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THE FEDERAL LAW OF PRESCRIPTION DRUGS†

The grip of federal authority upon local business operations was effectively tightened and, indeed, reached a unique peak with the enactment on October 26, 1951, of the Prescription Drug Amendment to the Federal Food, Drug, and Cosmetic Act.¹

The Prescription Drug Amendment became effective April 26, 1952. It brought under close federal regulation that indispensable service to local communities traditionally rendered by pharmacists through the local drug store — the filling of doctors' prescriptions.

The new law amended Section 503 (b) ² of the Federal Food, Drug, and Cosmetic Act to require that drugs shipped in interstate commerce which are unsafe for lay use shall be dispensed by the druggist only upon the prescription of a licensed practitioner and that such drugs shall bear the legend "Caution: Federal law prohibits dispensing without prescription." The amendment further prohibits the refilling of prescriptions for such unsafe drugs, unless refilling is authorized in the original prescription or by subsequent oral order of the prescriber.

The retail druggist or pharmacist who violates these provisions is subject to severe criminal penalties and he may be enjoined from further violations by a federal district court.³

It is evident that legal counsel for the fifty thousand or more drug stores in the United States are, by reason of the Prescription Drug Amendment, going to have an increasing concern with federal regulation of the activities of their

† This article was submitted for publication on February 15, 1952. [Editor's note.]

¹ 52 STAT. 1040 (1938), 21 U.S.C. § 301 *et seq.* (1946), as amended, 65 STAT. 648 (1952); [1951] U.S.C. Cong. & Adm. Serv. 663. Subsequent citations to this enactment will be made to Pub. L. No. 215, 82d Cong., 1st Sess. (Oct. 26, 1951). The Prescription Drug Amendment is quoted in full in the Appendix to this article.

² 52 STAT. 1051 (1938), 21 U.S.C. § 353 (b) (1946).

³ 52 STAT. 1043 (1938), 21 U.S.C. § 333 (c) (1946).

clients and with the laws under which that regulation proceeds. The fact that even the local druggist's prescription files themselves will be subject to federal inspection serves to indicate the intimate character of the control which will be exercised.⁴

Of basic importance, but in a more common field of federal control, is a further requirement of the Prescription Drug Amendment that the labels of drugs unsafe for lay use except under medical supervision shall bear, when shipped in interstate commerce, the official caution statement that federal law prohibits their dispensing without prescription.

Proposed regulations for the enforcement of the amendment were published in the Federal Register for February 5, 1952. Industry comments on the proposal were invited.

The concepts underlying the prohibitions of the new law were derived from the so-called Rx or prescription regulations of the Federal Security Administrator⁵ which the amendment superseded when it became effective in April. But now, for the first time, the Congress has accepted and enlarged upon those concepts by specific statutory enactment. The doubts of judicial acceptance which have long dictated a cautious program of enforcement of the Rx regulations will no longer hamper the enforcement agencies either in areas of interstate or local operation.

As background we ought to examine, before making an analysis of the provisions of the new amendment, the question of the constitutionality of the local regulation provided

⁴ Cf. SEN. REP. No. 946, 82d Cong., 1st Sess. 6 (1951), on H.R. 3298 which became the Prescription Drug Amendment.

⁵ The Food, Drug, and Cosmetic Act is administered by the Food and Drug Administration under the supervision of the Federal Security Administrator, who heads the Federal Security Agency. The Food and Drug Administration is a constituent unit of that agency. The Rx regulations were promulgated October 9, 1944, and became effective October 10, 1945. 21 CODE FED. REGS. § 1.106 (1949). They were examined in detail by the writer in Williams, *Exemption from the Requirement of Adequate Directions for Use in the Labeling of Drugs*, 2 FOOD DRUG COSMETIC L.Q. 155 (1947).

by it, and the reasons for its enactment. The discussion of reasons for enactment will include a consideration of the Rx regulations.

I.

Constitutionality of the Prescription Drug Amendment

Is the control of the business of the local druggist under the Prescription Drug Amendment a constitutional regulation? The Food, Drug, and Cosmetic Act of 1938,⁶ as enacted, provided for limited control of local sales. Section 301(k)⁷ prohibited the doing of an act resulting in the misbranding of a food, drug, device, or cosmetic, "if such act is done while such article is held for sale after shipment in interstate commerce. . . ." Violators of the prohibition were subject to criminal penalties.⁸

*United States v. Sullivan*⁹ is the principal case involving this provision. The Government charged, by criminal information, that Sullivan, a retail pharmacist in Columbus, Georgia, had violated Section 301(k) by misbranding certain sulfathiazole tablets while they were being held for sale by him after shipment in interstate commerce. Sullivan had removed some of the tablets from the properly labeled bottle in which they were shipped interstate, had placed them in boxes bearing only the name of the drug, and had sold them over-the-counter (i.e., without a doctor's prescription). The acts of removing, repacking and disposing by sale were alleged to have caused the misbranding and violation of Section 301(k), since the tablets, when sold by Sullivan, did not bear adequate directions for use as required

⁶ The Federal Food, Drug, and Cosmetic Act of 1938, 52 STAT. 1040 (1938), 21 U.S.C. § 301 *et seq.* (1946), succeeded the Food and Drugs Act of 1906, 34 STAT. 768 (1906).

⁷ 52 STAT. 1042 (1938), 21 U.S.C. § 331 (k) (1946).

⁸ 52 STAT. 1051 (1938), 21 U.S.C. § 333 (a) (1946).

⁹ 332 U.S. 689, 68 S. Ct. 331, 92 L. Ed. 297 (1948).

by clause (1) of Section 502(f), or adequate warnings as required by clause (2) of that section.¹⁰

The defendant attacked the constitutionality of Section 301(k) and maintained that it was inapplicable to the local acts which allegedly caused the misbranding of the drug. Sullivan was convicted in the lower court and his conviction was upheld by the Supreme Court of the United States.

