickeners or starchy substances in a proportion of not more than 2 percent; stabilized with the substances permitted under (e) Concentrated Milk; sweetened or unsweetened; with or without the addition of flavors and colors authorized by this Code or the health authority. The acidity, expressed as lactic acid, shall be less than 0.25 percent.

k. Albumin or protein-enriched milk: Milk obtained from buttermilk to which lactic proteins have been added, with or without the addition of carbohydrates, fats or other permitted products. It must be sold in hermetically sealed sterilized containers.

l. Milk jellied with rennet: A product prepared from whole or modified milk, with or without the addition of sugars and permitted aromatics, coagulated by the action of the rennet. The addition of thickeners, stabilizers and preservatives is prohibited. It must be kept at a temperature of below 10° C.

m. Maternalized or humanized milk: Milk obtained by modifying milk so as to assimilate the proportions of its principal components to those of human milk. When liquid, it must be sold sterilized.

n. Irradiated milk: Milk enriched with Vitamin D by adequate irradiation. The vitamin content must be stated in the labeling.

o. Malted milk: Milk obtained by mixing whole or partially separated milk, which may or may not be concentrated or dried, with flours to which dextrin or malt has been added. It must contain not less than 5 percent of butter fat and not more than 6 percent of moisture. The percentage composition shall be stated in the labeling.

p. Modified milk: This name covers in general liquid and solid milks subjected to a treatment intended to change their physico-chemical or biological composition, improve its digestibility or lend it new properties. Liquid modified milk shall be sold sterilized.

Article 716.—If the name of a food for regimens (dietetic product) includes the name of a vegetable (spinach, tomato, etc.), its dry residue must contain the vegetable named in an amount of not less than 15 percent.

When foods for regimens (dietetic products) are marked "salt-free," "salt-poor," or similar, the percentage of their maximal sodium chloride content must be stated in their labeling.

Article 717.—The designation "low-priced protein foods" applies to modern products with a base of different flours (of fish, cotton, soybean, sorghum, corn, etc.), vitamins and salts, which have a high protein content (between 26 and 65 percent), contain not more than 5 percent of crude fiber, have a biological value of not less than 10 percent of that of casein, and a not unpleasant insipid flavor which may be changed by additives. In view of the good results of the tests conducted in several areas, these products can be expected to be used with good success in the future:

a. Cottonseed meal: Percentage composition: water, not more than 10; protein, not less than 50; fat, between 0.1 and 6; crude fiber, not more than 5; free gossypose, not more than 0.055; free fatty acids, less than 1.8; lysine, not less than 3.6 percent of the nitrogen. Its bacterial plate count shall not exceed 20,000 nonpathogenic bacteria per gram and shall prove the absence of microorganisms of the groups Coli, Staphilococcus, Streptococcus, Shigella and Salmonella.

b. Fish meal: Percentage composition: water, not more than 10; protein, not less than 60; fat, less than 1; lysine, not less than 6.5 percent of the proteins. Its bacterial plate count shall not exceed 10,000 nonpathogenic bacteria per gram and prove the absence of bacteria of the groups Coli etc. named at letter (a).

c. Incaparin: A product developed by the Institute of Nutrition of Central America and Panama (INCAP), which is prepared with 29 percent of yellow corn meal; 29 percent of sorghum meal; 38 percent of cottonseed cake; 3 percent of spherical yeast; 1 percent of calcium carbonate; 4,000 I.U. of vitamin A acetate (1,200 mcg. of vitamin A potency per centum). Average percentage composition: water 12; protein 26; fat 4; assimilable carbohydrates 51; crude fiber 2.7; ash 4.3. **[The End]**

Physician Owned Pharmaceutical Companies — A Wrong Without a Remedy

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The fiduciary relationship between professional and client involves certain restrictions on the professional man's methods of charging. It requires that the practitioners shall be financially disinterested in the advice he gives, or at least, that the possibility of conflict between duty and self-interest shall be reduced to a minimum.[1]

IT HAS BEEN ESTIMATED that at least 5,000 physicians[2] violate this principle by acquiring substantial ownership[3] of small pharmaceutical firms which market prescription medication under a brand name of the firm.

Such ownership is likely to have a detrimental effect, not only on the patients of the physician owners, but also on the pharmaceutical industry in general. A study by the authors of the prescribing habits of some physician owners[4] shows that these detrimental effects do occur.

[1] Alexander M. Carr-Saunders and P. A. Wilson, *The Professions* (Oxford: Clarendon Press, 1933), p. 426.

[2] *Physician Ownership in Pharmacies and Drug Companies,* Hearings Before the Subcommittee on Antitrust and Monopoly of the Committee on the Judiciary, United States Senate, 88th Cong., 2d Sess. (1964), p. 2.

[3] As used in this paper, words indicative of possession of a financial interest do not mean that a physician is merely one of many thousands of shareholders in a large, national pharmaceutical company, or that a physician is necessarily the sole owner of a pharmaceutical company. Rather, the frame of reference is that he has a financial interest in a relatively small pharmaceutical company owned primarily by physicians actively engaged in the practice of medicine. Thus, by using, recommending or prescribing the products of this company, he can influence materially its profitability and his income as an owner of the company.

[4] Maven J. Myers, *Prescribing Habits of Physicians Who Own Pharmaceutical Companies,* unpub. Ph.D. dissertation, University of Wisconsin (Pharmacy), 1966.

For example, among a sample of original prescription orders issued during 1963 and 1964 by fifteen physicians, 16.3% were for a brand marketed by the company which the physician owned. In contrast, the National Prescription Audit reported that the company whose brands were most frequently specified on original prescription orders during 1963 accounted for only 8.8% of the total market.[5] In spite of the fact that this leading national company[6] had a broad product line,[7] quality products,[8] productive research[9] and aggressive marketing,[10] it only obtained on a national level approximately half the market penetration which the physician-owned companies obtained among their physician owners.

Thus, the existence of such ownership effects a foreclosure of competition. Nonphysician-owned companies cannot compete effectively for the prescription orders generated by physician owners.

An evaluation of the major physician-owned brands of the companies in the study showed no contribution to the therapeutic armamentar-

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[5] *National Prescription Audit, General Information Report, College Edition,* 1963 (Dedham, Mass: R. A. Gosselin and Company, May, 1964), p. 29.

[6] The Director of Marketing Research of a major pharmaceutical manufacturer confirmed identification of this firm as Eli Lilly and Company.

[7] Not counting various dosage forms, strengths or package sizes, the *1963 PDR* lists approximately 500 products marketed by this firm. *Physicians' Desk Reference* (17th Ed.), (Oradell, N. J.: Medical Economics, 1962), pp. 155-159.

[8] For example, for the five year period from 1959 through 1963 during which this company had sales of about one billion dollars, there were no notices of judgment against this company reported by the Federal Food and Drug Administration. *Notices of Judgment Under the Federal Food, Drug, and Cosmetic Act, Drugs and Devices,* United States Department of Health, Education, and Welfare, Food and Drug Administration, January, 1959, through December, 1963. Judgment notices 5381 through 7260.

[9] During 1963 this company spent $25.2 million (10.4% of sales) on research and development. "Total Sales & Profits in 1963 for 'Top 14' US Pharmaceutical Firms Show Larger Percentage Increases than Diversified Group: Recent Trend Reversed," *Food-Drug-Cosmetic Reports* ("The Pink Sheet"), Vol. 26: No. 16 (April 13, 1964), p. 12.

