

United States Vs. Sullivan

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SooperKanoon Citation : sooperkanoon.com/98282

Court : US Supreme Court

Decided On : Jan-19-1948

Appeal No. : 332 U.S. 689

Appellant : United States

Respondent : Sullivan

Judgement :

United States v. Sullivan - 332 U.S. 689 (1948)

U.S. Supreme Court United States v. Sullivan, 332 U.S. 689 (1948)

United States v. Sullivan

No. 121

Argued December 9, 1947

Decided January 19, 1948

332 U.S. 689

CERTIORARI TO THE CIRCUIT COURT OF APPEALS

FOR THE FIFTH CIRCUIT

SYLLABUS

1. It is a violation of 301(k) of the Federal Food, Drug, and Cosmetic Act of 1938 for a retail druggist who has purchased sulfathiazole tablets from a wholesaler in the same State (who had obtained them by way of an interstate shipment) to remove a dozen of them from a properly labeled bulk container in which they were shipped in interstate commerce and in which they were being held for resale, place them in a pill box labeled "sulfathiazole" but not containing the statutorily required directions for use or warnings of danger, and sell them locally to a retail purchaser. Pp. [332 U. S. 695](#) -697.

(a) The removal of drugs from a container labeled in accordance with the requirements of the Act to one not so labeled is the doing of an act which results in their being "misbranded" within the meaning of 301(k). P. [332 U. S. 695](#) .

(b) Although a previous intrastate sale had occurred following the interstate shipment, and although the retail sale in question occurred over six months after completion of the shipment in interstate commerce, the sulfathiazole tablets in this case were "held for sale after shipment in interstate commerce" within the meaning of 301(k). Pp. [332 U. S. 695](#) -696.

(c) The purpose of the Act is to safeguard the consumer by applying its requirements to articles from the moment of their introduction into interstate commerce all the way to the moment of their delivery to the ultimate consumer. Pp. [332 U. S. 696](#) -697.

2. As thus construed, the Act does not exceed the constitutional power of Congress under the Commerce Clause or invade the powers reserved to the states. *McDennott v. Wisconsin*, [228 U. S. 115](#) . Pp. [332 U. S. 697](#) -698.

3. A restrictive interpretation should not be given a statute merely because Congress has chosen to depart from custom or because

giving effect to the express language employed by Congress might require a court to face a constitutional question. Pp. [332 U. S. 692](#) -694.

4. The scope of the offense which Congress defined in, 301(k) of the Act is not to be judicially narrowed as applied to drugs by envisioning extreme possible applications of its provisions relating to food and cosmetics, especially in view of the broad discretion given the Administrator to excuse minor violations with a warning and to issue regulations exempting many articles from the labeling requirements when compliance is impractical. Pp. 332 U. S. 694 -695.

161 F.2d 629 reversed.

Respondent was convicted in a Federal District Court of violating 301(k) of the Federal Food, Drug, and Cosmetic Act of 1938. 67 F.Supp. 192. The Circuit Court of Appeals reversed. 161 F.2d 629. This Court granted certiorari. 332 U.S. 753. *Reversed*, p. [332 U. S. 698](#) .

MR. JUSTICE BLACK delivered the opinion of the Court.

Respondent, a retail druggist in Columbus, Georgia, was charged in two counts of an information with a violation of 301(k) of the Federal Food, Drug, and Cosmetic Act of 1938. That section prohibits

"the doing of any . . . act with respect to a . . . drug . . . if such act is done while such article is held for sale after shipment in interstate commerce and results in such article's being misbranded. [[Footnote 1](#)]"

Section 502(f) of the Act declares a drug

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"to be misbranded . . . unless its labeling bears (1) adequate directions for use, and (2) such adequate warnings against use . . . dangerous to health, or against unsafe dosage . . . as are necessary for the protection of users."

The information charged specifically that the respondent had performed certain acts which resulted in sulfathiazole's being "misbranded" while "held for sale after shipment in interstate commerce."

