

# AN APPRAISAL OF THE NEW DRUG AND COSMETIC LEGISLATION FROM THE VIEWPOINT OF THOSE INDUSTRIES

JAMES F. HOGG\*

Conjecture, rather than appraisal, would be the better title. The new legislation consists of the Federal Food, Drug, and Cosmetic Act,<sup>1</sup> and amendments to the Federal Trade Commission Act.<sup>2</sup> The latter concern the false advertisement of foods, drugs, devices, and cosmetics. They are already in effect. The former concerns the adulteration and misbranding of these products. Except for a few sections, it will not be effective until June 25, 1939. It is by far the more innovative and comprehensive of the two.

Interpretative regulations are just now published.<sup>3</sup> Hearings on substantive regulations—those which are affirmative in character and have the effect of law—have not so much as begun. Appraisal at this time, therefore, rests much on conjecture and, if one is affected, on faith. Unorthodox as that may seem, faith is not a bad word for it. The new legislation is right much the fruit of faith. The late Senator Copeland, a physician, made it a major effort of his public career. Walter G. Campbell, Chief of the Food and Drug Administration, championed it for years.<sup>4</sup> And industry—or a large part of it—though raked and mucked in the fashion of the times, foresaw the practical worth of it to producer and consumer. And, of course, the faith did not stop abruptly at the enactment. Administration and compliance are necessarily to be the confirmation of it. They are still in the future. Neither can be accomplished without an interlude of confusion and disturbance to both administrators and those subject to the law. Patience and tolerance must be more than ideals on the part of both. They must be present realities.

Regulation by law is a new thing to the cosmetic industry. Except as its advertising has been supervised by the Federal Trade Commission as a method of competi-

\* LL.B., 1922, Wake Forest College. Member of the New York Bar. Member of the firm of Rogers, Ramsay & Hogg, New York City, counsel for The Proprietary Association. Author of articles on food and drug legislation and other problems of trade regulation.

<sup>1</sup> 52 STAT. 1040 (1938), 21 U. S. C. A. §§301-392 (Supp. 1938) (The Copeland Act).

<sup>2</sup> 52 STAT. 111 (1938), 15 U. S. C. A. c. 2 (Supp. 1938) (The Wheeler-Lea Act).

<sup>3</sup> 3 FED. REG. 3161-3171 (Dec. 28, 1938).

<sup>4</sup> Senator Copeland and Mr. Campbell advocated the inclusion of provisions against false advertisements in the Food, Drug, and Cosmetic Act.

tion, and except for three state statutes<sup>5</sup> recently enacted, it has not known governmental supervision. It, therefore, comes virginal to the overlordship of government. It was in infancy when the existing law<sup>6</sup> was enacted. It reached maturity only in modern times and perhaps under the impetus of modern advertising.

The drug industry, on the other hand, is not unused to control. The Federal Trade Commission has been the monitor of its advertising for a number of years.<sup>7</sup> Its products have been subject to the Federal Food and Drugs Act since 1906. Laws corresponding to the federal were enacted in forty-seven states in the years following 1906. Pharmacy laws, narcotic acts, laws regulating the sale of barbiturics, marihuana, and poisons, and many others in the different states, and ordinances in the cities, have applied in numerous particulars to the supervision of the drug business. A little more seasoned is the drug industry, but so vast is the potential sweep of the new legislation that it, too, stands before an unexplored terrain.

#### THE ENLARGED SCOPE

Advertising heretofore came under the jurisdiction of the Federal Trade Commission as a method of competition. False advertisements were construed to constitute unfair methods. The Commission was required to prove the existence of competition—that the advertising was a “method of competition in commerce.”<sup>8</sup> The new legislation removes that requirement. Sections were added to the Federal Trade Commission Act dealing specifically with advertisements of foods, drugs, devices, and cosmetics, making it unlawful to disseminate any false advertisement pertaining to such products.

Definitions of foods, drugs, devices, and cosmetics, and of false advertisements were included, and new procedures and penalties provided.<sup>9</sup> In its definitions, it coincides with the Federal Food, Drug, and Cosmetic Act. With the passage of time, the administrative policy and judicial interpretation pertaining to the one will, quite probably, be applied, insofar as applicable, to the other. Assuming that, it is better to conserve the space allotted to this paper by passing on to the dominant piece of the new legislation—the Federal Food, Drug, and Cosmetic Act.

<sup>5</sup> Louisiana, Acts 1936, act no. 142; North Dakota, Laws 1937, c. 136; and Virginia, Acts 1938, c. 414. There is a registration statute in Maine, Laws 1935, c. 109, but it provides little supervision.

<sup>6</sup> The Federal Food and Drugs Act, of June 30, 1906, as amended, 21 U. S. C. c. 1.

<sup>7</sup> The annual report of the Federal Trade Commission for 1938 shows that for the four-year period July 1, 1934 to June 30, 1938, under the limited powers before the Wheeler-Lea amendments, the Commission examined 2,069,306 newspaper, magazine, and radio advertisements. During the last year, it reviewed 490,670 copies of commercial radio broadcast continuities amounting to 1,069,944 pages of typewritten script. An average of 2,905 pages of radio script was read each working day. Drugs, drug products, drug component preparations, and alleged remedies made up 30.5% of this work; cosmetics and toiletries 6.1%; and health devices 5.3%.

<sup>8</sup> Federal Trade Commission v. *Raladam Co.*, 283 U. S. 643 (1931).

<sup>9</sup> The Commission proceeds by cease and desist procedure, by application to the federal courts for injunction, and by criminal prosecution in cases of false advertisements disseminated with intent to defraud or mislead and with respect to false advertisements where the use of the commodity as advertised may result in injury to health. In addition, the Commission's order to cease and desist now becomes final after the lapse of a specified time, and violation of a final order subjects the violator to a civil penalty not to exceed \$5,000. The Commission also proceeds informally, by stipulation.