The tablets sold by Sullivan had originally been shipped interstate to a distributor in Georgia who, in turn, had sold them to Sullivan. Thus, the Supreme Court in this case found Section 301(k) to be within the power of Congress even as applied to a *second* sale after completion of the interstate shipment.

After the *Sullivan* decision, Section 301(k) was amended, by legislation initiated before the Supreme Court had acted in that case, making specific the application of Section 301(k) to sales following the first sale after interstate shipment.¹¹

The so-called seizure section¹² authorizing actions *in rem* against offending drugs, was similarly amended to permit the seizure, pursuant to libels of information filed in federal court, of "Any article of . . . drug . . . that is adulterated or misbranded when introduced into or while in interstate

¹⁰ 52 STAT. 1051 (1938), 21 U.S.C. § 352 (1946): "A drug shall be deemed to be misbranded . . . (f) Unless its labeling bears (1) adequate directions for use; and (2) such 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, in such manner and form, as are necessary for the protection of users: *Provided*, That where any requirement of clause (1) of this paragraph, as applied to any drug or device, is not necessary for the protection of the public health, the Administrator shall promulgate regulations exempting such drug or device from such requirement."

¹¹ The Miller Amendment, Act of June 24, 1948, 62 STAT. 582 (1948), 21 U.S.C. § 331 (k) (Supp. 1951). As amended, Section 301 (k) reads: "The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to, a food, drug, device, or cosmetic, if such act is done while such article is held for sale (whether or not the first sale) after shipment in interstate commerce and results in such article being adulterated or misbranded." The extension of the provision to adulteration is not, of course, relevant to this discussion.

¹² 52 STAT. 1044 (1938), 21 U.S.C. § 334 (a) (1946).

commerce *or while held for sale (whether or not the first sale) after shipment in interstate commerce. . .*” The italicized words were added by the Miller Amendment.¹³

It is evident, therefore, that even prior to the enactment of the Prescription Drug Amendment, both Congress and the Supreme Court had regarded the local field to which the amendment will extend, as legitimate territory for federal regulation.

II.

Need for the New Legislation:

The Rx Regulations

The basic need for the Prescription Drug Amendment is largely traceable to the inadequacy of the so-called Rx regulations which it superseded and of Section 502(f) of the Act¹⁴ upon which those regulations rely for their authority.

It is useful, first, to examine the Rx regulations. Their basic purpose was the same as that of the amendment — to control the dispensing of drugs which are of such a nature that they are unsafe except when used under qualified medical supervision.

The proviso to Section 502(f), under which the regulations were promulgated, directs the Federal Security Administrator to exempt a drug from clause (1) of that section, requiring that the labeling of drugs bear adequate directions for use, where such directions are not necessary for the protection of the public health.

The Rx regulations establish, in effect, several types of exemption from the requirement of adequate directions. Our present interest extends only to the first type, which is applicable to interstate shipments of drugs which are not

¹³ 62 STAT. 582 (1948), 21 U.S.C. § 334 (a) (Supp. 1951).

¹⁴ See note 10 *supra*.

recognized by qualified experts as safe or efficacious for use except under medical supervision.¹⁵ This exemption is not optional with the shipper of such drugs. Its effect is that drugs of the class to which it applies must either be marketed in accordance with the requirements established by the regulations for so-called exempt drugs or be exposed to the hazards of legal proceedings. This result follows from the fact that adequate directions for use by the layman cannot be written for such drugs. If their labels bear directions, therefore, they are misbranded under Section 502 (f) (1), and they may be misbranded under other provisions of the Act.¹⁶ This means, in general, that, when shipped, such drugs must bear the prescription legend "Caution: To be dispensed only by or on the prescription of a physician" (or "dentist" or "veterinarian," as the case may be),¹⁷ and that they must not be sold by the retail druggist except upon a doctor's prescription.

The theory and operation of the regulations is reflected in the opinion of the United States Court of Appeals for the Ninth Circuit in the *El-O-Pathic Pharmacy* case.¹⁸ There, the court directed the issuance of permanent injunctions against several firms, appellees, who were found to have misbranded certain sex hormones, principally testosterone, a male hormone.

The drugs had been shipped to appellees in interstate commerce labeled with the prescription legend, as provided by the Rx regulations. Appellees then relabeled the drugs, eliminating the legend. The new labels stated that "before taking testosterone a physician should be consulted," but they also included a suggested dosage and information as to how the tablet should be taken.¹⁹ The court found appel-

¹⁵ 21 CODE FED. REGS. § 1.106 (b) (1949).

¹⁶ Under Section 403 (a) their labeling may be misleading, 52 STAT. 1047 (1938), 21 U.S.C. § 343 (a) (1946), or under Section 502 (j) they may be dangerous to health, 52 STAT. 1051 (1938), 21 U.S.C. § 352 (j) (1946).

¹⁷ The Prescription Drug Amendment does not apply to veterinary drugs.

¹⁸ *United States v. El-O-Pathic Pharmacy*, 192 F. (2d) 62 (9th Cir. 1951).

¹⁹ *Id.* at 73 n.6.

lees' collateral advertising, advising "every man and woman that they can buy these dangerous drugs at their favorite drugstore,"²⁰ to be entirely inconsistent with the appellees' avowed intent that the purchasers use the drugs only under medical supervision. After reciting in detail the expert testimony presented on behalf of the Government as to the highly dangerous character of testosterone in the hands of a layman, the court accepted the Government's argument that, for such a drug, adequate directions for the layman could not be written.

The legal position was therefore this: under the Rx regulations the drugs were "exempt" from the requirement of adequate directions when shipped in interstate commerce and when received by appellees, since they bore the prescription legend. Appellees' elimination of the legend removed the exemption and the drugs thereupon became subject to the requirement that their labels bear adequate directions for use. Since, however, under the court's decision, neither the directions prepared by appellees, nor any other, would satisfy the legal concept of adequacy, the drugs were misbranded, among other reasons, *for failure to bear adequate directions for use.*²¹

This rather curious result exemplifies the character of the so-called exemption, as defined by the Rx regulations. It is decidedly not the characteristic "you don't have to" or relaxing type of exemption, such as, for example, that (found also in the Rx regulations) for drugs "with respect to common uses, adequate directions for which are known by the ordinary individual."²² It is, instead, a mandatory

²⁰ *Id.* at 76.