Of the 16 new chemical entities marketed as pharmaceuticals in the United States in 1963, this company was responsible for two (Oncovin for cancer chemotherapy, and Anhydron, a diuretic). The company marketed ten additional new preparations and four new dosage forms during 1963. "Only 16 New Chemical Entities & 2 New Biologicals Marketed in 1963; Totals for All Categories, Except Duplicates, Smallest Since 1948: De Haen's Count," *Id.,* Vol. 26: No. 3 (January 20, 1964), pp. 20 & 23. Among the "Recent Patents" listed in *Drug and Cosmetic Industry* during 1963, this company was awarded six. "Recent Patents," *Drug and Cosmetic Industry,* Vol. 92: Nos. 1-6 and Vol. 93: Nos. 1-6 (January through December, 1963).

[10] For example, the company employs nearly 1,000 professional service representatives. "Marketing," *Careers with Eli Lilly and Company,* ed., Robert D. Riedle (Indianapolis: Eli Lilly and Company, undated), p. 10.

ium. Most national brands cost the pharmacist less than related physician-owned preparations, and physician-owned preparations cost more than qualitatively equivalent generic drugs.

From the data representing prescription orders dispensed during 1963, the sample mean daily medication cost to physician owners' patients was 74.9¢, while that to patients of a group of control physicians was only 56.4¢. The 1964 means were 69.3¢ and 57.7¢ respectively.

Physician owners of companies which marketed penicillin preparations prescribed penicillin at a rate approximately eight times greater than did control physicians. This higher rate was reflected in both a higher rate of prescribing antibiotics (including penicillins) in general and in a lower rate of prescribing broad spectrum antibiotics and sulfonamides. The data suggest that physician owners over-prescribe products marketed by their company, both by prescribing penicillin products where no antibiotic therapy is indicated and by prescribing penicillin where some other antibiotic is indicated.

The American Medical Association (AMA) has condemned physician ownership of pharmaceutical companies:

> It is unethical for a physician to have a financial interest in a drug repackaging company.
>
> It is unethical for a physician to own stock in a pharmaceutical company which he can control or does control while actively engaged in the practice of medicine.
>
> These practices are contrary to the best interest of the public and the medical profession.[11]

However, as one publication noted: "While the AMA promises that members who won't obey the 1963 ban will be subject to disciplinary measures, so far the prohibition apparently hasn't had much deterrent effect on the doctor-stockholders."[12]

Legal Implications of Ownership for the Physician

If professional organizations are unable to deal effectively with physician ownership of pharmaceutical companies, is there existing legislation which can perform the task?

This question will be dealt with in three contexts. First, whether physician ownership of a pharmaceutical company amounts to unethical conduct which would support an action for suspension or revocation of the physician's license to practice medicine; second, whether ownership constitutes a conspiracy in restraint of trade under

[11] *Opinions and Reports of the Judicial Council, 1964* (Chicago: American Medical Association), p. 51.

[12] Jerry Landauer, "MDs Under Fire," *The Wall Street Journal*, December 17, 1964, p. 21.

Section 1 of the Sherman Act;[13] and third, whether ownership is an unfair method of competition under Section 5 of the Federal Trade Commission Act.[14]

However, before considering these administrative and statutory sanctions, one should consider whether there are constitutional limitations which prevent effective governmental action against physician owners of pharmaceutical companies.

The Fifth and Fourteenth Amendments

The constitutional questions are raised by the due process clauses and the equal protection clause of the fifth and fourteenth amendments:

No person shall be . . . deprived of life, liberty, or property, without due process of law.[15]

No State shall . . . deprive any person of life, liberty, or property, without due process of law; nor deny to any person within its jurisdiction the equal protection of the laws.[16]

It will be noted that the fourteenth amendment applies specifically to action by a state government, while the due process clause of the fifth amendment would apply to action by the federal government. This does not necessarily mean that, since there is no explicit equal protection clause applying to the federal government, the federal government can deny equal protection. To a large extent, the fifth amendment's guarantee of due process implies a guarantee of equal protection.[17]

It is convenient to explore these constitutional questions in terms of goals and affected groups.[18] One goal of a prohibition of physician ownership of pharmaceutical companies would be the prevention of patient exploitation, inferior medical care and foreclosure of competition because of this ownership—an exercise of the police power to protect the health and welfare of the citizenry.

If the group affected includes only those within the prohibition implied in the goal—if governmental action were taken only against physicians who used their ownership with their prescribing privilege

[13] 26 Stat. 209 (1890), 15 U. S. C. § 1 (1964).

[14] 38 Stat. 719 (1914), as amended, 52 Stat. 111 (1938), 15 U. S. C. § 45 (1964).

[15] U. S. Const. amend. V.

[16] U. S. Const. amend. XIV, § 1.

[17] Compare *Brown v. Board of Educ.*, 347 U. S. 483 (1954), in which the equal protection clause of the fourteenth amendment was invoked against state-administered school segregation, with *Bolling v. Sharpe*, 347 U. S. 497 (1954), in which the due process clause of the fifth amendment was invoked against federally-administered school segregation in the District of Columbia.

[18] Joseph Tussman and Jacobus tenBroek, "The Equal Protection of the Laws," *California Law Review*, Vol. 37: No. 3 (September, 1949), p. 341.

to the detriment of their patients and fair competition—no serious constitutional question of equal protection or due process would arise.[19]

However, administrative practicality precludes such a narrow definition of the affected group. Since only certain individuals may prescribe medication, the decision as to what medication and what quantity should be prescribed requires individual judgment by a specially trained person after examination of each patient. Prescribing habits between two physicians may be expected to vary greatly.

Whether a physician's prescribing habits result in exploitation of his patients or inferior medical care, or whether they reflect merely the exercise of reasoned professional judgment, is a question which even an agency possessing expertise, such as a state medical board, may be unable to decide.

The standards of exploitation and inferior medical care are subjective. When viewed on the basis of the prescribing habits of an individual physician, the question ceases to be one of proof and exists merely as a difference between expert opinions. While evidence might indicate exploitation or inferior medical care by an individual physician, the only real proof is the motive, conscious or unconscious, of the physician.

Thus, if physician ownership is detrimental to the physician owner's patients, effective governmental action would necessitate a ban on ownership by all persons having the right to prescribe medication. It is at this point that the affected group now encompasses not only the target group but all prescribers who own or desire to own pharmaceutical companies. The affected group is now what Tussman and tenBroek classify as "overinclusive." These authors note that:

> Such classifications fly squarely in the face of our traditional antipathy to assertions of mass guilt and guilt by association. Guilt, we believe, is individual, and to act otherwise is to deprive the individual of due process of law.[20]

The question then arises as to whether this variation between target and affected groups is such that prescribers are being deprived of property without due process or are being denied the equal protection of the laws.

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[19] "But neither the amendment . . . nor any other amendment, was designed to interfere with the power of the State . . . to prescribe regulations to promote the health, peace, morals, education, and good order of the people. . . . Class legislation, discriminating against some and favoring others, is prohibited, but legislation which, in carrying out a public purpose, is limited in its application, if within the sphere of its operation it affects alike all persons similarly situated, is not within the amendment." *Barbier v. Connally*, 113 U. S. 27, 31-32 (1885).

[20] Tussman and tenBroek, work cited at footnote 18, p. 352.