The facts alleged were these: a laboratory had shipped in interstate commerce from Chicago, Illinois, to a consignee at Atlanta, Georgia, a number of bottles, each containing 1,000 sulfathiazole tablets. These bottles had labels affixed to them, which, as required by 502(f)(1) and (2) of the Act, set out adequate directions for the use of the tablets and adequate warnings to protect ultimate consumers from dangers incident to this use. [[Footnote 2](#)] Respondent bought one of these properly labeled bottles of sulfathiazole tablets from the Atlanta consignee, transferred it to his Columbus, Georgia, drugstore, and there held the tablets for resale. On two separate occasions,

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twelve tablets were removed from the properly labeled and branded bottle, placed in pill boxes, and sold to customers. These boxes were labeled "sulfathiazole." They did not contain the statutorily required adequate directions for use or warnings of danger.

Respondent's motion to dismiss the information was overruled, a jury was waived, evidence was heard, and respondent was convicted under both counts. 67 F.Supp. 192.

The Circuit Court of Appeals reversed. 161 F.2d 629, 630. The court thought that, as a result of respondent's action, the sulfathiazole became "misbranded" within the meaning of the Federal Act, and that, in its "broadest possible sense," the Act's language "may include what happened." However, it was also of the opinion that the Act ought not to be taken so broadly, "but held to apply only to the holding for the first sale by the importer after interstate shipment." Thus, the Circuit Court of Appeals interpreted the statutory language of 301(k) "while such article is held for sale after shipment in interstate commerce" as though Congress had said "while such article is held for sale by a person who had himself received it by way of a

shipment in interstate commerce." We granted certiorari to review this important question concerning the Act's coverage.

First. The narrow construction given 301(k) rested not so much upon its language as upon the Circuit Court's view of the consequences that might result from the broader interpretation urged by the Government. The court pointed out that the retail sales here involved were made in Columbus nine months after this sulfathiazole had been shipped from Chicago to Atlanta. It was impressed by the fact that, if the statutory language "while such article is held for sale after shipment in interstate commerce" should be given its literal meaning, the criminal provisions relied on would

"apply to all intrastate

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sales of imported drugs after any number of intermediate sales within the State, and after any lapse of time, and not only to such sales of drugs, but also to similar retail sales of foods, devices, and cosmetics, for all these are equally covered by these provisions of the Act."

The court emphasized that such consequences would result in far-reaching inroads upon customary control by local authorities of traditionally local activities, and that a purpose to afford local retail purchasers federal protection from harmful foods, drugs, and cosmetics should not be ascribed to Congress in the absence of an exceptionally clear mandate, citing *Federal Trade Commission v. Bunte Bros.*, [312 U. S. 349](#) . Another reason of the court for refraining from construing the Act as applicable to articles misbranded while held for retail sale, even though the articles had previously been shipped in interstate commerce, was its opinion that such a construction would raise grave doubts as to the Act's constitutionality. In support of this position, the court cited *Labor Board v. Jones & Laughlin Steel Corporation*, [301 U. S. 1](#) , [301 U. S. 30](#) , and *Schechter Poultry Corporation v. United States*, [295 U. S. 495](#) .

A restrictive interpretation should not be given a statute merely because Congress has chosen to depart from custom or because giving effect to the express language employed by Congress might require a court to face a constitutional question. And none of the foregoing cases, nor any other on which they relied, authorizes a court in interpreting a statute to depart from its clear meaning. When it is reasonably plain that Congress meant its Act to prohibit certain conduct, no one of the above references justifies a distortion of the congressional purpose, not even if the clearly correct purpose makes marked deviations from custom or leads inevitably to a holding of constitutional invalidity. Although criminal statutes must be so precise and unambiguous that the ordinary person can know how to avoid unlawful conduct, See [Kraus & Bros.](#),

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Inc. v. United States, [327 U. S. 614](#) , [327 U. S. 621](#) -622, even in determining whether such statutes meet that test, they should be given their fair meaning in accord with the evident intent of Congress. *United States v. Raynor*, [302 U. S. 540](#) , [302 U. S. 552](#) .