²¹ Evidently the court was of the opinion that the relabeled drugs were misbranded under Section 502 (a) because their labeling was misleading, 52 STAT. 1050 (1938), 21 U.S.C. § 352 (a) (1946); because they failed to comply with Section 502 (f) (2) which requires adequate warning, 52 STAT. 1051 (1938), 21 U.S.C. § 352 (f) (2) (1946); and because, under Section 502 (j), they were dangerous to health, 52 STAT. 1051 (1938), 21 U.S.C. § 352 (j) (1946).

²² 21 CODE FED. REGS. § 1.106 (g) (1949). A similar exemption is contained in the proposed new Prescription Drug Regulations. Proposed Rule Making, Federal Security Agency, § 1.106 (h), 17 FED. REG. 1131 (1952).

exemption. Its essential purpose is not to exempt from a certain legal obligation, but to impose instead another and entirely different obligation — that certain drugs be sold to laymen only on prescription.

Technically, the court of appeals found that appellees had violated Section 301(k) ²³ by so relabeling the drugs as to misbrand them while they were held for sale after shipment in interstate commerce, and that they had violated Section 301(a) ²⁴ by reshipping some of the misbranded drugs in interstate commerce. Under the Rx regulations, the drugs ceased to be exempt from the requirement of adequate directions when they were relabeled and disposed of otherwise than on prescription. We have seen that, therefore, since no directions could be written for the drugs which would be regarded as adequate, no refuge from the legal stigma of misbranding existed for them.

Thus is illustrated the actual mechanics in the operation of the Rx regulations. It will be observed that they need never be pleaded to the court at all since they are merely collateral to the proceeding. The violation alleged is failure of the drug to bear adequate directions for use as required by Section 502(f)(1), or the violation may be that the directions are misleading, or that the drug is dangerous to health when taken in accordance with such directions.²⁵

Significance of Rx Regulations

It would be difficult to dispute the thesis of the Food and Drug Administration that many potent drugs should be restricted to use under medical supervision, in the interest of the public health; and when a court is faced with the impressive testimony of outstanding experts that a drug is

²³ See note 7 *supra*.

²⁴ 52 STAT. 1042 (1938), 21 U.S.C. § 331 (a) (1946). This section prohibits "the introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded."

²⁵ See note 21 *supra*.

highly dangerous for lay use, as was the court of appeals in the *El-O-Pathic Pharmacy* case, it is usually reluctant to disturb the rules and policies of a Government agency which are supported by such testimony. That the leading elements of the drug industry have recognized the validity of the Food and Drug Administration's position, on the basic prescription drug question, was demonstrated by their support of the new prescription drug law. The differences between industry and the Food and Drug Administration involved not the principle that dangerous drugs should be restricted to prescription use, but the method by which the agreed purpose was to be attained.

The Rx regulations are, therefore, not objectionable because they result in limiting certain drugs to prescription sale. They have been subjected to the basic criticism, however, that they are founded upon a tenuous and in some respects self-contradictory interpretation of the statutory law. They exemplify a regulatory viewpoint which, perhaps, is too frequently duplicated by other Government agencies in the interest of far less worthy causes.

It cannot be said, therefore, that there was a clear statutory mandate for the Rx regulations. On the contrary the history of the statute furnishes reason to believe that the language of the statute authorizing exemption from adequate directions for use where such directions are "not necessary for the protection of the public health" contemplated, essentially, situations where the uses of the drug were so well known that directions were unnecessary to guide the layman.²⁶ This would appear to be the normal and natural interpretation of that language. We can all find satisfaction, however, in the circumstance that, in the instance of the prescription drug problem, the proper branch

²⁶ See Williams, *supra* note 5 at 163 *et seq.* It has been noted, note 22 *supra*, that the Rx regulations do contain an exemption of drugs for common uses, for which adequate directions are known by the ordinary individual, and that this exemption is retained in the proposed new Prescription Drug Regulations.

— the legislative — has now acted, with the support of both Government and industry.

In the *El-O-Pathic Pharmacy* case the court of appeals declared, with reference to dangerous drugs: ²⁷

The only adequate instructions for use in such cases would seem to be a caution that it [the drug] be used only on the prescription of a physician. . . . The inscription on a label, "Caution—To be used only by or on the prescription of a physician," would appear to constitute what is comprised within "adequate directions for use" according to the intentment of the law.

The court cited *United States v. Sullivan* ²⁸ in support of this position and pointed out that appellees' argument was in conflict with this view since it urged that "when the Administrator exempts a drug from such directions, he has no authority to do anything more, such as, in this case, requiring, by regulation" the use of the official caution legend.²⁹

Then the court turned to the Government's argument that the conditional exemption imposed by the Rx regulations is valid and concluded that the purposes of the Act require it to sustain that argument. It is hardly necessary to dwell upon the inconsistency of these two positions assumed, one after the other, by the court of appeals. How can the Rx regulations operate to provide an *exemption* from the requirement of adequate directions if that requirement is, in fact, met by the use of the caution statement upon which the regulations insist as a *condition* of the exemption? If the court's view is correct it would presumably be unnecessary to comply with the conditions of the Rx regulations other than use of the prescription legend, in order to get the benefit of the exemption.

Yet this kind of incongruity is hardly surprising where, as often occurs today, a Government position of dubious valid-

²⁷ *United States v. El-O-Pathic Pharmacy*, 192 F. (2d) 62, 74 (9th Cir. 1951).

²⁸ 332 U.S. 689, 691, 68 S. Ct. 331, 92 L.Ed. 297 (1948). The Court, per Justice Black, observed that the official caution statement of the Rx regulations appeared to constitute adequate directions, since it was required by the regulations.