First, it may be noted that what is involved is an economic right, not a civil or personal right. There are many who feel that, at least as far as the fourteenth amendment is concerned, mere economic rights will find little protection against state action.[21]

Mr. Justice Goldberg, while contending that the amendment still has some vitality in the economic area, recognized and attempted to rationalize its limited application to economic regulation.[22]

The change in the Court's thinking since the 1930s may be seen by comparing two cases closely related to the present problem.

In *Liggett v. Baldridge,* a Pennsylvania statute which, in effect, prohibited the ownership of a pharmacy by anyone not a pharmacist was declared unconstitutional. The majority opinion stated:

> And, unless justified as a valid exercise of the police power, the act assailed must be declared unconstitutional because the enforcement thereof will deprive appellant of its property without due process of law. . . .
>
> The claim, that mere ownership of a drug store by one not a pharmacist bears a reasonable relation to the public health, finally rests upon conjecture, unsupported by anything of substance. This is not enough; and it becomes our duty to declare the act assailed to be unconstitutional as in contravention of the due process clause of the Fourteenth Amendment.[23]

Two decades later the Court was faced with a related problem in *Daniel v. Family Security Life Ins. Co.* In this case the challenged South Carolina statute prohibited undertakers from serving as agents

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[21] "When these [due process] cases were taken together with a companion series in which the Equal Protection Clause was given a similarly permissive scope, there could be little doubt as to the practical result: no claim of substantive economic rights would now be sustained by the Supreme Court." Robert G. McCloskey, "Economic Due Process and the Supreme Court: An Exhumation and Rebuttal," *1962: The Supreme Court Review,* ed., Philip B. Kurland (Chicago: University of Chicago Press, 1962), p. 38. But see, *Morey v. Doud,* 354 U. S. 457 (1957), invalidating an Illinois statute regulating the sale of money orders. The statute was invalidated on equal protection grounds because it specifically exempted persons selling American Express money orders.

[22] "It has been said that the Court since the late 1930's has unduly expanded the meaning of equal protection in cases involving personal rights and unduly contracted the clause in cases involving economic regulation. This is in effect charging the creation of a 'double standard.' I do not believe that this charge can be sustained by reference to the intent of the framers. There is every evidence that the Thirty-ninth Congress intended the Civil War amendments to protect the newly freed slaves, and personal rights in general. There is not even a scintilla of evidence in the debates and reports that the fourteenth amendment was otherwise to abridge or curtail the police power of the state." Arthur J. Goldberg, "Equality and Governmental Action," *New York University Law Review,* Vol. 39: No. 2 (April, 1964), p. 212.

[23] *Liggett v. Baldridge,* 278 U. S. 105, 111, 114 (1928).

for life insurance companies.[24] In deciding that the statute was constitutional the Court said:

> We are not equipped to decide desirability; . . . . The forum for the correction of ill-considered legislation is a responsive legislature.
>
> We cannot say that South Carolina is not entitled to call the funeral insurance business an evil. Nor can we say that the statute has no relation to the elimination of those evils. There our inquiry must stop.[25]

In this area, the Court appears to have shifted from a position that challenged legislation is unconstitutional unless it can be justified to the position that it is constitutional unless there is no possible justification for it.

Both of these cases were decided primarily on the basis of due process; however, the Court appears to view economic regulation with the same permissiveness when equal protection is the issue. "The prohibition of the Equal Protection Clause goes no further than the invidious discrimination."[26]

The suggested prohibition against physician ownership is quite similar to the case before the Court in *Daniel v. Family Security Life Ins. Co.*[27] There undertakers were forbidden to be life insurance agents; here prescribers are forbidden to be owners of pharmaceutical companies. Being a life insurance agent or an owner of a pharmaceutical company is, in itself, lawful. However, when this lawful activity is combined with another activity which may lead to a prohibited result, the constitutionality of governmental restraint appears to be supported by *Daniel v. Family Security.*

In both the funeral insurance situation and the present situation, the affected group is overinclusive. It includes not only those who abuse their combination of activities, but also those whose ethical standards are sufficiently high that they could be entrusted with the combined activities.

It also may be noted that in neither situation is a person being denied the right to make a living. The prohibition merely states that if a person makes a living from two sources, the combination of which may injure the public health or welfare, the person must make a choice between the two.

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[24] The statute apparently was aimed at an insurance company owned primarily by undertakers. The implication was that the proceeds of the life insurance policies sold would be used to pay the insureds' funeral expenses and that the funeral services would be performed by the agent selling the policy.

[25] *Daniel v. Family Security Life Ins. Co.*, 336 U. S. 220, 224 (1949).

[26] *Williamson v. Lee Optical Co.*, 348 U. S. 483, 489 (1955).

[27] 336 U. S. 220 (1949).

One difference between the two situations must be noted. In the funeral insurance situation, there was a specific legislative ban on the combination of activities. In the physician ownership situation, no specific ban exists. In the following discussion the legislative prohibitions apply to unethical conduct by physicians, restraints of trade and unfair methods of competition. In considering these prohibitions, the legislatures likely never thought of physician ownership of pharmaceutical companies as an evil to be corrected by statute.

Ownership as Unethical Conduct

The medical and osteopathic licensing acts of most states provide that the license of a practitioner may be revoked or suspended for unethical conduct (or a term of similar meaning).[28]

Although the AMA has declared physician ownership of pharmaceutical firms to be unethical, it is doubtful that ownership, per se, would amount to unethical conduct within the present interpretation of most licensing acts.

Generally, "unethical conduct" has been held not to embrace a professional code of ethics:

> A physician's license cannot be revoked merely for violating professional ethics . . .[29]

> Grossly immoral or unprofessional conduct excludes the idea that a license may be revoked . . . for a violation of what might be regarded as mere professional ethics.[30]

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[28] The following are examples of such statutes:

The Wisconsin act licensing physicians provides for revocation or suspension of a license for "immoral or unprofessional conduct." Wis. Stat. § 147.20(2) (1963). This term is defined in the statute to include, "engaging in conduct unbecoming a person licensed to practice or detrimental to the best interests of the public." Wis. Stat. § 147.20(1)(g) (1963).

The Pennsylvania act licensing medical doctors provides, "The Board of Medical Education and Licensure may . . . revoke . . . a license . . . upon satisfactory proof of grossly unethical practice . . ." Pa. Stat. Ann. tit. 63, § 410 (1964 Supp.).

The Pennsylvania act licensing osteopathic physicians provides, "The State Board of Osteopathic Examiners may . . . revoke . . . the right to practice osteopathy for . . . unethical conduct." Pa. Stat. Ann. tit. 63, § 271 (1959). In interpreting this statute, the Superior Court rejected the contention that "unethical conduct" had a meaning different from that of the phrase used in the act licensing medical doctors. *State Board of Osteopathic Examiners v. Berberian*, 200 Pa. Super. 533, 190 A. 2d 330 (1963).

The Illinois act licensing physicians provides, "The Department may revoke . . . the license . . . to practice medicine . . . upon . . . engaging in dishonorable, unethical or unprofessional conduct of a character likely to deceive, defraud or harm the public." Ill. Rev. Stat. ch. 19, § 16 a (1963).

[29] *Sapero v. State Bd. of Medical Examiners*, 90 Colo. 568, 577, 11 P. 2d 555, 558 (1932).

[30] *Aiton v. Board of Medical Examiners*, 13 Ariz. 354, 358, 114 Pac 962, 963 (1911), appeal dismissed, 232 U. S. 733 (1913).