Second. Another consideration that moved the Circuit Court of Appeals to give the statute a narrow construction was its belief that the holding in this case with reference to misbranding of drugs by a retail druggist would necessarily apply also to "similar retail sales of foods, devices and cosmetics, for all these," the court said, "are equally covered by these provisions of the Act." And, in this Court, the effect of such a possible coverage of the Act is graphically magnified. We are told that its application to these local sales of sulfathiazole would logically require all retail grocers and beauty parlor operators to reproduce the bulk container labels on each individual item when it is taken from the container to sell to a purchaser. It is even prophesied that, if 301(k) is given the interpretation urged by the Government, it will later be applied so as to require retail merchants to label sticks of candy and sardines when removed from their containers for sale.

The scope of the offense which Congress defined is not to be judicially narrowed as applied to drugs by envisioning extreme possible applications of its different

misbranding provisions which relate to food, cosmetics, and the like. There will be opportunity enough to consider such contingencies should they ever arise. It may now be noted, however, that the Administrator of the Act is given rather broad discretion -- broad enough undoubtedly to enable him to perform his duties fairly without wasting his efforts on what may be no more than technical infractions of law. As an illustration of the Administrator's discretion, 306 permits him to excuse minor violations with a warning if he believes that the public interest will thereby be adequately

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served. And the Administrator is given extensive authority under 405, 503, and 603 to issue regulations exempting from the labeling requirements many articles that otherwise would fall within this portion of the Act. The provisions of 405 with regard to food apparently are broad enough to permit the relaxation of some of the labeling requirements which might otherwise impose a burden on retailers out of proportion to their value to the consumer.

Third. When we seek the meaning of 301(k) from its language, we find that the offense it creates and which is here charged requires the doing of some act with respect to a drug (1) which results in its being misbranded, (2) while the article is held for sale "after shipment in interstate commerce." Respondent has not seriously contended that the "misbranded" portion of 301(k) is ambiguous. Section 502(f), as has been seen, provides that a drug is misbranded unless the labeling contains adequate directions and adequate warnings. The labeling here did not contain the information which 502(f) requires. There is a suggestion here that, although alteration, mutilation, destruction, or obliteration of the bottle label would have been a "misbranding," transferring the pills to nonbranded boxes would not have been, so long as the labeling on the empty bottle was not disturbed. Such an argument cannot be sustained. For the chief purpose of forbidding the destruction of the label is to keep it intact for the information and protection of the consumer. That purpose would be frustrated when the pills the consumer buys are not labeled as required, whether the label has been torn from the original container or the pills have been transferred from it to a nonlabeled one. We find no ambiguity in

the misbranding language of the Act.

Furthermore, it would require great ingenuity to discover ambiguity in the additional requirement of 301(k)

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that the misbranding occur "while such article is held for sale after shipment in interstate commerce." The words accurately describe respondent's conduct here. He held the drugs for sale after they had been shipped in interstate commerce from Chicago to Atlanta. It is true that respondent bought them over six months after the interstate shipment had been completed by their delivery to another consignee. But the language used by Congress broadly and unqualifiedly prohibits misbranding articles held for sale after shipment in interstate commerce, without regard to how long after the shipment the misbranding occurred, how many intrastate sales had intervened, or who had received the articles at the end of the interstate shipment. Accordingly, we find that the conduct of the respondent falls within the literal language of 301(k).

Fourth. Given the meaning that we have found the literal language of 301(k) to have, it is thoroughly consistent with the general aims and purposes of the Act. For the Act as a whole was designed primarily to protect consumers from dangerous products. This Court so recognized in *United States v. Dotterweich*, [320 U. S. 277](#) , [320 U. S. 282](#) , after reviewing the House and Senate Committee Reports on the bill that became law. Its purpose was to safeguard the consumer by applying the Act to articles from the moment of their introduction into interstate commerce all the way to the moment of their delivery to the ultimate consumer. Section 301(a) forbids the "introduction or delivery for introduction into interstate commerce" of misbranded or adulterated drugs; 301(b) forbids the misbranding or adulteration of drugs while "in interstate commerce;" and 301(c) prohibits the "receipt in interstate commerce" of any misbranded or adulterated drug, and "the delivery or proffered delivery thereof for pay or otherwise." But these three paragraphs alone would not supply protection all the way to the consumer. The words of paragraph (k) "while

such article is held for sale after shipment in interstate commerce" apparently were designed to fill this gap, and to extend the Act's coverage to every article that had gone through interstate commerce until it finally reached the ultimate consumer. Doubtless it was this purpose to insure federal protection until the very moment the articles passed into the hands of the consumer by way of an intrastate transaction that moved the House Committee on Interstate and Foreign Commerce to report on this section of the Act as follows:

"In order to extend the protection of consumers contemplated by the law to the full extent constitutionally possible, paragraph (k) has been inserted prohibiting the changing of labels so as to misbrand articles held for sale after interstate shipment. [[Footnote 3](#)]"

We hold that 301(k) prohibits the misbranding charged in the information.