It exceeds the scope of the old law by including therapeutic devices and cosmetics. It broadens the definition of the term "drug" to include all "articles" used in the treatment or prevention of disease.<sup>10</sup> It authorizes restraint of violations by injunction.<sup>11</sup> It has greatly extended the definitions of adulteration and misbranding. The burden of proving fraudulent intent in actions against false therapeutic claims has been removed. Penalties for violation have been substantially increased. Controls have been provided for new and potent drugs. Wide administrative authority has been granted for the formulation of regulations of exemptive, substantive,<sup>12</sup> and procedural nature.

Where the old law was almost entirely negative in its application to drugs, the new law is distinctly affirmative. That is, the old law required almost nothing in the way of affirmative action by the makers and distributors of drugs.<sup>13</sup> The maker of a drug was enjoined only from "false or misleading" statements with respect to the identity, description, or origin of the article, and from any statement that was "false and fraudulent" with respect to the curative or therapeutic effect of it.<sup>14</sup>

The new law moves entirely away from the old definitions and prohibitions. For the phrase "false and fraudulent," the phrase "false or misleading" is substituted not only with respect to identity, description, and origin, but with respect to curative or remedial claims. The law applies to materials which are intended for use in the manufacture of drugs, medicinal preparations, and cosmetics, whereas the old did not.

The fact that positive statements with respect to an article and its uses should, for the complete protection of the public, appear upon a label was not recognized by the old law. Silence brought immunity. The new law commands as well as restrains. It requires that the name and address of a manufacturer must appear upon the label; that a statement of the quantity of the contents must be made; that the active ingredients must be disclosed; that the presence of certain narcotic drugs must be declared, together with the quantities and a warning of habit-forming possibilities;

<sup>10</sup> Gauze bandages have been held to be "drugs" within the definition of the old law. *U. S. v. 48 Dozen Packages of Gauze Bandage*, 94 F. (2d) 641; (C. C. A. 2d, 1938). Catgut ligatures have been held to be "drugs" and the Administration has made extensive seizures of rubber prophylactics as "adulterated" and misbranded "drugs." *Notices of Judgment*, November and December, 1938.

<sup>11</sup> The prompt and drastic effect with which this new procedure may be applied should greatly strengthen enforcement—and should not be overlooked by industry.

<sup>12</sup> Section 701(e) authorizes regulations to prescribe appropriate tests or methods of assay for official drugs when those in the compendiums are inadequate, to determine habit-forming derivatives (which must be declared with a warning) of narcotic drugs, to determine drugs liable to deterioration, and to prescribe the manner of packaging and a label statement of precautions therefor, and to certify coal tar colors which are harmless and suitable for use in drugs and cosmetics.

"Such regulations are not merely interpretive. They have the force and effect of law and must be observed. Their violation may result in the imposition of criminal penalties, or in the confiscation of the goods involved if shipped in interstate commerce, or in their exclusion from the country if imported." *H. R. REP. NO. 2139*, 75th Cong., 3d Sess. (1938) 10.

<sup>13</sup> The only affirmative showing was the requirement that the label declare the presence and quantity of any alcohol, morphine, opium, cocaine, heroine, alpha or beta eucaine, chloroform, cannabis indica, chloral hydrate, or acetanilid, or any derivative or preparation of any such substances.

<sup>14</sup> The *Sherley Amendment*, adopted after the Supreme Court's decision in *U. S. v. Johnson*, 221 U. S. 488 (1911), holding that the words "false or misleading" in §8 did not apply to statements other than those respecting identity, description, and origin.

that there must be adequate directions for use and adequate warnings against use in conditions in which its use might be dangerous; that if it is a drug liable to deterioration, it must be packaged and labeled as required by regulations.

#### PROBLEMS OF COMPLIANCE

The problems confronting the industries as they endeavor to comply with the new legislation, except for those of a mechanical nature, are really problems of interpretation. As such, they are, at the same time, problems confronting the administrators.

Where the viewpoints of the administrators differ essentially from the viewpoints of the industries in the approach to these problems, the ultimate solution, of course, must await judicial decision. So early upon the enactment of the law, it is difficult even for viewpoints to take definite form. And, for conflicting viewpoints to be adjusted through judicial interpretation will be, as with most comprehensive laws, a continuing matter and in no case a development of much consequence for a few years.

#### *Application to Local Transactions*

The language of the Act and announcements by the Administration raise questions of territorial jurisdiction which in the end must be settled by judicial decision on points of constitutional law. The amendments to the Federal Trade Commission Act make it unlawful to disseminate a false advertisement by the mails, or in commerce by any means, for the purpose of inducing the purchase of these commodities. They also make it unlawful to disseminate a false advertisement by any means (whether in commerce or not) for the purpose of inducing the purchase *in commerce* of commodities. Thus, the Act would seem to be applicable to local advertisements by a retailer of commodities which he receives in the course of interstate commerce.

Section 301(c) of the Federal Food, Drug, and Cosmetic Act makes it unlawful to receive in interstate commerce, and deliver, any food, drug, device, or cosmetic that is adulterated or misbranded. The old law made it unlawful to receive and deliver *in original unbroken packages*.

Section 301(h) makes it unlawful to give a guaranty which is false, and the only reason so far advanced for it is that it will be a means of reaching a manufacturer who sells to a distributor in an intrastate transaction. Otherwise, there is no occasion for making the giving of a false guaranty an offense. If a guaranty (given, perhaps, in good faith) turns out to be false, it will be because the article covered by it has been found later to be adulterated or misbranded, and punishment will be on that score. Making the giving of a guaranty which turns out to be false also an offense is simply repetitious and unnecessarily punitive.