²⁹ 192 F. (2d) at 75.

ity is urged upon the court, but which the court regards as reflecting a sound and desirable policy. This viewpoint demands a degree of sympathy where, as in this case, the Government agency involved is pressing for an end which is generally viewed as *pro bono publico*. But general agreement upon either the philosophy or the particular aims of Government agencies is by no means always present. In this quandary judicial legislation is abhorrent and in any case dangerous when its possible benefits are weighed against its undemocratic implications.

Inadequacies of Existing Law and Regulations

The House Committee reported: ³⁰

The present law and regulations do not provide a satisfactory method for determining the drugs which properly fall within the prescription class. Furthermore, these matters should be regulated by specific statutory provisions rather than, as at present, largely through administrative regulations.

The Committee thought that there was great confusion and lack of uniformity in the application of the official prescription legend, to the disadvantage of the public, and the retail druggist who might innocently violate the law.³¹

Moreover, the problem of oral prescriptions and refilling of prescriptions required specific regulations in the interest of the public, the retail druggist and the physician.³² The old law did not specifically recognize the dispensing of drugs on oral prescription — a practice which is sometimes unavoidable; and the Food and Drug Administration has interpreted the statute to prohibit the unauthorized refilling of any prescription, regardless of the character of the drug involved. Unauthorized refills of habit-forming drugs have become of great concern to the Administration.³³

³⁰ H.R. REP. No. 700, 82d Cong., 1st Sess. 4 (1951).

³¹ *Id.* at 2, 4.

³² The original Senate and House bills were, in fact, confined to these matters.

³³ H.R. REP. No. 700, 82d Cong., 1st Sess. 1, 7 (1951).

The House Committee proposed to deal with the confusion, which it believed existed in the use of the official prescription legend, by providing for a list of prescription drugs.³⁴ The House bill,³⁵ as reported by the Committee, contemplated that such a list would be formulated by the Federal Security Administrator.³⁶ This proposal constituted such an explosive issue that it resulted in the defeat of the Committee bill. The listing provision had been opposed before the Committee by the American Drug Manufacturers Association, the Proprietary Association, the American Pharmaceutical Manufacturers' Association, and the American Pharmaceutical Association. These organizations were joined by the American Medical Association and the combination delivered the fatal punch. Basically, their objection was that the listing provision constituted too great an extension of Government authority over drugs, the industry and the medical profession.³⁷

On the other hand, the listing provision was powerfully supported by the National Association of Retail Druggists. This organization insisted that, with a list to consult, which had the force of law and was therefore authoritative, the druggist would be protected both from dependence upon the decision of the manufacturer or shipper and from the hazard of making his own decision, as to whether a particular drug could legally be sold over-the-counter. In practice, the manufacturer's labeling was accepted as proper by most druggists who desired to follow the regulations of the Food

³⁴ At the hearings before both the House and Senate Committees, industry witnesses, other than those for the National Association of Retail Druggists, repeatedly insisted that the alleged confusion between prescription and non-prescription drugs was largely non-existent.

³⁵ H.R. 3298, 82d Cong., 1st Sess. (1951).

³⁶ See note 33 *supra*.

³⁷ See, for example, the statement of Mr. Charles Wesley Dunn, counsel for the American Pharmaceutical Manufacturers' Association. *Hearings before the Committee on Interstate and Foreign Commerce, House of Representatives, on H.R. 3298, 82d Cong., 1st Sess. 81 (1951)*. Some members of Congress were strongly influenced, as the House debate demonstrated, by their opposition to the policies of the incumbent Federal Security Administrator.

and Drug Administration. We shall see, in discussing the new legislation itself, that no real substitute was obtained for the administrative list which was defeated on the floor of the House of Representatives.

III.

Analysis of Provisions of Prescription Drug Amendment

The Prescription Drug Amendment, amended Section 503(b)(1),³⁸ provides that unsafe drugs, except narcotics subject to the Internal Revenue Code,³⁹ shall be dispensed only (i) upon a written prescription, or (ii) upon an oral prescription which is reduced promptly to writing and filed by the pharmacist, or (iii) by refilling the oral or written prescription, upon authorization of the prescriber. This authorization may appear in the original written prescription or may be given by oral order which must promptly be reduced to writing by the pharmacist.

The drugs so restricted are:

- A. Habit forming drugs.⁴⁰
- B. Dangerous drugs. This category comprises every drug which, "because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a practitioner licensed by law to administer such drug."
- C. New drugs which are subject to control under Section 505 of the Act,⁴¹ and which under that section have

³⁸ For convenience the first section of the amendment is referred to herein in terms of the new Section 503 (b) of the Food, Drug, and Cosmetic Act.

³⁹ 52 STAT. 1052, 21 U.S.C. § 353 (b) (1946), as amended, Pub. L. No. 215, 82d Cong., 1st Sess. (Oct. 26, 1951).

⁴⁰ Defined in Federal Food, Drug, and Cosmetic Act, 52 STAT. 1050 (1938), 21 U.S.C. § 352 (d) (1946). Such drugs include the habit-forming narcotics and the barbiturates. Under Section 503 (b) of the amendment, habit-forming drugs and new drugs (Class C) may be removed from the prescription requirements where such requirements are not necessary for the protection of the public health.

been permitted to use the channels of interstate commerce only upon the condition that they be used under the professional supervision of practitioners licensed to administer them.

The act of dispensing a drug of class A, B, or C, without prescription or otherwise contrary to these provisions, is an act which results in the drug being misbranded while held for sale. Thus Section 301(k) and the criminal and civil sanctions of the Act are brought in the amendment. It is clear, therefore, that the local druggist who fails to observe the prescription requirement will be subject to those sanctions.

An unsafe drug is also misbranded under paragraph (4) "if, at any time prior to dispensing, its label fails to bear the statement 'Caution: Federal law prohibits dispensing without prescription.'" In this manner the manufacturer who fails to place the caution or Rx legend upon a drug before interstate shipment is brought within the area of civil or criminal enforcement action.