We do not wish to be understood as declaring that the phrase "grossly unethical practice" embraces the code of the AMA.[31]

However, in a disbarment proceeding, one court stated: "Unprofessional conduct is that which violates the rules or ethical code of a profession. . . ."[32] But there is doubt that this would be applied to medical ethics.[33]

Courts have explained unethical conduct in the following terms:

"Unprofessional conduct" is conduct which violates those standards of professional behavior which through professional experience have become established, by the consensus of the expert opinion of the members, as reasonably necessary for the protection of the public interest.[34]

The words must have been used in the light of the fundamental purpose of the statutes to regulate the profession in the public interest and they can only be construed as intending to include conduct within their fair purport which either shows that the person guilty of it is intellectually or morally incompetent to practice the profession or has committed an act or acts of a nature likely to jeopardize the interest of the public.[35]

[Grossly unethical practice includes]. . . . "those breaches of trust, confidence and reliance, necessarily attendant upon the intimate relationship of physician and patient, which amount to gross abuses of the standards of professional conduct generally recognized as essential to the proper practice of medicine and surgery"—to which we add—and which are within the scope of the purpose of the Act and within the limits of the police power.[36]

Although some consideration will be given to a professional code of ethics, the more important consideration appears to be whether this conduct is such that a consensus of local medical opinion recognizes, as a commonly accepted standard, that the fact of physician ownership is such that it is necessary for the protection of the public that the practice be disallowed.

In most jurisdictions, it is doubtful that ownership, per se, is grounds for the revocation of a license. A different conclusion is likely if, in each case, either convincing proof of patient exploitation or inferior medical care or both are available. However, such proof is likely to be unobtainable in most cases.

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[31] *State Bd. of Medical Educ. & Licensure v. Ferry,* 63 Dauphin Co. Rep. 243, 255 (1952), aff'd, 172 Pa. Super. 372, 94 A. 2d 121 (1953).

[32] *People ex rel. Chicago Bar Ass'n v. Gorman,* 346 Ill. 432, 444, 178 N. E. 880, 885 (1931).

[33] For example, in contrasting legal ethics with dental ethics, a New York court said, "In the profession of the law, no person can plead ignorance as palliation for professional misconduct. In . . . dentistry . . . professional standards are perhaps less uniform, less well understood, and less rigidly defined." *Cherry v. Board of Regents of the Univ. of the State,* 289 N. Y. 148, 158, 44 N. E. 2d 405, 412 (1942).

[34] *Reyburn v. Minnesota State Bd. of Optometry,* 247 Minn. 520, 523-24, 78 N. W. 2d 351, 355 (1956).

[35] *Sage-Allen Co. v. Wheeler,* 119 Conn. 667, 679, 179 Atl. 195, 200 (1935).

[36] *State Bd. of Medical Educ. & Licensure v. Ferry,* 172 Pa. Super. 372, 378-79, 94 A. 2d 121, 124 (1953).

Ownership as Violating Section 1 of the Sherman Act

This discussion and the following section on unfair methods of competition will consider only federal law. Although state antitrust legislation exists, its efficacy in most jurisdictions is doubtful.[37]

The relevant portion of Section 1 of the Sherman Act states: "Every contract, combination . . ., or conspiracy, in restraint of trade or commerce among the several States . . . is declared to be illegal."[38]

The authority of the federal government to regulate in this area is derived from the commerce clause in Article 1, Section 8 of the Constitution. The relevant portion of this section states: "The Congress shall have Power . . . To regulate Commerce . . . among the several States . . ." Since some physician-owned companies sell their products in only one state, it might be suggested that this is not trade or commerce among the several States. However in interpreting "commerce . . . among the several States," it is important to note the broad coverage the Supreme Court has given this phrase.

The Sherman Act has been held to apply not only to an interstate act which restrains commerce among the states, but also to an intrastate act which affects the flow of such commerce.

> The source of the restraint may be intrastate, as the making of a contract or combination usually is; the application of the restraint may be intrastate, as it often is; but neither matters if the necessary effect is to stifle or restrain commerce among the states. If it is interstate commerce that feels the pinch, it does not matter how local the operation which applies the squeeze.[39]

Thus, even though a physician-owned company does not sell its products outside of a state, the physicians may come within the jurisdiction of the Sherman Act if such ownership affects interstate commerce. If, by conspiring to prescribe their own products, the physician owners restrain the flow of other pharmaceuticals into the state, interstate commerce is affected.

However, not all combinations which restrain trade are illegal. Courts usually[40] apply the "rule of reason" in interpreting the act:

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[37] "State authorities, with few exceptions, have not been active in enforcing their antitrust statutes. State and local governments seem to display more interest in restricting competition than in maintaining it." Mark S. Massel, *Competition and Monopoly: Legal and Economic Issues* (Washington, D. C.: The Brookings Institution, 1962), p. 64.

[38] 26 Stat. 209 (1890), 15 U. S. C. § 1 (1964).

[39] *United States v. Women's Sportswear Mfrs. Ass'n,* 336 U. S. 460, 464 (1949).

[40] Contrasted with the "rule of reason" is the doctrine of per se illegality which may be applied to "agreements or practices which because of their pernicious effect on competition and lack of any redeeming virtues are conclusively presumed to be unreasonable and therefore illegal without elaborate

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The absence of any definition of restraint of trade . . . leaves room for but one conclusion, which is, that it was expressly designed . . . to leave it to be determined by the light of reason, guided by the principles of law and the duty to apply and enforce the public policy embodied in the statute, in every given case whether any particular act or contract was within the contemplation of the statute.[41]

One can conceive of a physician-owned company in which the medication ordered by the physician owners accounts for only a small proportion of the firm's sales. Because of superior efficacy, price or marketing of the products, other physicians in the state prescribe them to the extent that the shipment of pharmaceuticals into the state is reduced appreciably. Obviously, this is not the type of restraint on interstate commerce at which the Sherman Act is aimed. The situation described increases, rather than decreases, effective competition.

However, this is not the typical situation. Rather, the product choice of a physician owner frequently is influenced, not by product superiority, but by his ownership. It also is likely that few non-owners prescribe these products. Under these assumptions, competition is not increased but is at least partially foreclosed. In this situation, physician ownership is a restraint of the type sought to be forbidden by the Sherman Act.

However, the rule of reason does not concern itself only with the nature of the restraint. There are some restraints which, although they may or do have an undesirable effect on interstate commerce, are not violative of the Sherman Act:

Given a restraint of the type forbidden by the Act, though arising in the course of intrastate or local activities, and a showing of actual or threatened effect upon interstate commerce, the vital question becomes whether the effect is sufficiently substantial and adverse to Congress' paramount policy declared in the Act's terms to constitute a forbidden consequence. If so, the restraint must fall. . . .[42]

Thus, inquiry must be directed to determining whether the effect is "sufficiently substantial." To some extent, the courts have con-

(Footnote 40 continued.)
inquiry as to the precise harm they have caused or the business excuse for their use." *Northern Pac. Ry. v. United States,* 356 U. S. 1, 5 (1958). One author notes that the per se doctrine usually is applied only in cases in which the challenged "practice has been before the courts on numerous occasions and has been universally condemned." Jerrold G. VanCise, "The Future of Per Se in Antitrust Law," *Virginia Law Review,* Vol. 50: No. 7 (November, 1964), p. 1172.

[41] *Standard Oil Co. v. United States,* 221 U. S. 1, 63-64 (1911).