Section 304(a) authorizes the seizure of articles which are adulterated or misbranded or which are contraband under sections 404 or 505 while they are in interstate commerce *or at any time thereafter*. The old law authorized seizure of articles while in interstate commerce or, which, having been transported in such commerce,

remained "unloaded, unsold, or in original unbroken packages." The Supreme Court held that, under that language, the federal authority extended into retail stores and that the provision was constitutionally valid.<sup>15</sup> But the new Act goes an unlimited distance further and, if taken literally, would permit the seizure of articles at any time and at any place provided simply that at one time they had been in interstate commerce.

Section 501(a) defines a drug as adulterated if it has been prepared, packed, or held under insanitary conditions. Section 601 makes the same requirement as to cosmetics. These provisions rest on the well-established power of Congress to close the channels of interstate commerce. The basic provisions of the whole Act rest on that; *i.e.*, interstate transportation of adulterated and misbranded articles is prohibited. Section 704 authorizes factory inspection.

Regulations explain that the law's definition of labeling includes all written, printed or graphic matter accompanying an article at any time *after* shipment in interstate commerce. This interpretation contemplates Section 301(k) which prohibits the alteration of any part of the labeling of, "or the doing of any other act with respect to," an article if the act is done while the article is held for sale *after* shipment in interstate commerce and results in the article being misbranded.

Regulations under Section 502(f) (which requires adequate directions for use) exempt potent drugs which are labeled with a warning statement that the drug is to be used only by or on the prescription of a physician, dentist, or veterinarian, but withdraw the exemption when the article is offered or sold (at retail) for any other use. That does not mean that the sale by a dealer of the drug for any use other than by or on the prescription of a physician makes the manufacturer liable. The regulation states that the withdrawal of the exemption is not retroactive; that "the causing by any person of such exemption so to expire shall be considered to be an act of misbranding for which such person shall be liable."

That would apply, for instance, to the dealer and fix the liability upon him, under Section 301(k). Just how applicable that section may be is another question. Branding is a matter of labeling. Perhaps if a retailer sells such drug to the laity, without a prescription, he has committed an act which results in the article being misbranded. At any rate, that is the proposition the government would have to sustain. The position would be, presumably, that the law declares a drug to be misbranded unless its labeling contains "adequate directions for use"; that the article in question was relieved from that requirement solely by exemption authorized by the Act; that the immunity is conditioned upon the terms of the exemption and continues only so long as the terms are complied with.

This regulation does, however, condition the exemption on the manufacturer's delivering the article "for use exclusively by, or on the prescription of, physicians, dentists, or veterinarians." And informal statements by officials of the Administration have implied that the manufacturer is under obligation to exercise some control over

<sup>15</sup> *McDermott v. Wisconsin*, 228 U. S. 115 (1913).

the sale of his product in this respect. Certainly the regulation contemplates that the manufacturer in labeling so as to take advantage of the exemption should do so in good faith and in the circumstances of sale of the article and in his announcements to the trade should make it clear that the article is being sold, as the label declares, for use only by or on the prescription of a physician. It certainly means that the manufacturer must not be a party to any subterfuge or scheme whereby the article enjoys immunity as it passes through interstate commerce but then becomes readily available for purchase by the laity.<sup>16</sup>

Regulations at this point, and at other places in the law where exemptions are provided, have wide range. The law does not state the exemption. It authorizes the formulation of the exemptions by regulations. Therefore, unless contrary to law, arbitrary, or unreasonable, the terms of the exemptions can be prescribed in the discretion of the Administration.

### *Official Drugs*

A drug purporting to be one recognized in the United States Pharmacopoeia, the Homeopathic Pharmacopoeia, or the National Formulary must conform to the standards of strength, quality, and purity laid down in those publications. If it does not, then its variation must be noted not for the purpose of ascertaining, as at present, whether its own standard is indicated on the label, but whether the difference between it and the official product is accurately and plainly set forth.

Manufacturers have objected to showing the differences between the official standards and those of articles which vary from those standards. They have not been averse to disclosing the true standards of the varying products. They have apprehended that declaring "differences" would imply to the uninformed purchaser that the product which varies is inferior to the official one. Drugs are developed by manufacturers before they appear in these "official" publications. The publications then at a later time include the drug, and in doing so frequently make some minor change in the formula. And after that is done, the manufacturer of the original product must state on his label wherein his product differs from the official. These publications originate nothing. They simply take that which has been introduced by some manufacturer, usually with certain changes in title or formula, and sometimes without change. Such manufacturers have felt that the requirement of the new law forces them so to label their original products as to convey the idea that because of an admitted difference in formula their products are somehow inferior.

On the other hand, earnest and sincere recommendations were made for the deletion of any variation. The argument was that standards are of no value unless observed, and that an authorized sweeping variation from the requirements is tantamount to a repeal; that there can be no excuse for legislation permitting the sale of one drug product under the name of another.

<sup>16</sup>These comments apply equally to exemptions for "manufacturing use only," and generally to regulations under §§503(a) and 603 which authorize exemptions where articles are to be repacked. Note the distinction drawn between an exemption becoming "void *ab initio*" and an exemption "expiring at the beginning of the act of removing."

It is contended that the regulations inject a further departure from the old law,<sup>17</sup> or the practice thereunder, when they require that every drug designated by a name recognized in these publications shall comply in identity with the specifications in them. The regulations are addressed to Section 501(b), but they may be sustained by other sections of the law. Section 501(d) declares a drug adulterated if any substance has been substituted wholly or *in part* therefor. Section 502(g) declares a drug misbranded if it purports to be a drug the name of which is recognized in an official compendium unless it is packaged and labeled as prescribed therein. And Section 502(a) is the all-covering provision that a drug is misbranded if its labeling is false or misleading in any particular. This further support does not remove the difficulty for the industry. It may aggravate it. But whether the difficulty is a substantial one or merely one which will require practical adjustment remains for future determination.