Finally, insofar as this portion of the analysis of the amendment is concerned, a drug which is *not* unsafe is misbranded under paragraph (4) if, at any time prior to dispensing, its label bears the caution statement. This provision follows, in spirit at least, the Rx regulations replaced by the amendment. These regulations did not exempt from the requirement of adequate directions those non-dangerous drugs which can be used effectively by the layman with adequate directions to guide him. The effect was that, under the regulations, these drugs had to bear directions.⁴²

⁴¹ 52 STAT. 1052 (1938), 21 U.S.C. § 355 (a) (1946). This section provides: "No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an application filed pursuant to subsection (b) is effective with respect to such drugs." Section 201 (p) defines the term "new drug." 52, STAT. 1041 (1938), 21 U.S.C. § 321 (p) (1946).

⁴² The proposed new regulations, provide that a drug not subject to the amendment will not be misbranded under paragraph (4) because it bears, in addition to "adequate directions," a statement that the user should consult a physician. Proposed Rule Making, Federal Security Agency, § 1.108 (f), 17 FED. REGS. 1132 (1952).

It will be recalled that a principal aim of that segment of the industry which sponsored the bill as reported by the House Committee, was to relieve the retail druggist of the responsibility for deciding whether a given drug must be limited to prescription sale. The initial effort to achieve this result by authorizing the Federal Security Administrator to formulate a list of prescription drugs failed, as has been noted, on the floor of the House of Representatives.

An understanding was reached on this point by the interested industry groups while the bill was before the Senate.⁴³ It is reflected in Section 2 of the new law, which amends Section 303 (c) of the Act.⁴⁴ Under this provision a druggist who receives in interstate commerce a drug *other than one which is unsafe* within the meaning of the Prescription Drug Amendment is given protection against criminal prosecution for selling the drug without adequate directions and warnings as required by Section 502 (f), if he uses the directions and warnings which were on the label of the drug when he received it and if he does so "in good faith." But this qualified protection does not extend to *unsafe* drugs covered by the amendment.⁴⁵

Consequently, the druggist is in the same position as he was before the amendment, as far as his responsibility for failure to properly identify unsafe drugs and to restrict them to sale on prescription is concerned. As a matter of fact, the Food and Drug Administration has never brought a prosecution against a druggist under the circumstances described in Section 2 of the Prescription Drug Amendment — where an over-the-counter drug was repackaged and sold with the

⁴³ SEN. REP. No. 946, 82d Cong., 1st Sess. 2, 3 (1951). *Hearings before the Subcommittee on Health of the Committee on Labor and Public Welfare, U.S. Senate, on S. 1186 and H.R. 3298*, 82d Cong., 1st Sess. 76 *et seq.* (1951).

⁴⁴ 52 STAT. 1043 (1938), 21 U.S.C. § 333 (c) (1946).

⁴⁵ The Senate report emphasizes the fact that the responsibility for proper labeling of non-prescription drugs is upon the manufacturer, but that the law offers the druggist "... no protection against violations which arise if he sells a dangerous drug covered by paragraph (1) of the bill without meeting the prescription requirements." SEN. REP. No. 946, 82d Cong., 1st Sess. 7, 10 (1951).

same directions as those which the manufacturer had placed on the interstate container, and official doubt has been expressed that such a prosecution would be authorized by Section 303 (c) of the statute.⁴⁶

Most druggists will continue to depend upon the classification made by the manufacturer or shipper, unless guidance is furnished by an informal advisory list, without force of law, issued either by the industry or the Food and Drug Administration. The interested industry groups have considered the publication of a list — an action which might avoid the promulgation of one by the Federal Security Administrator. This project has apparently been abandoned. The Food and Drug Administration, however, is committed to a listing of prescription drugs and will presumably act if the industry does not do so. Although an advisory list issued by the Food and Drug Administration would not have the force of law, it would generally be followed as if it were a regulation with full legal effect.⁴⁷

Paragraph (2) of amended Section 503 (b) exempts drugs dispensed on prescription from the misbranding provisions of Section 502 of the Act with certain important exceptions, including those provisions under which a drug is deemed to be misbranded if its labeling is false or misleading,⁴⁸ if it is an imitation of, or offered for sale under the name of, another drug,⁴⁹ or if it is not packaged as prescribed pursuant to law.⁵⁰ A specific condition of this exemption is that the

⁴⁶ See statement of Mr. George Larrick, Deputy Commissioner of Food and Drugs, *Hearings, supra* note 43, at 156.

⁴⁷ If the advisory list were issued as an interpretative regulation pursuant to Section 701 (a), 52 STAT. 1055 (1938), 21 U.S.C. § 371 (a) (1946), and the pertinent substantive provisions of the Act, it would probably be given some weight by the courts, as is usual for such regulations, in the absence of indication by Congress that it should be treated differently.

⁴⁸ 52 STAT. 1050 (1938), 21 U.S.C. § 352 (a) (1946).

⁴⁹ 52 STAT. 1051 (1938), 21 U.S.C. § 352 (i) (2), (3) (1946).

⁵⁰ 52 STAT. 1051 (1938), 21 U.S.C. § 352 (g), (h) (1946). Special provisions relating to insulin and certain anti-biotics also remain effective for prescription drugs. 55 STAT. 851 (1941), 21 U.S.C. § 352 (k) (1946); 59 STAT. 463 (1945), 21 U.S.C. § 352 (1) (1946).

label of the prescription drug must bear, at the time of dispensing, certain information, essential for the patient, which is customarily placed on prescription labels, including any directions for use and cautionary statements contained in the prescription.⁵¹

This exemption does not apply to a drug dispensed in violation of the prescription requirements of paragraph (1) of amended Section 503(b) as if, for example, it were dispensed without a prescription or refilled without authorization of the prescriber.

Nor does the exemption apply to a drug dispensed in the course of the conduct of a business of dispensing drugs pursuant to diagnosis by mail. The House bill had included in the non-exempt class those drugs which were dispensed "without examination of the patient," but the Senate eliminated that language.⁵²

IV.