Fifth. It is contended that the Act as we have construed it is beyond any authority granted Congress by the Constitution, and that it invades the powers reserved to the States. A similar challenge was made against the Pure Food and Drug Act of 1906, 34 Stat. 768, and rejected, in *McDermott v. Wisconsin*, [228 U. S. 115](#) . That Act did not contain 301(k), but it did prohibit misbranding and authorized seizure of misbranded articles after they were shipped from one State to another, so long as they remained "unsold." The authority of Congress to make this requirement was upheld as a proper exercise of its powers under the commerce clause. There are two variants between the circumstances of that case and this one. In the *McDermott* case, the labels involved were on the original containers; here, the labels are required to be put on other than the original containers -- the boxes to which the tablets were transferred. Also, in the *McDermott* case, the possessor of the labeled cans held for sale had

himself receive them by way of an interstate sale and shipment; here, while the petitioner had received the sulfathiazole by way of an intrastate sale and shipment,

he bought it from a wholesaler who had received it as the direct consignee of an interstate shipment. These variants are not sufficient, we think, to detract from the applicability of the *McDermott* holding to the present decision. In both cases alike, the question relates to the constitutional power of Congress under the commerce clause to regulate the branding of articles that have completed an interstate shipment and are being held for future sales in purely local or intrastate commerce. The reasons given for the *McDermott* holding, therefore, are equally applicable and persuasive here. And many cases decided since the *McDermott* decision lend support to the validity of 301(k). See, e.g., *United States v. Walsh*, [331 U. S. 432](#) ; *Wickard v. Filburn*, [317 U. S. 111](#) ; *United States v. Wrightwood Dairy Co.*, [315 U. S. 110](#) ; *United States v. Darby*, [312 U. S. 100](#) ; see *United States v. Olsen*, 161 F.2d 669.

Reversed.

[[Footnote 1](#)]

"Sec. 301. The following acts and the causing thereof are hereby prohibited:"

" * * * *"

"(k) 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 after shipment in interstate commerce and results in such article's being misbranded."

52 Stat. 1042, 21 U.S.C. 331(k).

[[Footnote 2](#)]

The following inscription appeared on the bottle labels as a compliance with 502(f)(1) which requires directions as to use: "Caution. -- To be used only by or on the prescription of a physician." This would appear to constitute adequate directions, since it is required by regulation issued by the Administrator pursuant to authority of the Act. 21 C.F.R.Cum.Supp. 2.106(b)(3). The following appeared on the label of the bottles as a compliance with 502(f)(2) which requires warnings of

danger:

"Warning. -- In some individuals, Sulfathiazole may cause severe toxic reactions. Daily blood counts for evidence of anemia or leukopenia and urine examinations for hematuria are recommended."

"Physicians should familiarize themselves with the use of this product before it is administered. A circular giving full directions and contraindications will be furnished upon request."

[[Footnote 3](#)]

H.Rep. 2139, 75th Cong., 3d Sess., 3.

MR. JUSTICE RUTLEDGE, concurring.

This case has been presented as if the Federal Food, Drug, and Cosmetic Act of 1938 had posed an inescapable dilemma. It is said that we must either (1) ignore Congress' obvious intention to protect ultimate consumers of drugs through labeling requirements literally and plainly made applicable to the sales in this case, or (2) make criminal every corner grocer who takes a stick of candy from a properly labeled container and sells it to a child without wrapping it in a similar label.

The troublemaking factor is not found in the statute's provisions relating specifically to drugs. Those provisions, taken by themselves, are clear and unequivocal in

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the expressed purpose to protect the ultimate consumer by the labeling requirements. So is the legislative history. Standing alone, therefore, the drug provisions would cover this case without room for serious question.