That the adoption of these publications, which are privately owned and controlled, was an unsatisfactory solution of the problem is perhaps generally admitted by government and industry. The continuance of them in the new law as so-called official standards is not an evidence of satisfaction but more an act of expediency. Neither government nor industry seems to have come upon any better way of fixing standards for drugs. Eventually, some governmental, or governmentally controlled, agency will have to take over this important task.

The legality of the establishment of the standards in these private works has always been open to question, especially with respect to revisions after the enactment of the statute. A real test of the question never developed under the old law, presumably because, with the permission for a variation, manufacturers have not had occasion to make a point of it. The changes made by the new law and the position of the Administration as disclosed by the regulations may open it up. For illustration, "legal" drug standards, and tests and methods of assay therefor, are to be fixed from time to time in the future by "the appropriate *body* charged with the revision of such compendium." What these "bodies" are, and how they are "charged" with the revision of the compendiums, does not appear. The three "compendiums" themselves, however, show that the "bodies" referred to are the United States Pharmacopoeial Convention, the American Institute of Homeopathy, and the American Pharmaceutical Association. Suppose, for further illustration, these bodies sold their rights, as corporations may do, in the "compendiums" they publish. If the delegation of legislative authority made in this law is valid, the purchaser or assignee, regardless of qualifications, would be authorized to fix drug standards for the United States. That would be delegation of legislative authority "unconfined and vagrant."<sup>17</sup>

In three cases, the right of state legislatures to adopt standards for drugs to be fixed in editions of the United States Pharmacopoeia not in existence at the time of adoption has been denied, expressly or by implication, and the same principle would

<sup>17</sup> *Schechter Poultry Corporation v. U. S.*, 295 U. S. 495 (1935).

apply with respect to standards fixed by the Homeopathic Pharmacopoeia of the United States and the National Formulary and supplements to them.

The question arose in *State v. Emery*,<sup>18</sup> decided by the Supreme Court of Ohio in 1896, under a statute that provided that a drug should be deemed adulterated "if, when sold under or by a name recognized in the United States Pharmacopoeia, it differs from the standard of strength, quality, or purity laid down therein." Emery, convicted of selling drugs adulterated within the meaning of this rule, challenged the validity of the pharmacopoeial standard on which the prosecution was based. The court said:

"The reference in the statute to the United States Pharmacopoeia could be to no other than the edition of the book in use and recognized when the statute was enacted and went into effect, which was the edition known as that of 1880. It is not to be supposed that the legislature intended to adopt by reference . . . an edition of the book not then in existence, and of which the legislature could then have no knowledge. . . . *To hold that the sale could thus be made unlawful would be equivalent to holding that the revisers of the book could create and define the offense, a power which belongs to the legislative body and cannot be delegated.*"<sup>19</sup> (Italics added.)

*State v. Holland*,<sup>20</sup> decided by the Supreme Court of Maine, in 1918, is to the same effect. There the court said:

"We think that, when the legislature of 1907 referred to the United States Pharmacopoeia and National Formulary for the guidance of registered apothecaries in this state, it must have referred to the compilations known by those names, then recognized as authorities among apothecaries. *It is not to be supposed that the legislature intended to adopt compilations not then made and of whose contents . . . it could have no knowledge.*"<sup>21</sup> (Italics added.)

In Pennsylvania, the same principle has been followed. There a statute provided that a drug should be deemed adulterated if so altered that it did not correspond to the recognized formula in the latest edition of the Pharmacopoeia. It was contended that this constituted an unauthorized delegation of legislative authority. The Pennsylvania district court held:

"If the words 'latest edition' were construed to mean that the editors of those Pharmacopoeia could introduce new standards for formulae and tests, after the passage of the act, then there should be force in the argument that the editors of the books could and would exercise or delegate legislative power, for they could make that an adulteration and an offense against the statute which was not so at the time the act was approved; but construing the act to mean the latest edition at the time the act was approved, there would not be any delegation of legislative power by the simple reference to standard works for definition and for tests and formulae. This is not prohibited either by letter or spirit of the Constitution of Pennsylvania."<sup>22</sup>

<sup>18</sup> 55 Ohio St. 364, 45 N. E. 319 (1896).

<sup>19</sup> *Id.* at 369, 45 N. E. at 319.

<sup>20</sup> 117 Me. 288, 104 Atl. 159 (1918).

<sup>21</sup> *Id.* at 290, 104 Atl. at 159.

<sup>22</sup> *Commonwealth v. Costello*, 18 Pa. Dist. 1067, 1069 (1908).



### *New Drugs*

The introduction into interstate commerce of a "new drug"<sup>23</sup> is prohibited if the Secretary of Agriculture, after a hearing, finds that (1) the investigations by the manufacturer do not include adequate tests by all methods reasonably applicable to show whether or not such drug is safe for use under the conditions prescribed in its proposed labeling; (2) the results of the tests show that the drug is unsafe, or do not show that it is safe, for use under such conditions; (3) the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of the drug are inadequate to preserve its identity, strength, quality, and purity; or (4) upon the basis of the information submitted to him as part of the application, or upon the basis of any other information before him with respect to the drug, he has insufficient information to determine whether the drug is safe for use under such conditions.

The Secretary may suspend "the effectiveness of an application" if, after hearing, he finds that "clinical experience, tests by new methods, or tests by methods not deemed reasonably applicable when such application became effective, show that such drug is unsafe for use under the conditions of use upon the basis of which the application became effective."