The New Prescription Drug Regulations: Their Basic Character

Circumstances permit only selective consideration of the proposed new prescription drug regulations published in the Federal Register for February 5, 1952. The discussion will be confined chiefly to the basic character of the question of whether a drug is unsafe within the meaning of the Prescription Drug Amendment because it is inefficacious for use except under medical supervision.

Section 1.106(b), as proposed, provides that

A drug subject to the requirements of section 503(b)(1) of the act, as amended by 65 STAT. 648 [i.e., a prescription drug], shall be exempt from section 502(f)(1) [the requirement of adequate directions] if all of the following conditions are met.

⁵¹ The other information required is the name and address of the dispenser, the serial number and date of the prescription or of its filing, the name of the prescriber, and, if stated in the prescription, the name of the patient.

⁵² SEN. REP. NO. 946, 82d Cong., 1st Sess. 7 (1951).

Some of the conditions set forth in the regulation are based upon the Prescription Drug Amendment — for instance, the condition that the label of an unsafe drug bear the statement “Caution: Federal law prohibits dispensing without prescription.” Other conditions are not provided for in the amendment: for example, the condition that the label bear a statement of “the recommended or average dose.”

Let us examine the legal situation which the proposed regulations apparently aim to create. If a drug subject to the Prescription Drug Amendment at any time prior to dispensing fails to bear the legend “Caution: Federal law prohibits dispensing without prescription,” it is misbranded under paragraph (4) of the amendment. Under the proposed regulations, since it fails to bear the legend, such a drug would not be exempt from the requirement of adequate directions for use under Section 502(f)(1). By definition, adequate directions cannot be written for such a drug. This was pointed out in the *El-O-Pathic Pharmacy* case. Therefore, it is misbranded for failure to bear such directions regardless of what attempt to write them may have been made, just as it would be under the Rx regulations.

Consider now a drug which complies in all respects with the Prescription Drug Amendment, but which is not exempt under the proposed regulations from the requirement of adequate directions for use because, for example, its label fails to bear the recommended or average dose and thus does not meet one of those conditions of the proposed regulations *not* based upon the Prescription Drug Amendment. Evidently it is intended that such a drug also shall be regarded as misbranded under Section 502(f)(1) for failure to bear adequate directions for use.

It has been noted that a principal motivation for the new law was to establish a firm statutory basis for the classification and regulation of prescription drugs, in lieu of the

existing system of Section 502(f)(1) exemptions. The committees of Congress which considered the Prescription Drug Amendment accepted the view of the Food and Drug Administration, illustrated in the *El-O-Pathic Pharmacy* case, that adequate directions could not be written for the use by laymen of certain unsafe drugs. The history of the prescription legend, as it has developed around the Rx regulations, features the incompatibility of the legend and directions for use by laymen.

It is implicit in the Prescription Drug Amendment that an unsafe drug, when shipped by the manufacturer, shall bear no directions destined for the layman, and it was patently contemplated that a drug bearing the legend should, by reason of that fact, be exempt from Section 502(f)(1). It may be questioned, therefore, by what authority the Administrator can refuse to grant to a drug in interstate commerce an exemption from the requirement of adequate directions for laymen, upon conditions foreign to the Prescription Drug Amendment which he is not specifically authorized by any other provision of law to impose. If he can establish non-statutory conditions, there seems no reason to suppose that he is limited to those named in the proposed regulations.

The situation brings to mind the decision of the Supreme Court of the United States in the recent *Imitation Jam* case.⁵³ Section 403(c) of the Act⁵⁴ provides that a food is misbranded if it is an imitation of another food "unless its label bears . . . the word 'imitation' and, immediately thereafter, the name of the food imitated." This the Supreme Court regarded as an authorization to market imitation jam in interstate commerce when labeled as such, refusing

⁵³ 62 Cases of *Jam v. United States*, 340 U.S. 593, 71 S. Ct. 515, 95 L. Ed. 566 (1951).

⁵⁴ 52 STAT. 1047 (1938), 21 U.S.C. § 343 (c) (1946) provides that a food shall be deemed to be misbranded ". . . if it is an imitation of another food, unless its label bears, in type of uniform size and prominence the word 'imitation' and, immediately thereafter, the name of the food imitated."

to accept the Government's argument that it was misbranded under another provision of the Act, Section 403(g), on the ground that it purported to be the "genuine" jam for which a Government standard had been promulgated.⁵⁵ Concededly the Supreme Court did not intend to permit the marketing of imitations regardless of how they might be misbranded under other provisions of the statute; but it evidently thought that Section 403(c) relieved imitations labeled as such from a charge of misbranding based, in effect, upon the fact that they *are* imitations.

The Prescription Drug Amendment provides that an unsafe drug shall be misbranded "if at any time prior to dispensing its label fails to bear" the prescription legend therein set forth. By reasoning parallel to that of the Supreme Court in the *Imitation Jam* case, it might well be concluded that the quoted language is an authorization to market in interstate commerce drugs which bear the prescription legend. We need not suggest that this authorization extends to all misbrandings; but it might with some force be maintained that it surely relieves unsafe drugs from a charge of misbranding based, in effect, upon the fact that they are unsafe, and it seems evident that considerations of safety are the basis for the proposed refusal to exempt drugs which fail to meet all the conditions of the regulations.

These comments have not dealt with the question of the desirability of the conditions which would be established by the proposed regulations. Some of these conditions may be useful from the standpoint both of Government and industry. It seems indeed unfortunate that, if additional authority was needed to meet the prescription drug problem, it was not obtained when the recent amendment was enacted. It

⁵⁵ 62 Cases of *Jam v. United States*, 340 U.S. 593, 600, 71 S. Ct. 515, 95 L. Ed. 566 (1951). By the terms of the statute, 52 STAT. 1047 (1938), 21 U.S.C. § 343 (g) (1946), a food is misbranded which "... purports to be or is represented to be a food for which a definition and standard of identity has been prescribed by regulations as provided by section 401 unless (1) it conforms to such definition and standard. ..."

must be recognized, however, that it is inherent in the cumbersome character of the legislative process that, at one time or another during its course, the executive must calculate to a delicate nicety the very least authority needed to gain the critical core of the legislative proposals. This was perhaps true of the Prescription Drug Amendment.