[42] *Mandeville Island Farms, Inc. v. American Crystal Sugar Co.,* 334 U. S. 219, 234 (1948).

sidered this question as relating to jurisdiction, acknowledging federal jurisdiction only if the effect on interstate commerce is substantial.[43]

Yet, the Supreme Court has stated that the amount of interstate commerce involved is immaterial: "It is the nature of the restraint and its effect on interstate commerce and not the amount of the commerce which are the tests of violation."[44] In *United States v. Yellow Cab Co.* the Court stated: "Section 1 of the Act outlaws unreasonable restraints on interstate commerce, regardless of the amount of commerce affected."[45] However, the Court then goes on to state: "Hence it is enough if some appreciable part of interstate commerce is the subject of a monopoly, a restraint or a conspiracy."[46]

It is suggested that in rejecting "amount of commerce affected" as a criterion, the Court is merely saying that the dollar value of the commerce is immaterial, while in retaining "appreciable part of interstate commerce" the Act is being limited in application to those situations in which there is a notable, or not insignificant, effect.

Thus, percentage of the market was one of the criteria which the Court applied in *United States v. Columbia Steel Co.:*

> In determining what constitutes unreasonable restraint, we do not think the dollar volume is in itself of compelling significance; we look rather to the percentage of business controlled, the strength of the remaining competition . . . . consumer demands, and other characteristics of the market.[47]

When one considers the "appreciable" or "sufficiently substantial" requirement, it is probable that most physician owners and their companies are not violating the act.[48]

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[43] "The courts have consistently required that in order for federal antitrust jurisdiction to be sustained the effect of an alleged antitrust violation in a local area must be direct and substantial, and not merely inconsequential, remote or fortuitous." *Page v. Work,* 290 F. 2d 323, 332 (9th Cir.), cert. denied, 368 U. S. 875 (1961).

[44] *Apex Hosiery Co. v. Leader,* 310 U. S. 469, 485 (1940).

[45] *United States v. Yellow Cab Co.,* 332 U. S. 218, 225 (1947).

[46] See footnote 45.

[47] *United States v. Columbia Steel Co.,* 334 U. S. 495, 527 (1948).

[48] However, Sec. 4 of the Clayton Act permits any person who is injured in his business by acts forbidden in the antitrust laws to bring a private suit against the offender for treble damages. 38 Stat. 731 (1914), 15 U. S. C. § 15 (1964). The Supreme Court interpreted this as meaning that a private person need only prove injury to himself, not injury to the public. "The district judge . . . refused to permit counsel to try to prove their conspiracy charge, holding that they must first prove . . . that defendants' actions had resulted in an economic injury to the public—an erroneous holding since we have held that the right to recovery of a plaintiff in a treble damage antitrust case does not depend at all on proving an economic injury to the public." In re *McConnell,* 370 U. S. 230, 231 (1962).

Sec. 4 states that a private suit may be brought in a federal district court "without respect to the amount in controversy." Absent this provision, ju-

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In spite of the fact that the Sherman Act is applicable to a "market which is less than nationwide in area,"[49] it is doubtful that an individual physician-owned company would have an appreciable effect on the pharmaceutical market in an area.[50] Although the combined effect of all such companies in a market area may be significant, it is not the companies which are combined in restraint of trade but the physicians in each individual company.

One also may question the legal significance of the "combination". The Supreme Court has never ruled on the question of whether a combination in restraint of trade can exist among the shareholders of a corporation. However, it has found an illegal conspiracy to exist between separate corporations under common ownership.[51]

The sixth circuit found an illegal conspiracy to exist among the officers and agents of one corporation.[52] However, the fifth circuit later held that a conspiracy could not exist between a corporation and its officers, agents or employees: "A corporation cannot conspire with itself any more than a private individual can, and it is the general rule that the acts of the agent are the acts of the corporation."[53]

In the present situation, it is likely that the requirement of a combination is satisfied. One must distinguish between a corporate act and an individual act which benefits the corporation. The former can occur only if the person doing the act does so under the authority of and in the name of the corporation.

(Footnote 48 continued.)
risdiction of a federal district court likely would be limited to cases in which the amount in controversy exceeds $10,000. 28 U. S. C. §§ 1331-32 (1964).

The absence of the necessity of proving public injury or the usual jurisdictional amount may indicate that a private action under Sec. 4 could be used to obviate the "appreciable" or "sufficiently substantial" requirement.

However, it is unlikely that a pharmaceutical company would bring such a private suit against a group of physician owners. The amount of damages suffered would have to be proved with some degree of certainty; however, this amount likely can only be speculated, not quantified.

[49] *United States v. Columbia Steel Co.*, 334 U. S. 495, 519 (1948).

[50] The result might be otherwise if the relevant market was limited to the market for prescription medication prescribed by the physician owners of an individual company. Such a market definition appears appropriate since it is likely that some of the firms do not promote their products to physicians other than those who are owners of the company. However, geographic area and functional interchangeability appear to be the primary factors considered in market definitions under the antitrust laws.

[51] *Timken Roller Bearing Co. v. United States*, 341 U. S. 593 (1951); *Kiefer-Stewart Co. v. Joseph Seagram & Sons*, 340 U. S. 211 (1951); *United States v. Yellow Cab Co.*, 332 U. S. 218 (1947).

[52] *Patterson v. United States*, 222 Fed. 599 (6th Cir.), cert. denied, 238 U. S. 635 (1915).

[53] *Nelson Radio & Supply Co. v. Motorola, Inc.*, 200 F. 2d 911, 914 (5th Cir., 1952), cert. denied, 345 U. S. 925 (1953).

The decision as to what product to prescribe is part of the practice of medicine and not a corporate act. However, when these decisions of the individual physician are made pursuant to a common plan, expressed or implied, among a group of physicians, a combination or conspiracy may exist.

A corporation, since it is a legal entity, cannot combine with itself to restrain trade;[54] however, it can serve as a medium through which a combination in restraint of trade is facilitated.

However, the fact that a restraint of trade must be "material" or "sufficiently substantial" indicates that, under current interpretations of a relevant market, it is unlikely that a violation of Section 1 of the Sherman Act could be shown.

Ownership as Violating Section 5 of the Federal Trade Commission Act

The relevant portion of the Federal Trade Commission Act, as amended, states:

(a) Unfair methods of competition in commerce, and unfair or deceptive acts or practices in commerce are declared unlawful.

(b) Whenever the Commission shall have reason to believe that any . . . person . . . has been or is using any unfair method of competition or deceptive act or practice in commerce, and if it shall appear to the Commission that a proceeding by it in respect thereof would be to the interest of the public, it shall issue . . . a complaint. . . .[55]

The phrase unfair methods of competition has never been defined by the courts:

Debate apparently convinced the sponsors of the legislation that these words [unfair competition], which had a well settled meaning at common law, were too narrow. . . . Undoubtedly the substituted phrase [unfair methods of competition] has a broader meaning but how much broader has not been determined. It belongs to that class of phrases which does not admit of precise definition, but the meaning and application of which must be arrived at by . . . "the gradual process of judicial inclusion and exclusion."[56]

The absence of a comprehensive definition apparently was an intentional omission which allows the phrase to have a flexible meaning:

Congress deemed it better to leave the subject without precise definition, and to have each case determined upon its own facts, owing to the multifarious means by which it is sought to effectuate such schemes.[57]

Originally, the Court interpreted the phrase rather narrowly, holding that it was not "applicable to practices never heretofore regarded

[54] Although it apparently can combine with another corporate entity which it controls.