However, those provisions do not stand entirely separate and independent in the Act's structure. In some respects, particularly in 301(k), they are interlaced with

provisions affecting food and cosmetics. And from this fact is drawn the conclusion that this decision necessarily will control future decisions concerning those very different commodities.

If the statute as written required this, furnishing no substantial basis for differentiating such cases, the decision here would be more difficult than I conceive it to be. But I do not think the statute has laid the trap with which we are said to be faced. Only an oversimplified view of its terms and effects could produce that result.

The Act is long and complicated. Its numerous provisions treat the very different subjects of drugs, food, and cosmetics alike in some respects, differently in others. The differences are as important as the similarities, and cannot be ignored. More is necessary for construction of the statute than looking merely to the terms of 301(k) and 502(f).

It is true that 301(k) deals indiscriminately with food, drugs, devices, and cosmetics, on the surface of its terms alone. Hence, it is said that the transfer of sulfathiazole, a highly dangerous drug, from a bulk container to a small box for retail sale could not be "any other act" unless a similar transfer of candies, usually harmless, also would be "any other act." From this hypothesis, it is then concluded that the phrase must be interpreted with reference to the particularities which precede it -- namely, "alteration, mutilation, destruction, obliteration,

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or removal" of any part of the label, and must be limited by those particularities.

That construction almost, if not quite, removes "any other act" from the section. And, by doing so, it goes far to emasculate the section's effective enforcement, especially in relation to drugs. Any dealer holding drugs for sale after shipment in interstate commerce could avoid the statute's effect simply by leaving the label intact, removing the contents from the bulk container, and selling them, however deadly, in broken parcels without label or warning.

I do not think Congress meant the phrase to be so disastrously limited. For the "doing of any other act with respect to, a food, drug, device, or cosmetic" is prohibited by 301(k) only "if such act . . . results in such article's being misbranded." And the statute provides not a single common definition of misbranding for foods, drugs, and cosmetics, but separate and differing sections on misbranded foods, misbranded drugs and devices, and misbranded cosmetics. 403, 502, 602.

The term "misbranded," as used in 301(k), therefore is not one of uniform connotation. On the contrary, its meaning is variable in relation to the different commodities and the sections defining their misbranding. So also necessarily is the meaning of "any other act" which produces those misbranding consequences. Each of the three sections therefore must be taken into account in determining the meaning and intended scope of application for 301(k) in relation to the specific type of commodity involved in the particular sale, if Congress' will is not to be overridden by broadside generalization glossed upon the statute. As might have been expected, Congress did not lump food, drugs, and cosmetics in one indiscriminate hopper for the purpose of applying 301(k), either in respect to misbranding or as to "any other

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act" which produces that consequence. Brief reference to the several misbranding sections incorporated by reference in 301(k) substantiates this conclusion.

The three sections contain some common provisions. [[Footnote 2/1](#)] But the fact that each section is also different from the other two in important respects indicates that each broad subdivision of the Act presents different problems of interpretation. Neither the misbranded foods section nor the misbranded cosmetics section contains any provision directly comparable to 502(f), which the respondent here has violated. That section, however, is to be contrasted with 403(k), one of the subsections dealing with misbranded foods. Comparison of the two provisions indicates that the doing of a particular act with respect to a drug may result in misbranding, whereas the same method of selling food would be proper.

Section 502(f) provides that a drug shall be deemed to be misbranded:

"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."

This provision, dealing with directions for use and warnings against improper use, in terms is designed "for the protection of users." To be effective, this protection

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requires regulations of the label which the container bears when the drug reaches the ultimate consumer. [[Footnote 2/2](#)] The legislative history leaves no doubt that the draftsmen and sponsors realized the importance of having dangerous drugs properly labeled at the time of use, not just at the time of sale. [[Footnote 2/3](#)] The intent to protect the public health is further emphasized by the limited scope of the proviso, which directs the Administrator to make exemptions only when compliance with clause (1) "is not necessary for the protection of the public health."