Devices and Veterinary Drugs

Sections 1.106(c) and (d) of the proposed regulations provide exemptions from the requirement of adequate directions for use for unsafe veterinary drugs and for devices, for which adequate directions cannot be prepared, upon conditions roughly similar to those imposed for drugs for human use. The Prescription Drug Amendment does not, of course, apply to devices or veterinary drugs. However, the report of the Senate Committee states: ⁵⁶

Under the committee bill, drugs intended for use under the supervision of a veterinarian will not require a prescription, although it will be possible under section 502(f) to exempt such drugs from adequate directions for use if they are to be used by or under the supervision of a veterinarian.

Presumably this indication of the Committee's attitude is regarded by the Administrator as sufficient authority to regulate prescription veterinary drugs as well as prescription devices, under Section 502(f)(1). To the extent that this regulation fails to include conditions not imposed for drugs for human beings by the Prescription Drug Amendment, the statement quoted from the Committee Report doubtless adds strength to the position of the Administrator.

Exemptions for Other Drugs and for Prescription Chemicals

Subsections (g) and (h) of Section 1.106 provide for exemptions for new drugs, which are controlled under Section 505 of the Act, and for drugs or devices when directions

⁵⁶ SEN. REP. NO. 946, 82d Cong., 1st Sess. 8 (1951).

are commonly known, which are required to meet no conditions whatever. Subsections (i) through (l) of that Section provide for exemptions for inactive ingredients, for diagnostic reagents, for prescription chemicals and other prescription components, and for bulk drugs and devices to be processed, repacked, or used in the manufacture of another drug. These exemptions do not raise the problems discussed above. Their purpose is primarily to relax statutory requirements rather than to impose another obligation. Under subsections (i) through (l) the option is given to the manufacturer either to label with adequate directions for use, except in the case of new drugs and unsafe drugs exempt under subsections (k) and (l), or, by meeting certain conditions, to take advantage of the exemption offered. This distinguishing characteristic of these provisions, as contrasted with the mandatory exemptions for unsafe drugs provided under proposed Section 1.106(b) of the regulations, is emphasized by the language of Section 1.106(n). Under this section an exemption expires if the exempt drug or device is disposed of for an unauthorized purpose, and it is provided: ⁵⁷

The causing of an exemption to expire shall be considered an act which results in such drug or device being misbranded unless it is disposed of for use otherwise than as a drug or device *or unless, in the case of a drug subject to paragraph (i), (j), (k), or (l) of this section, prior to such disposal, it is relabeled to comply with the requirements of section 502(f)(1) of the act.* [Emphasis supplied.]

An unsafe drug exempt under Section 1.106(k) or (l) cannot be relabeled with adequate directions pursuant to Section 502(f)(1) because adequate directions cannot be prepared for such a drug. This is, of course, true whether it is exempt under this section or Section 1.106(b). An over-the-counter drug which is exempt from adequate directions

⁵⁷ Proposed Rule Making, Federal Security Agency, § 1.106 (n), 17 FED. REG. 1132 (1952).

under subsections (i), (j), (k), or (l) may, however, be relabeled as provided in the provision above quoted.

Under this section of the regulations the placing of conditions upon the exemptions does not remove the choice of the manufacturer either to follow the regulation or to label the drug with adequate directions or, in the case of unsafe drugs, to follow the provisions of Section 1.106(b). The fact that, in some instances, there may be serious practical difficulties to placing directions on some preparations does not derogate from this principle. No *legal* impediment is raised by the regulations or the administrative interpretation of the law. Herein lies the contrast between the two types of exemptions. The elective type seems soundly conceived, in principle, and consistent with the terms of the statute.

The Question of Efficacy

The Rx regulations, which were superseded by the Prescription Drug Amendment, exempted a drug from the requirement of adequate directions for use if it was generally recognized by qualified experts as not being "safe" and "efficacious" for use except by or under the supervision of a physician.⁵⁸ The prescription drug bill as reported by the House Committee retained "efficacy" as one of the tests of a prescription drug.⁵⁹ This test was stricken from the bill on the House floor with the support of at least some of the majority members of the Committee which had reported the bill.⁶⁰ One member of the majority indicated that, in his opinion, the word "safe," as used in the bill, "applies to poisonous drugs, those drugs that are toxic."⁶¹

In its revision, as we have seen, the Senate Committee did not reinsert the efficacy test, but confined the scope

⁵⁸ 21 CODE FED. REGS. § 1.106 (b) (1949).

⁵⁹ H.R. REP. NO. 700, 82d Cong., 1st Sess. 1 (1951).

⁶⁰ 97 CONG. REC. 9544 (August 1, 1951).

⁶¹ Statement by Mr. Harris, *id.* at 9545.

of the bill to a drug "not safe for use except under the supervision of a practitioner licensed by law to administer such drug." This is now paragraph (1) of (B) of amended Section 503(b). However, its report states: ⁶²

This omission is not intended to mean that the only matter to be considered in applying the definition is whether or not a particular drug is poisonous.

The word "safe", as used in the definition, is intended to have its ordinary meaning. . . . When this language is given judicial interpretation consistent with the over-all purpose of the Federal Food, Drug, and Cosmetic Act to protect the public health it will effectively restrict to prescription sale all drugs that require professional supervision for their use.

The report mentions quinidine sulfate, used in heart conditions, as an example of non-toxic drugs which are not safe for self-medication "because their unsupervised use may indirectly cause injury or death." ⁶³

The interpretations, in the new regulations, of the terms "other potentiality for harmful effect" under Section 1.108 (a)(3), ⁶⁴ "method of its use" under Section 1.108(a)(4), ⁶⁵ and "collateral measures necessary to its use" in Section 1.108(a)(5), ⁶⁶ follow the implications of the preceding quotations from the report of the Senate Committee.