[55] 38 Stat. 719 (1914), as amended, 52 Stat. 111 (1938), 15 U. S. C. § 45 (1964).

[56] *FTC v. Raladam Co.*, 283 U. S. 643, 648 (1931).

[57] *FTC v. Beech-Nut Packing Co.*, 257 U. S. 441, 453 (1922).

as opposed to good morals . . . or as against public policy because of their dangerous tendency unduly to hinder competition or create monopoly."[58]

To a considerable extent, the other antitrust acts tend to serve as a guide to the interpretation of the Federal Trade Commission Act:

> The "unfair methods of competition" which are condemned by § 5(a) of the Act, are not confined to those that were illegal at common law or that were condemned by the Sherman Act. . . . The Federal Trade Commission Act was designed to supplement and bolster the Sherman Act and Clayton Act . . .—to stop in their incipiency acts and practices which, when full-blown, would violate those Acts . . ., as well as to condemn as "unfair methods of competition" existing violations of them.[59]

> Although all conduct violative of the Sherman Act may likewise come within the unfair trade practice prohibitions of the Trade Commission Act, the converse is not necessarily true. It has long been recognized that there are many unfair methods of competition that do not assume the proportions of Sherman Act violations.[60]

One can conclude that, in its narrowest sense, Section 5 condemns and makes unlawful the type of practices condemned by the Sherman Act, even though the practices do not actually violate the Sherman Act. It has been stated that physician ownership of pharmaceutical companies is likely to result in some restraint of interstate commerce, although the result from an individual company may not meet the "sufficiently substantial" test of Section 1 of the Sherman Act.

However, one may note that the phrase "unfair methods of competition" is probably also limited to a requirement of substantiality. The requirement under Section 5 appears to be that there be substantial injury to competition, although the injury need not be actual, but merely potential:

> It is enough that there be present or potential substantial competition, which is shown by proof, or appears by necessary inference, to have been injured, or to be clearly threatened with injury, to a substantial extent, by the use of the unfair methods complained of.[61]

This case was decided prior to 1938 when Section 5 made unlawful only "unfair methods of competition." This phrase was interpreted to mean that there must be actual or potential injury to competition for the section to be applied. The Wheeler-Lea Amendment in 1938 added the phrase, "and unfair or deceptive acts of practices." This has been interpreted as indicating a Congressional intent that

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[58] *FTC v. Gratz,* 253 U. S. 421, 427 (1920).

[59] *FTC v. Motion Picture Advertising Serv. Co.,* 344 U. S. 392, 394-95 (1953).

[60] *FTC v. Cement Institute,* 333 U. S. 683, 694 (1948).

[61] *FTC v. Raladam Co.,* 283 U. S. 643, 651 (1931).

actual or potential injury either to competition or to the public would make the act applicable:

> The failure to mention competition in the later phrase shows a legislative intent to remove the procedural requirement set up in the *Raladam* case and the Commission can now center its attention on the direct protection of the consumer where formerly it could protect him only indirectly through the protection of the competitor.[62]

Thus one could suggest that, in addition to actual or potential injury to competition, physician ownership also may be unfair and deceptive to the consumer. A physician should treat his patients to the best of his ability, unhampered by any desire to supplement his professional income through his right to prescribe. A physician's failure to do so is grossly unfair to the patient, is deceptive unless the patient knows of the physician's interest, and may otherwise lead to injury of the patient.

It is suggested that physician ownership of pharmaceutical companies may be one of the "multivarious means"[63] of unfair and deceptive methods and practices at which Section 5 was aimed. Yet, ownership, in and of itself, merely suggests the possibility of the result. It raises a suspicion, but fails to give proof.

It is doubtful, therefore, that the practice is within the jurisdiction of the Federal Trade Commission (FTC), at least as to companies which do not actually engage in interstate commerce. Unlike the rather broad interpretation given to the Sherman Act through the "affectation doctrine," the phrase "in commerce" in Section 5 has been interpreted as requiring that the method or practice be used in interstate commerce:

> This case presents the narrow question of what Congress did, not what it could do. And we merely hold that to read "unfair methods of competition in [interstate] commerce" as though it meant "unfair methods of competition in any way affecting interstate commerce," requires, in view of all the relevant considerations, much clearer manifestation of intention than Congress has furnished.[64]

Thus, even if physician ownership was an unfair method of competition or an unfair or deceptive practice, the FTC would be able to deal with it only to the extent that the methods or practices are "in commerce."

"Medical Restraint of Trade Act" (S. 2568)

An attempt is being made to correct this wrong without a remedy. Senator Philip A. Hart (D. Mich.) has introduced in the United

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[62] *Pep Boys—Manny, Moe & Jack, Inc. v. FTC*, 122 F. 2d 158, 161 (3d Cir. 1941).

[63] *FTC v. Beech-Nut Packing Co.*, 257 U. S. 441, 453 (1922).

[64] *FTC v. Bunte Bros.*, 312 U. S. 349, 355 (1941).

States Senate the "Medical Restraint of Trade Act."[65] The proposed bill would "strengthen the antitrust law by prohibiting . . . receipt by persons licensed to . . . practice medicine, of profit . . . in connection with the supplying to patients . . . products prescribed by such licensees."[66] In addition to physician-owned pharmaceutical companies, the bill also attacks a corollary problem, ownership of pharmacies by physicians.

In introducing the bill, the Senator noted: "I turn to the Congress as a court of last resort. The Department of Justice and the FTC have told me they cannot move in this area. The AMA . . . has consistently turned down efforts . . . which might have reversed the trend toward more and more doctor-ownership."[67]

The proposed bill represents a recognition of the public health and competitive dangers caused by physician ownership. The principle of the bill is one which deserves the support of all who are interested in maintaining standards of health care at the highest possible level and insuring fair competition in the distribution of pharmaceuticals.

However, S. 2568 as introduced contains wording which may frustrate its admirable purpose. Essentially, the bill attempts to make it unlawful for a "licensee" to profit from the drugs he prescribes.

Section 3(b) of the Act defines "licensee" as "any person licensed by any State . . . to engage in the practice of medicine." Although "practice of medicine" may generally be thought of as encompassing all health practitioners who are licensed to prescribe, the qualifying phrase "licensed by any State" appears to limit the scope of the Act to the "practice of medicine as defined by the licensing State."

The danger here may be demonstrated by a consideration of Pennsylvania's statutory scheme. In Pennsylvania, the functions of a medical doctor and an osteopathic physician are practically identical. Medical doctors hold the degree of doctor of medicine while osteopathic physicians hold the degree of doctor of osteopathy. Both groups have similar legal rights to treat the sick, including the right to prescribe medication. However, the licensing statutes for these groups indicate that the "practice of medicine" refers only to medical doctors. Consider the following provisions from the Pennsylvania act licensing medical doctors:

> This act shall be known . . . as the "Medical Practice Act." . . . It shall not be lawful for any person . . . to engage in the practice of medicine . . . unless he . . . has first . . . received a certificate of licensure from the board.[68]

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[65] S. 2568 (89th Cong., 1st Sess.).

[66] See footnote 65.

[67] "Floor Remarks by Senator Philip A. Hart (D. Mich.) on Introducing Bill Prohibiting Doctors from Profiting from Sale of Products." mimeo., pp. 4-5.

[68] Pa. Stat. Ann., tit. 63, § 401a (1964 Supp.).