The provisions on this subject are the most important in potential consequence of any in the law. They came as a result of the tragedies and the widespread publicity attendant upon the introduction of the so-called Elixir of Sulfanilamide in the autumn of 1937. They were formulated in an earnest effort to prevent, so far as possible, a recurrence of any similar cases. And, surely, if possible to prevent, there should be no repetition. Also, surely, in good conscience and good business, no drug (new or old) should be offered for sale until it has been tested by all known and appropriate methods to determine its safety and usefulness.

No problem arises on the purpose and principle. The only problem—and time alone will tell whether there is a problem—lies in the future application of the provisions by the Administration. Therein, because of the deep wells of power in the provisions, may be much of the future of therapeutics in the United States.

The definition of a "new drug" includes new combinations, proportions, and uses of old drugs. The regulations explain that a drug may be a "new drug" by reason of the newness for drug use (1) of any substance which composes the drug, in whole or in part, whether it be an active substance or a menstruum, excipient, carrier, coating, or other component; (2) of a combination of two or more substances, none of which is a new drug; (3) of the proportion of a substance in a combination, even though such combination containing such substance in other proportions is not a new drug; or (4) the newness of use of the drug in diagnosing, curing, mitigating, treating, or preventing a disease, or to affect a structure or function of the body, even though the drug is not a new drug when used in another disease or to affect another

<sup>23</sup> Section 201(p) defines, in part, a "new drug" as one which "is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety of drugs, as safe for use under the conditions prescribed, recommended, or suggested in the labeling thereof."

structure or function of the body; or (5) the newness of a dosage, or method or duration of administration or application, or other condition of use prescribed in the labeling of the drug, even though when used in other dosage, or other method or duration of administration or application, or different condition, it is not a new drug.

There can not be any serious objection to those regulations. There has been considerable misunderstanding of them. The impression has gone abroad that they are enlargements upon the definition in the law. Instead, they are explanatory of it. They, in effect, explain that a drug (including mixtures of drugs) may not be one that is generally recognized as safe by virtue of the circumstances, or contingencies, set out above. And, that is quite true. Combination, proportion, use, dosage, and disease are all important determinatives of drugs. Almost everything pertaining to them, first as to definition and then as to use and effect, is relative. Seldom in this field does absolutism apply.

While there can not be serious objection to these definitions, the very things just said about drugs can give form to problems in the practical applications of the definition. Industry is prone—and not without reason—to enlarge upon the consequences of them. The bigger problem, however, concerns the new, inherently potent, revolutionary discoveries—as heretofore, insulin, barbital, aspirin, novocain, adrenalin, sulfanilamide, and many others.

“Safety,” as applied to drugs, is relative. Valuable drugs with potentiality for good also have potentiality for harm because of wide and varied uses among many people, with many and different reactions. Useful information about the relative safety of drugs is derived from experiments on animals, but many side effects must be established by experience in human patients. For instance, the sulfanilamide compounds (not the fatal elixir of sulfanilamide) have been historically dramatic in their acceptance and performance. They have demonstrated specific action in streptococcus infections and high effectiveness in gonorrhoea and in hitherto fatal forms of meningitis. But so-called toxic effects on some people have been reported. On the basis of them, arbitrary critics might be moved to condemn the drugs, disregarding their brilliant record of high service in combating serious diseases.

Now, in the exercise of these new powers, the Food and Drug Administration may have a poignant influence on the progress of therapeutics. When an application to introduce a new drug is rejected, or an application previously effective is suspended, by official action, the usefulness of the drug will either be destroyed or indefinitely postponed, notwithstanding a later correction of the action, and the introduction of new drugs which are potent in character and significant in consequence will be materially discouraged.

### *Control of Therapeutics*

The extent of the possible influence upon therapeutics does not stop with the control over introduction of new drugs. And in the possible extension there is a question of interpretation. Did Congress intend to authorize the control of thera-

peutics and therapeutic representations? If it did, is it empowered, under the Constitution, to do so? Or, assuming the enactment valid when administered within well-defined realms of false therapeutic representations, will the extension of the administration into realms of opinion be sanctioned by the courts? The law as written is one thing. Administration may be another, for the language of the law—inclusive and adaptable—offers the temptation to invade the highly controversial fields of therapeutic opinion.

For instance, a new drug is defined as one, the composition of which is such that it is not “generally recognized, among experts qualified by scientific training,” as safe for use under “conditions prescribed in the labeling.” Now, what is “generally recognized,” and what is “fact” may be, and frequently are, two different things. In other words, what experts think may not be synonymous with fact. The progress of therapeutics has been quite illustrative that it is not. The name of Pasteur stands for that proposition. Yet, in this law, the current opinion of experts is made the criterion.

An appeal is allowed the manufacturer from an order of the Secretary refusing to permit an application to become effective or suspending the effectiveness of an application previously allowed. But, and here is the clincher, “the finding of the Secretary as to the *facts*, if supported by substantial evidence, shall be conclusive.”

The determination of safety under the new drug section of the law hinges much on whether the Administration takes the view of safety of “composition” or safety of “therapeutic” use. At the present, there is some indication that the former is the view. That is the safer view from this standpoint. The other view leads straight into the mass of medical opinion respecting dosage, methods and duration of application, and a host of points for unending therapeutic debate.

But, if that question is not there, it may come up in other sections of the law. A drug is misbranded if it is dangerous to health when used in the “dosage, or with the frequency or duration” prescribed in its labeling, or if its labeling does not include adequate directions for use and adequate warnings against use in “those pathological conditions or by children where its use may be dangerous to health or against unsafe dosage or methods or duration of administration or application.” How long shall an individual take a given medicine? Some individuals respond more quickly to medication than others, and there are many factors to be considered. The value of a drug or the time of activity cannot be definitely determined in animal experimentation. The same as to dosage.