The question of whether the efficacy test was to be written into the amendment was regarded by the manufacturers as one of an importance second only to the matter of the administrative listing of prescription drugs itself. For ex-

⁶² SEN. REP. NO. 946, 82d Cong., 1st Sess. 4 (1951).

⁶³ *Ibid.*

⁶⁴ The term "other potentiality for harmful effect" is defined to mean "the capability of causing harm otherwise than by toxicity," for example, the masking of symptoms of a progressive disease condition by earache drops with a local anaesthetic. 17 FED. REG. 1132 (1952).

⁶⁵ The term "method of its use" means "the route, the procedures, and the equipment employed in the administration of the drug." 17 FED. REG. 1132 (1952).

⁶⁶ "The term 'collateral measures necessary to its use' includes the professional skills and laboratory and other technical tests and procedures which the practitioner . . . employs. . . ." 17 FED. REG. 1132 (1952).

ample, the inclusion of the efficacy test was characterized as "an obvious step toward socialized medicine by which the Government will elect to prescribe what medicines we shall take and under what circumstances," since questions of efficacy are far less susceptible of objective determination than are questions of toxicity.⁶⁷

It was as a result of the vigorous opposition of the manufacturers that the efficacy test was excluded. The quotation above set forth from the report of the Senate Committee and the interpretations of statutory terms proposed in the new regulations indicate, however, that, to a substantial extent, questions of efficacy are to be included within the bases upon which the Administrator will determine whether a particular drug is subject to the Prescription Drug Amendment or is available for over-the-counter sale.

V.

Conclusion

The passage of the Prescription Drug Amendment marks perhaps the most significant development in federal drug law since the enactment of the Food, Drug, and Cosmetic Act of 1938. It may be hoped that this law, and the regulations issued to implement it, will mark the end of the fundamental disagreement of legal approach which, to a considerable extent, has characterized the points of view of important elements of the industry and the Food and Drug Administration on the prescription drug problem.

The new law is generally recognized as expressive of a sound public policy. Its penetration into the operations of local businesses evokes perhaps a tinge of nostalgia for the old ideals of local autonomy and states' rights; but too often

⁶⁷ Statement of Mr. George H. Sibley, Vice President, E. R. Squibb & Sons, *Hearings*, *supra* note 43, at 154.

the states have failed to exercise their rights and have, as here, found a more powerful and effective federal authority moving in to protect the public interest. No doubt it will happen again.

*Edward Brown Williams**

APPENDIX

PUBLIC LAW 215 — 82d CONGRESS

Chapter 578 — 1st Session

H. R. 3298

AN ACT

To amend sections 303 (c) and 503 (b) of the Federal Food, Drug, and Cosmetic Act, as amended.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That subsection (b) of section 503 of the Federal Food, Drug, and Cosmetic Act, as amended, is amended to read as follows:

(b) (1) A drug intended for use by man which —

(A) is a habit-forming drug to which section 502(d) applies; or

(B) because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a practitioner licensed by law to administer such drug; or

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(C) is limited by an effective application under section 505 to use under the professional supervision of a practitioner licensed by law to administer such drug.

shall be dispensed only (i) upon a written prescription of a practitioner licensed by law to administer such drug, or (ii) upon an oral prescription of such practitioner which is reduced promptly to writing and filed by the pharmacist, or (iii) by refilling any such written or oral prescription if such refilling is authorized by the prescriber either in the original prescription or by oral order which is reduced promptly to writing and filed by the pharmacist. The act of dispensing a drug contrary to the provisions of this paragraph shall be deemed to be an act which results in the drug being misbranded while held for sale.

(2) Any drug dispensed by filling or refilling a written or oral prescription of a practitioner licensed by law to administer such drug shall be exempt from the requirements of section 502, except paragraphs (a), (i) (2) and (3), (k), and (l), and the packaging requirements of paragraphs (g) and (h), if the drug bears a label containing the name and address of the dispenser, the serial number and date of the prescription or of its filling, the name of the prescriber, and, if stated in the prescription, the name of the patient, and the directions for use and cautionary statements, if any, contained in such prescription. This exemption shall not apply to any drug dispensed in the course of the conduct of a business of dispensing drugs pursuant to diagnosis by mail, or to a drug dispensed in violation of paragraph (1) of this subsection.

(3) The Administrator may by regulation remove drugs subject to section 502 (d) and section 505 from the requirements of paragraph (1) of this subsection when such requirements are not necessary for the protection of the public health.

(4) A drug which is subject to paragraph (1) of this subsection shall be deemed to be misbranded if at any time prior to dispensing its label fails to bear the statement "Caution: Federal law prohibits dispensing without prescription". A drug to which paragraph (1) of this subsection does not apply shall be deemed to be misbranded if at any time prior to dispensing its label bears the caution statement quoted in the preceding sentence.

(5) Nothing in this subsection shall be construed to relieve any person from any requirement prescribed by or under authority of law with respect to drugs now included or which may hereafter be included within the classifications stated in section 3220 of the Internal Revenue Code (26 U.S.C. 3220), or to marihuana as defined in section 3238 (b) of the Internal Revenue Code (26 U.S.C. 3238 (b)).

Sec. 2. Subsection (c) of section 303 of the Federal Food, Drug, and Cosmetic Act, as amended, is amended by striking out the period at the end of clause (3) and inserting in lieu thereof a semicolon and the following: "or (4) for having violated section 301(b), (c) or (k) by failure to comply with section 502 (f) in respect to an article received in interstate commerce to which neither section 503 (a) nor section 503(b) (1) is applicable, if the delivery or proffered delivery was made in good faith and the labeling at the time thereof contained the same directions for use and warning statements as were contained in the labeling at the time of such receipt of such article."

Sec. 3. The provisions of this Act shall take effect six months after the date of its enactment.

Approved October 26, 1951.