The provisions of this act shall not apply either directly or indirectly . . . to affect the practice of osteopathy.[69]

On the other hand, the Pennsylvania act licensing osteopathic physicians contains the following provisions:

The phrase "osteopathy and surgery" . . . means a complete school of the healing art . . . practiced . . . by physicians and surgeons possessing the degree of doctor of osteopathy.[70]

Nothing contained in this act shall be construed as affecting the so-called practice of medicine.[71]

Thus as far as Pennsylvania is concerned,[72] S. 2568 likely would not apply to osteopathic physicians, although the need for public protection is just as great whether the physician owner is an osteopath or a medical doctor.

It is suggested that the phrase "to engage in the practice of medicine" in section 3(b) of S. 2568 be replaced by the phrase, "to prescribe a drug or device." This would bring within the act all those who might misuse their right to prescribe for private gain.

Even more importantly, it is highly questionable whether the Act in its present form makes it unlawful for a physician to profit from the prescriptions he orders. The relevant portion of the act makes it unlawful, "for any licensee to accept . . . any profit on or resulting from the sale, rental, furnishing, or supplying by such licensee of any drug or device . . ."[73]

However, when a physician prescribes a product, he is not making a rental or sale of such product. The sale is made by the pharmacist who dispenses the prescription. Nor is it likely that a convincing argument could be made that the physician is "furnishing or supplying" the drug. The physician is merely furnishing a prescription order which permits his patient to obtain the medication in a pharmacy.

There appears to be little merit to the theory that since the prescription order authorizes the pharmacist to dispense the medication, agency doctrines could be invoked to hold that the pharmacist

[69] Pa. Stat. Ann., tit. 63, § 411 (1964 Supp.).

[70] Pa. Stat. Ann. tit. 63, § 266 (1959).

[71] Pa. Stat. Ann. tit. 63, § 270 (1964 Supp.).

[72] In some states where osteopathy is recognized, the statute includes osteopathy in the practice of medicine. For example, "Applicants for licensure to practice medicine and surgery shall present to the board a diploma from a reputable medical or osteopathic college . . . ." Wis. Stat. Ann. § 147.15 (1965 Supp.).

[73] S. 2568 § 4(a) (89th Cong., 1st Sess.). The act excludes providing a drug or device in an emergency and the administration of a unit dose of a drug to a patient.

is the physician's agent. Under this theory the physician would have to be held to have furnished the drug through his agent, the pharmacist.

Yet, if a pharmacist negligently errs in dispensing a prescription, liability for the error rests on the pharmacist, not the prescriber. An agent owes certain duties to his principal; yet a pharmacist who dispenses medication owes no legal duty to the prescriber.

It is suggested that in addition to making it unlawful for a physician to accept profit from the "sale, rental, furnishing, or supplying" of a drug, the section be amended to include profit from prescribing a drug.

In summary, physician ownership of pharmaceutical companies creates dangers to the public health and fair competition in the pharmaceutical industry. Organized medicine has not been able to prevent this practice. Existing legislation appears to be impotent in this area.

The Medical Restraint of Trade Act is intended to close this gap —to prevent a minority of prescribers from exploiting their patients and hindering fair competition. With minor changes in wording, this proposed act can do much to prevent these abuses. **[The End]**

CONTRACT FOR FIELD ACTIVITIES STUDY AWARDED

Booz, Allen, and Hamilton, Inc. has been awarded a contract to perform a survey of FDA field activities, goals, objectives, organization and operations. More effective methods of regulating plant, process, and product inspection throughout the nation are expected to be found as a result of this survey. The results are also expected to increase consumer assurance that they are getting wholesome foods and safe, effective drugs.

FDA RECEIVES OBJECTIONS TO VITAMIN REGULATIONS

More than 300 objections to the regulations establishing new requirements for special diet foods and diet supplements have been received by the Food and Drug Administration. The regulations are based in part on an adaptation of Recommended Dietary Allowances established by the Food and Nutrition Board. The FDA will not determine whether public hearings should be set until it has evaluated supplementary information to the objections.

Rendezvous with Destiny

By JAMES F. HOGE

The Following Article Was Presented at the Second General Session of the 85th Annual Meeting of the Proprietary Association in White Sulphur Springs, West Virginia, on May 18, 1966. Mr. Hoge Is General Counsel of the Proprietary Association and a Member of the New York Bar.

THE DRUG INDUSTRY THIS YEAR has come to what may be its rendezvous with destiny. Its future is being cast in circumstances of scientific, political and social change; and also—as pertaining particularly to it—in circumstances of unfortunate events and unsympathetic attitudes. New laws have been enacted and more are proposed—laws designed to change the industry's relationship to the public and to the government. Saying that he was "aware of pressures to bring the drug industry under tighter federal control," Commissioner Goddard—who may be the catalyst of our destiny—last month told the Pharmaceutical Manufacturers' Association (PMA):

> There is a real danger that the pharmaceutical industry as you and I know it today may be altered significantly, altered beyond your present fears, and altered beyond recall.

The Commissioner related this danger to industrial irresponsibility. He gave that as his diagnosis of a disease which can undermine an industry, and he based his diagnosis on an enumeration of symptoms, including poorly prepared Investigational New Drugs (IND's) and New Drug Applications (NDA's), and improper labeling and advertising.

Taking that as a starting point, let me say that my long experience in this field does not support a charge of irresponsibility, or any comparable generalization. But it does impel me to say that the Commissioner is ever so right in associating these symptoms with the dangers of tighter federal control.

The Commissioner's remarks were directed specifically to the pharmaceutical part of the industry. But the proprietary part is not as separable as in the past, and time and events will make it even less so in its relation to public interest and control.

New Bills Affecting Proprietary Drugs

The 1962 Amendments will become increasingly applicable to proprietary drugs. Dr. Joseph F. Sadusk, Jr., recently retired Medical Director of the Food and Drug Administration (FDA), in a speech on April 19 to the American College of Physicians, said that full implementation of those amendments may take five years or more. Without waiting for that fulfillment, further amendments are proposed in bills recently introduced in both Senate and House which would apply directly to proprietary products and put them under controls comparable in practical extent to those now applicable to prescription drugs.

There are three of these bills, introduced in March after the President's "consumer message" and related to it. One of them, H. R. 13884, pertains to federal and state cooperation in the enforcement of federal, state and local laws. Another, H. R. 13885, would be called the "Drug Safety Act of 1966." As to proprietary drugs, it would amend existing law so substantially as to swallow up and replace nearly all other labeling requirements. The third, H. R. 13886, pertains primarily to the protection of children, dealing specifically with aspirin products and hazardous substances.

The "evil genius" of these bills is that they are embodied in "administrative law." That is a euphemism for executive government whereby the rules are both made and enforced by the executive department, and judicial review is so circumscribed as to be factually ineffectual.

So, H. R. 13885 would amend Section 502(f) of the existing law to empower the FDA to dictate the composition, manner and form of directions and warnings. Since 1938, the law has required adequate directions and adequate warnings. It was a highly important provision at the time of enactment, and is now. Presently, the adequacy of the directions and warnings is the responsibility of the manufacturer which he must meet at the risk of encountering the various sanctions of the law. Under this bill, directions and warnings would be shaped by regulations: warnings against (a) use in conditions or by children where its use may be dangerous to health, (b) unsafe dosage or methods of use, (c) risk of accidental injury.