Then there is the all-inclusive provision that a drug shall be misbranded if its labeling is “false or misleading in any particular.”<sup>24</sup> With that goes the provision that in determining whether labeling is “misleading” there shall be taken into account not only representations made but also the extent to which the labeling fails to reveal facts “material in the light of such representations or material with respect to consequences which may result from the use of the article . . . under the conditions

<sup>24</sup> See U. S. v. 95 Barrels of Vinegar, 265 U. S. 438, 443 (1924).

of use prescribed in the labeling thereof or under such conditions of use as are customary or usual."<sup>25</sup>

The regulations state that among facts which *may* be material in the light of a representation is the fact, when it exists, of a difference of opinion among experts qualified by scientific training and experience as to the truth of it, "if there is a material weight of opinion contrary to such representation."

The authority for that is the Congressional committee report:

"One of the important applications of section 201(n) relates to this problem. If only a few experts regard a label statement of curative value as true but the great body of qualified experts in that particular field regard the statement as untrue, then there may be substantial ground for concluding that the curative claim is misleading unless it is qualified in such a way as to show the existence of conflicting opinion as to its truth. Certainly a consumer seeking a remedy for a disease condition has the right to know, when it is a fact, that the representations of curative value have *only a narrow and limited support*; and if the labeling fails to reveal that fact, which is a material fact in the light of the representations made, then the labeling may be regarded as misleading. However, the misleading character of the label may be corrected by an appropriate qualifying statement revealing this material fact."<sup>26</sup> (Italics added.)

There is a distinction between the regulation and the report. The former takes the inverse of the latter. The report contemplated cases in which "only a few experts" regard a representation as true while "the great body" of experts regard it as untrue. But both contemplate the "opinion" of "experts." And both go back into the history of this legislation which, from the beginning, has attempted in one way or another to establish medical opinion as a criterion of truth.

In S. 1944, the Tugwell Bill, it was provided that a drug would be misbranded "if its labeling bears any representation, directly or by ambiguity or inference, concerning the effect of such drug which is contrary to the general agreement of medical opinion." In S. 2800 which followed (S. 2000 intervening), it was, "Any representation concerning any effect of a drug shall be deemed to be false under this paragraph if that representation is not supported by substantial medical opinion or by demonstrable scientific facts."

That provision, with variations, appeared in succeeding revisions of the bill and finally went out with the explanation, contained in the report above referred to, that:

"It was felt that if a nostrum maker were able to obtain two or more persons who could qualify as experts and would testify in support of the label claims, the Government's case would be lost despite the fact that every competent expert in the country would unqualifiedly declare the claims to be false. The committee therefore substituted for this provision section 201(n)."<sup>27</sup>

The argument for the inclusion of the various provisions on medical opinion has been that some form of them was needed for the validity of the law, as to therapeutic

<sup>25</sup> The amendments to the Federal Trade Commission Act have the same provision with respect to advertisements.

<sup>26</sup> H. R. REP. No. 2139, 75th Cong., 3d Sess. (1938) 8.

<sup>27</sup> *Id.* at 7.

claims, on the well-known principle that a statute providing punishment for the commission of an offense must describe the offense with a reasonable degree of certainty.<sup>28</sup> When the Supreme Court construed the phrase "false or misleading in any particular" as contained in Section 8 of the old law,<sup>29</sup> Mr. Justice Holmes held that it applied only to the identity, origin, and description of the article, and not to therapeutic or curative representations. The decision turned on construction of the language as used in the section. Although counsel had injected a question of constitutionality, it was not necessary for the Court to discuss it. Nevertheless, Mr. Justice Holmes did say:

"We shall say nothing as to the limits of constitutional power, and but a word as to what Congress was likely to attempt. It was much more likely to regulate commerce in food and drugs with a reference to plain matter of fact, so that food and drugs should be what they professed to be, when the kind was stated, than to distort the uses of its constitutional power to establishing criteria in the regions where opinions are far apart."<sup>30</sup>

There was a strong minority opinion by Mr. Justice Hughes (Justices Harlan and Day concurring), in which he said:

"The argument is that the curative properties of articles purveyed as medicinal preparations are matters of opinion, and the contrariety of views among medical practitioners, and the conflict between the schools of medicine are impressively described. But, granting the wide domain of opinion, and allowing the broadest range to the conflict of medical views, there still remains a field in which statements as to curative properties are downright falsehoods and in no sense expressions of judgment. This field, I believe, this statute covers. . . . I entirely agree that in any case brought under the act for misbranding—by a false or misleading statement as to curative properties of an article—it would be the duty of the court to direct an acquittal when it appeared that the statement concerned a matter of opinion. Conviction would stand only where it had been shown that, apart from any question of opinion, the so-called remedy was absolutely worthless, and hence the label demonstrably false; but in such case it seems to me to be fully authorized by the statute."<sup>31</sup>

In discussing S. 1944 before a Senate subcommittee, Mr. Campbell said:<sup>32</sup>

"All we are asking in this particular paragraph in this bill, is that language be employed which will create no doubt in the mind of the court as was done in this case about the legislative intent."

However, the injection of medical opinion as the criterion of truth, or the failure to declare differences of opinion as an element of misbranding, would seem to create uncertainty rather than certainty. The existence of differences of opinion between different schools of medicine and between different practitioners of the same school and the reversals of, and changes in, medical opinion are proverbial. But aside from the principle of certainty in describing the offense, the validity of the statute would

<sup>28</sup> *U. S. v. Cohen Grocery Co.*, 255 U. S. 81 (1921).    <sup>29</sup> *U. S. v. Johnson*, 221 U. S. 488 (1911).

<sup>30</sup> *Id.* at 498.

<sup>31</sup> *Id.* at 504, 507.