Section 403(k), which contains the principal basis for "making every retail grocer a criminal," is very different. By its terms, food is deemed to be misbranded:

"If it bears or contains any artificial flavoring, artificial coloring, or chemical preservative, unless it bears labeling stating that fact: *Provided*, That to the extent that compliance with the requirements of this paragraph is impracticable, exemptions shall be established by regulations promulgated by the Administrator. The provisions of this paragraph and paragraphs (g) and (i) with respect to artificial coloring shall not apply in the case of butter, cheese, or ice cream."

The section, in contrast to 502(f)'s coverage of drugs, applies not to all foods shipped interstate, but only to the restricted classes containing artificial flavoring or coloring or chemical preservatives. The labeling requirement is much simpler. And the proviso confers a much broader power of exemption upon the Administrator than does the proviso of 502(f). Under the latter, he is given no power to exempt on the ground that compliance is impracticable. He cannot weigh business

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convenience against protection of the public health. Only where he finds that labeling is not necessary to that protection is he authorized to create an exemption for drugs and devices. Health security is not only the first, it is the exclusive, criterion.

Under 403(k), however, in dealing with foods, the Administrator can dispense with labels much more broadly. In terms, the criterion for his action becomes "the extent that compliance . . . is impracticable," rather than, as under 502(f), "where any requirement of clause (1) [adequate directions for use] . . . is not necessary for the protection of the public health." Practical considerations affecting the burden of compliance by manufacturers and retailers, irrelevant under 502(f), become controlling under 403(k). Thus, under the statute's intent, a much more rigid and invariable compliance with the labeling requirements for drugs is contemplated than for those with foods, apart from its greatly narrower coverage of the latter. And the difficulty of compliance with those requirements for such articles as candies explains the difference in the two provisos. [[Footnote 2/4](#)]

These differences, and particularly the differences in the provisos, have a direct and an intended relation to the

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problem of enforcement. The labeling requirements for foods are given much narrower and more selective scope for application than those for drugs -- a difference magnified by the conversely differing room allowed for exemptions. What is perhaps equally important, the provisos are relevant to enforcement

beyond specific action taken by the Administrator to create exemptions.

His duty under both sections is cast in mandatory terms. Whether or not he can be forced by mandamus to act in certain situations, his failure to act in some would seem to be clearly in violation of his duty. Obviously there must be many more instances where compliance with the labeling requirements for foods will be "impracticable" than where compliance with the very different requirements for drugs will not be "necessary for the protection of the public health." That difference is obviously important for enforcement, particularly by criminal prosecution. I think it is one which courts are entitled to take into account when called upon to punish violations. The authors of the legislation recognized expressly that "technical, innocent violations . . . will frequently arise." S.Rep. No. 152, 75th Cong., 1st Sess. 4. In other words, there will be conduct which may be prohibited by the Act's literal wording, but which nevertheless should be immune to prosecution.

When that situation arises, as it often may with reference to foods, by virtue of the Administrator's failure to discharge his duty to create exemptions before the dealer's questioned action takes place, that failure, in my judgment, is a matter for the court's consideration in determining whether prosecution should proceed. Whenever it is made to appear that the violation is a "technical, innocent" one, an act for which the Administrator should have made exemption as required by 403(k), the prosecution should be stopped. This Court has not hesitated

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to direct retroactive administrative determination of private rights when that unusual course seemed to it the appropriate solution for their determination. *Addison v. Holly Hill Fruit Products*, [322 U. S. 607](#) . If that is permissible in civil litigation, there is much greater reason for the analogous step of taking into account in a criminal prosecution an administrative officer's failure to act when the commanded action, if taken, would have made prosecution impossible.

It is clear, therefore, that the corner grocer occupies no such position of jeopardy under this legislation as the druggist, and that the meaning of 301(k) is not

identical for the two, either as to what amounts to misbranding or as to what is "the doing of any . . . act" creating that result. The supposed dilemma is false. Congress had power to impose the drug restrictions, they are clearly applicable to this case, the decision does not rule the corner grocer selling candy, and the judgment should be reversed. I therefore join in the Court's judgment and opinion to that effect.

[[Footnote 2/1](#)]

E.g., 403(a), 502(a) and 602(a) are in identical language.

[[Footnote 2/2](#)]

See S.Rep. No.361, 74th Cong., 1st Sess.19.