The labeling would also include instructions for first aid treatment and such other information relating to "side effects, contra-indications, effectiveness and other matters" as FDA may require. And, remember, the proposed amendment specifically requires that the

labeling of these matters must be "in all respects in conformity" with such regulations as the FDA finds "necessary for the safe and effective use of drugs or of the specific drug or class involved."

The law now requires batch-by-batch certification of insulin and antibiotic drugs. This bill would extend that to *any drug or class of drugs* when the FDA concludes that that is necessary for the protection of the public health.

The present law requires the keeping of records and the making of reports with respect to new drugs. The new bill would authorize the FDA to extend this to all drugs. The records and reports would relate to clinical experience and other data or information received by the manufacturer bearing on the safety or effectiveness of the drug, or on whether it is adulterated or misbranded, as the FDA—by general or special regulation—may specify.

With respect to sampling, the law would forbid the use of the mails for any drug sample—prescription or otherwise—except upon prior written request of a licensed practitioner and, would prohibit door-to-door distribution of any sample drug (whether or not prescription) which has been in interstate commerce, or which is a stimulant or depressant drug. This, apparently, would be an outright prohibition of the sampling of proprietary drugs. The proposal has been engendered by the gradually developing interest of federal and local governments and by professional and consumer attitudes.

Commissioner Goddard has described unsolicited drug samples as a "questionable advertising practice." It is—I suggest to you—a practice that should be carefully examined by manufacturers of proprietary medicines. If legislation is needed—and many think it is—then manufacturers should contribute their experience and effort toward developing it.

The third bill, H. R. 13886, is related primarily to the protection of children. It is described as the "Child Safety Act of 1966." Under it, a drug would be adulterated if it is an aspirin or other form of salicylic acid preparation in a dosage form intended for use by children, and packaged in a retail container, if the aggregate quantity of the drug in such container exceeds a limit which has been established by regulations as being likely—if ingested at one time by a child of tender age—to cause death or serious injury.

This is not the first proposal with respect to aspirin for children. Senator McGovern introduced a bill on August 12, 1965, (S. 2404), comparable to the new one, and Mrs. Sullivan has introduced bills,

the latest being H. R. 1235 on January 4, 1965, which would forbid the flavoring of aspirin products. But even yet, it has not been established that legislation of this sort will accomplish the desired end. Here, again, we should participate in a thorough examination of the problem in the hope that a solution may be reached that is effective and that does not add unnecessarily to the mounting government regulation.

Any other drug in a retail container (including one to be dispensed on prescription) "whether or not such drug is intended for children," which the regulations require to be secured by a safety closure, would be adulterated unless its container is secured in conformity with such regulation.

A drug alleged to be in violation of these regulations would expose the manufacturer to criminal penalties and the drug to multiple seizures. The drug would be deemed "adulterated," and the law's limitation upon the number of seizures applies only in cases of misbranding. This should be related to one of the 1962 Amendments. There, too, the adulteration section was amended to provide that a drug—no matter how pure—would, nevertheless, be deemed to be adulterated if the methods, facilities and controls pertaining to its manufacture are not operated "in conformity with current good manufacturing practice." The 1962 Amendments did not provide—as had been proposed—that these practices were to be determined by regulations, but—in practice—they are.

Potential for Increased Control of Labeling

These new proposals must be further related to the 1962 Amendments with respect to effectiveness. A drug is now subject to the new drug provisions if it is not "generally recognized" by qualified experts as being effective under the conditions prescribed in its labeling.

For many years, proprietary drugs have been misbranded if they were not effective for their labeled claims. But, before this, the government has had the burden of proof, and has had to take the initiative to show by a preponderance of evidence that the article is not effective as represented. Under new drug control, the burden is on the manufacturer. He must show by "substantial evidence" that his product will be effective as represented. His labeling must be approved before—not after—introduction.

Here lies the potential for enlarged labeling and advertising controls. FDA control of prescription advertising came expressly with the 1962 Amendments. Control of proprietary advertising may

not come directly. It may come as a concomitant of other controls. New drug applications for proprietaries will not be approved unless satisfactory labeling is submitted. And, if the labeling as later used is found by FDA to be false or misleading in any particular, the approval, previously granted, may be withdrawn. In these circumstances, we may ponder whether advertising claims which are inconsistent with those in the approved labeling would long survive.

The destiny of the proprietary part of the industry is inseparably related to the integrity of its advertising. The Commissioner has already stated his apprehension about this. In an address at the end of April to the American Association of Advertising Agencies, he said: "We cannot tolerate false claims in advertising of drugs." And he warned the advertising community to sell products with facts or else risk tighter government controls.

It will become accepted, I think, that safe and effective home remedies will be essential to any scheme of government medicine. It is already accepted that there are not sufficient physicians and hospitals for the treatment of all the minor ailments of a population that is constantly expanding in its numbers and in its needs. If this be so, then I think it must follow that the government interest in proprietary medicines will also expand; that the requirements as to the safety and effectiveness of them will enlarge and that the interest of the public will increase and will relate to their manufacture, sale, advertisement and use. Our concern must be with the kind and tone of these requirements and interests.

Conclusion

We dare not be insensitive to the exigencies of a revolutionary time, and we know something of its complexities. We know that we are on an ascending scale of federal supervision. Over the span of three decades the old confines of interstate commerce have been left behind and federal authority has taken on the limitless boundaries of the welfare state. We should note how imperceptibly and with what little resistance the changeover has been accomplished.

When, at first, this industry was confronted with federal regulation, the move from local control was slow, and, at times, arduous. It was sixty years ago next month—June 30, 1906—when Congress enacted the Pure Food and Drugs Act. It was hardly an intimation of what was to come. On June 6, 1933, S. 1944—generally referred to as the "Tugwell Bill"—was introduced. It was a design for thorough-

going federal administrative control. After five years of Congressional debate, the bill was reshaped to conform to the concept of interstate commerce and to define and delimit the authority of the administrator.

In 1962, under the pressures of the Kefauver investigation and the thalidomide tragedy, amendments were quickly adopted, and even yet we do not know the full scope and impact of them. Add to them the proposed new legislation, build in the uncertainties of all, enlarge administrative regulation still more, and executive control will come full cycle—all and more than proposed in the "Tugwell Bill" of 1933—and transform the drug business into a federally administered industry.

Is that the destiny with which we now rendezvous? Let us understand the anatomy of it. There are the legislative proposals. The patent system is under strong attack. The trademark system must contend with outright government stricture. Pricing systems are under legislative, judicial and consumer inquiry. Advertising is suspect, and unfortunately not without reason. Legislative proposals at city, state and federal levels come constantly in numbers beyond count and in substance beyond analysis. And the industry's public image is distorted by an unrelenting press.

Is this the anatomy of our destiny, or of a challenge to greatness? Hopefully, the latter! In that case, the industry needs the best in heart and mind and hand of which it is possessed. It needs discipline within that it may resist it without. Let me quote to you the significant inscription which appears on the building which houses Columbia University's Graduate School of Business:

A great society is a society in which its men of business think greatly of their functions[1]

I remind you that when, on June 7, 1935, manufacturers endorsed the Food, Drug and Cosmetic Act, which, after much study and Congressional action, had then passed the Senate, the men of business in this Association thought greatly of their industrial, social and political functions, and acted accordingly. Again—and more so than ever before—the time is at hand when the men of business in this industry must think greatly of their functions, or else face the danger, described by Commissioner Goddard, that the industry may be altered beyond present fears and beyond recall. **[The End]**

[1] Alfred North Whitehead.

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