<sup>32</sup> *Hearings before a subcommittee of the Senate Committee on Commerce on S. 1944*, 73d Cong., 2d Sess. (Dec. 7, 8, 1933) 45.

be almost certainly imperiled if it attempted to set up medical opinion as the standard of truth and punish criminally any representations not in accord therewith.

The law should properly deal with fact. Mr. Justice Hughes recognized in his dissent in the *Johnson* case that there is a realm of fact pertaining to therapeutics. He held that Congress is empowered to legislate in that field. Although the question of Congress' limitation in this respect was not necessary to decision in that case, and although such a comprehensive and direct question has not been before the Court, it is likely that Mr. Justice Hughes touched upon the line of reasoning which the Court might adopt when, and if, the question is definitely presented to it.<sup>83</sup> Medical and scientific opinion can properly be dealt with under the misbranding provisions. Of course, the opinion of experts will constitute testimony in cases arising under the law and will be received, as heretofore, under the rules of evidence and for the purpose of determining issues of fact. But aside from that, opinion will doubtless enter in what may be called a negative, as distinguished from an affirmative, way—somewhat the reverse of the thought in the discussions during the legislative career of this law. The report previously referred to seems to contemplate that when, in explaining Section 201(n), it says:

“a consumer seeking a remedy for a disease condition has the right to know, when it is a fact, that the representations of curative value have only a narrow and limited support.”<sup>84</sup>

The report explains that if that is a fact and if the labeling fails to reveal that fact, and if that fact is material in the light of representations which are made, then the labeling may be regarded as misleading under the provisions of Section 201(n). Now, that approach to the question contemplates fact and not opinion, except as the latter bears upon the former. In other words, if the label represents a drug to have therapeutic efficacy in the treatment of a disease, or if it represents a certain dosage as correct, or certain methods and duration of use as correct, and makes these representations as facts when in truth they are not facts but merely opinions of certain experts—and at that of a very small or disqualified number—then the label will be deemed misleading unless the fact of such limited and opinionated support is declared—unless the customer is informed that the claims are merely opinions and is not left under the impression that they are facts.

Whatever the approach to the question, and whatever the expansion or limitation which may come through court decisions in the future, it seems certain that the administration of this law is going to include some control of therapeutics within the spheres in which it is applicable. And it also seems that there is a way in which, and an extent to which, the Administration may exercise that control without imperiling the validity of the Act. When that way and extent are developed, the resulting

<sup>83</sup> 7 Cases of *Eckman's Alternative v. U. S.*, 239 U. S. 510, 517 (1916) (upholding the *Sherley Amendment*); *U. S. v. American Laboratories*, 222 Fed. 104 (E. D. Pa. 1915); *Goodwin v. U. S.*, 2 F. (2d) 200, 201 (C. C. A. 6th, 1924); *McLean v. U. S.*, 253 F. 694, 696 (C. C. A. 8th, 1918); 11 *Gross Packages v. U. S.*, 233 Fed. 71, 73 (C. C. A. 3d, 1916); *Kar-Ru Chemical Co. v. U. S.*, 264 Fed. 921, 927 (C. C. A. 9th, 1920).

<sup>84</sup> H. R. REP. NO. 2139, 75th Cong., 3d Sess. (1938) 8.

control, most assuredly as to the labeling of the products for sale to the public, will be highly proper and salutary for the public welfare.

### *Labeling*

The labeling of drugs and cosmetics presents a practical problem that is extreme in its scope and acute in the shortness of time before the effective date of the Act. Because cosmetics were not subject to the old law, because that law was negative in its requirement as to drugs, and because the new law has so many affirmative requirements, almost every drug and cosmetic label will need some change. No one knows how many products there are. Some manufacturers have dozens, some hundreds, and some thousands. Many sell millions of packages a year. Normal production schedules call for anticipated orders from six months to a year in advance of the exhaustion period of current supplies.

Preparation of new labels, in addition to production and layout, will require legal and scientific advice. The amount of time required for the very mechanics of changes is inordinate. There is also the time and service needed in solving the many problems pertaining to correct dosage, warnings, and manner of stating ingredients and other information.

Drugs and cosmetics must declare the name and place of business of the manufacturer, packer, or distributor, and, pursuant to regulations (if the name is not that of the manufacturer), whether he is the packer or distributor. By regulations, the street address must also be included unless it appears in the telephone or city directory. The quantity of the contents of the package in terms of weight, measure, or numerical count must be declared. If it is a coal tar hair dye, the label must conspicuously display "Caution—this product contains ingredients which may cause skin irritation on certain individuals, and a preliminary test according to accompanying directions should first be made. This product must not be used for dyeing the eyelashes or eyebrows; to do so may cause blindness." And the labeling (as distinguished from the label) must bear adequate directions for the preliminary test.

In addition to statements common to drugs and cosmetics, drug labels must declare the name, quantity, and percentage of any narcotic drug specified in the statute or of any derivative thereof which has been designated by regulations as habit forming, and the statement, "in juxtaposition therewith," "Warning—may be habit forming." They must declare the active ingredients of the article and the name and proportion of any alcohol and certain drugs named in the statute or derivatives of those named. If it has been designated by regulations as liable to deterioration, its label must bear a statement of such precautions as shall be required by regulations. If it is listed in the United States or Homeopathic Pharmacopoeia or National Formulary, and differs from the standard of strength, quality, or purity set forth in such publication, its label must show all of the differences. If it is potent and is to have the exemption from declaring directions, the regulations require a statement, "Caution—to be used only by or on the prescription of a" physician, dentist, or veterinarian.

The labeling (as distinguished from the label) must contain adequate directions for use and adequate warnings against use in pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users. If, in stating the information, the label, or labeling, is false or misleading in any particular, the drug will be misbranded. Whether or not it is misleading will be determined, under Section 201(n), by considering whether there has been any failure to reveal facts material in the light of those disclosed, or with respect to consequences which may result from the use of the article under the conditions of use prescribed or under such conditions of use as are customary or usual.