[[Footnote 2/3](#)]

See H.R.Rep. No.2139, 75th Cong., 3d Sess. 8.

[[Footnote 2/4](#)]

"The proviso of this paragraph likewise requires the establishment of regulations exempting packages of assorted foods from the naming of ingredients or from their appearance in the order of predominance by weight where, under good manufacturing practice, label declaration of such information is impracticable. This provision will be particularly applicable, for example, to assorted confections which, under normal manufacturing practices, may vary from package to package not only with respect to identity of ingredients, but also in regard to the relative proportions of such ingredients as are common to all packages."

S.Rep. No.493, 73d Cong., 2d Sess. (1912). The proviso discussed is in 403(i), not in 403(k), but the discussion brings out the sort of considerations which require exemption when compliance is impracticable.

MR. JUSTICE FRANKFURTER, dissenting.

If it takes nine pages to determine the scope of a statute, its meaning can hardly be so clear that he who runs may read, or that even he who reads may read. Generalities regarding the effect to be given to the "clear meaning" of a statute do not make the meaning of a particular statute "clear." The Court's opinion barely faces what, on the balance of considerations, seems to me to be the controlling difficulty in its rendering of 301(k) of the Federal Food, Drug, and Cosmetic Act, 52 Stat. 1040, 1042, 21 U.S.C. 331(k). That section no doubt relates to articles "held for sale after shipment in interstate commerce and results in such article's being misbranded." But an article is "misbranded"

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only if there is

"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."

Here, there was no "alteration, mutilation, destruction, obliteration, or removal" of any part of the label. The decisive question is whether taking a unit from a container and putting it in a bag, whether it be food, drug or cosmetic, is doing "any other act" in the context in which that phrase is used in the setting of the Federal Food, Drug, and Cosmetic Act, and particularly of 301(k). *

As bearing upon the appropriate answer to this question, it cannot be that a transfer from a jar, the bulk container, to a small paper bag, without transferring the label of the jar to the paper bag is "any other act" when applied to a drug, but not "any other act" when applied to candies or cosmetics. Before we reach the possible discretion that may be exercised in prosecuting a certain conduct, it must be determined whether there is anything to prosecute. Therefore, it cannot be put off to some other day to determine whether "any other act" in 301(k) applies to the ordinary retail sale of candies or cosmetics in every drug store or grocery throughout the land, and so places every corner grocery and drug store under the hazard that the Administrator may report such conduct for prosecution. That

question is now here. It is part of this very case, for the simple reason that the prohibited conduct of 301(k) applies with equal force, through the same phrase, to food, drugs, and cosmetics insofar as they are required to be labeled. See 403, 502, and 602 of the Act.

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It is this inescapable conjunction of food, drugs, and cosmetics in the prohibition of 301(k) that calls for a consideration of the phrase "or the doing of any other act" in the context of the rest of the sentence and with due regard for the important fact that the States are also deeply concerned with the protection of the health and welfare of their citizens on transactions peculiarly within local enforcing powers. So considered, "the doing of any other act" should be read with the meaning which radiates to that loose phrase from the particularities that precede it -- namely "alteration, mutilation, destruction, obliteration, or removal" of any part of the label. To disregard all these considerations and then find "a clear meaning" is to reach a sum by omitting figures to be added. There is nothing in the legislative history of the Act, including the excerpt from the Committee Report on which reliance is placed, to give the slightest basis for inferring that Congress contemplated what the Court now finds in the statute. The statute in its entirety was, of course, intended to protect the ultimate consumer. This is no more true in regard to the requirements pertaining to drugs than of those pertaining to food. As to the reach of the statute -- the means by which its ultimate purpose is to be achieved -- the legislative history sheds precisely the same light on the provisions pertaining to food as on the provisions pertaining to drugs. If differentiations are to be made in the enforcement of the Act and in the meaning which the ordinary person is to derive from the Act, such differentiations are interpolations of construction. They are not expressions by Congress.

In the light of this approach to the problem of construction presented by this Act, I would affirm the judgment below.

MR. JUSTICE REED and Mr. JUSTICE JACKSON join in this dissent.

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"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 after shipment in interstate commerce and results in such article's being misbranded."

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