The Act then provides, Sections 502(c) and 602(c), that if any information required to appear on the label, or labeling, is not prominently placed with such conspicuousness (as compared with other information) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use, it will be misbranded. Whether or not a label, or labeling, violates these sections will be a question of fact in each case. One label may violate them by failure to disclose all this information on the front part or panel thereof. Another may violate them by cramming so much information on one panel. Frequently the information will stand out bolder and be the quicker seen by the customer and user for appearing upon panels other than the so-called front one. No hard and fast rule can be laid down for designing labels and declaring information on them applicable to all products and to all sizes and shapes of packages.

These sections were not taken up in public discussion during the legislative course. Their meaning appeared clear and understandable—to assure and command that in the making up of labels and labeling the required material should not be hidden in the folds and recesses of the labels or stated in size type not readily readable. Unless that is what they mean, and if administration gets into fixed specifications as to parts, panels, position, and arrangement, the sections could work the destruction of valuable property rights—without compensating public benefit—in that trademarks and package design would have to be eliminated or so altered as to lose sales appeal. They could not be complied with, in some cases, unless the entire design, ornamentation, and get-up which had been used for years were dropped, and a package that would be susceptible of no sales attraction or trademark protection substituted.

The regulations give informative and sound explanations of how a label *may* fail to comply with these sections and seem to recognize that with each label it will be a question of fact. But they are revealing of the numerous ways in which a label may violate them and so be misbranded. In fact—and in summary—that should be said of the regulations<sup>35</sup> under many sections of the law. In them is an appraisal of

<sup>35</sup> Anyone subject to this law should give careful study to these regulations. They cannot be regarded lightly. They are authorized (§701(a)) and are valid when consistent with, and truly interpretative of, the law and its purpose. See *U. S. v. Antikamnia*, 231 U. S. 654 (1914).



the new legislation—an illustration of the manifold and varied applications of this law to the making, packing, labeling, and selling of drugs, devices, and cosmetics.

#### CONCLUSION

The existence of these problems does not condemn the new legislation. Its scope, both as to provisions and application to large and diversified industries, naturally involves at the start, and for a considerable period thereafter, problems such as those discussed here and many others not now foreseen or too numerous for inclusion in the allotted space for this article. The balance between its problems and its ultimate benefits is overwhelmingly in favor of the latter. Its purpose is the protection of the public health.<sup>86</sup> It provides the definitions and procedures necessary to accomplish its purpose. In so doing, it will, at the same time, benefit industry. The interests of the consuming public are not adverse to the interests of the producing industry. Producer and consumer are necessary to each other. What serves the ultimate good of one serves the ultimate good of the other.

That does not mean that the effects of the new legislation are not far-reaching and in some ways revolutionary in their ultimate effect upon industry. The new Food, Drug, and Cosmetic Act is more than a "tightening-up" of the old law at a few specified places. It is more than a mere extension of that law to include therapeutic devices and cosmetics. Its philosophy goes far beyond that of the old. It sets up an entirely new system for affirmative control and regulation. The manufacturer who does not appreciate that is in for a rude awakening, and perchance in circumstances the more shocking if the awakening is deferred. The manufacturer who attempts to temporize or play hide-and-seek with this law is going to pay dearly for his fun. Here are not only expansive definitions, but also swift and effective restraints and punishments.

Perhaps the effects of the new legislation will be most generally noticeable among proprietary medicines advertised and sold to the public. It will work many changes in the composition, labeling, and advertising of many of them. It will accomplish the demise of some of them. But it will work ultimate good for them as a class. They will the better serve the public.<sup>87</sup> Only as they do serve the public have they a right to existence.

The manufacture of these products has developed into an industry, and with that development has come the establishment of an economic position—medicines compounded according to approved formulas, under standardized control, with uniformity of strength, conveniently packaged, and made available to the masses. The

<sup>86</sup>U. S. v. Lexington Mill & Elevator Co., 232 U. S. 399 (1914); Savage v. Jones, 225 U. S. 501 (1912); McDermott v. Wisconsin, 228 U. S. 115 (1913); U. S. v. Coca-Cola Co., 241 U. S. 265 (1916). The Act should be construed to accomplish the legislative intent, and therein is an ever-present key to interpretation and application of the Act in the solution of problems as they arise. Hipolite Egg Co. v. U. S., 220 U. S. 45 (1911); U. S. v. Antikamnia, *supra* note 35.

<sup>87</sup>"The bill is not intended to restrict in any way the availability of drugs for self-medication. On the contrary, it is intended to make self-medication safer and more effective." H. R. REP. NO. 2139, 75th Cong., 3d Sess. (1938) 8.

economic place of that industry, however, is not as broad as an advertising man's imagination.<sup>38</sup> There is no justification in economics, and even less in morals, for the sale of unnecessary goods through claims of efficacy beyond the real power of a product or through claims of uses for which the product is not fitted.

When one, for a business, sells medicines and drugs to people who are sick, and who are the more credulous because they are sick, he should assume the burden of using extraordinary care in determining the truth of what he says, and in stating it in clear terms that are not likely to be misleading. He, and not the public, should assume the risk of his ignorance or mistake. And that, finally, is the test—and the rule.

<sup>38</sup>In an address on October 27, 1938, before the Southwestern Association of Advertising Agencies, James A. Horton, Chief Examiner of the Federal Trade Commission, made the following statement: "It is quite apparent to me, as it should be to you, that because of this new concept, the day of the old-time copy writer is fast drawing to a close. With him will pass such practices as conducting product research in the office rather than by scientific development in the hands of trained laboratory specialists in a laboratory where it always belonged."