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Appendix B

The Legislative History of Section 801(e)(1)(B) of the Federal Food, Drug, and Cosmetic Act Demonstrates that FDA Has the Burden of Proving that Export of a Food or Cosmetic Violates Foreign Law

Section 801(e)(1)(B) of the Food , Drug, and Cosmetic Act (FD&C Act) provides that a food or cosmetic intended for export shall not be deemed to be adulterated or misbranded under the act if it:

(B) is not in conflict with the laws of the country to which it is intended for export.

This Appendix summarizes the legislative history of this provision. It establishes that (1) under the predecessor provision in the Federal Food and Drugs Act of 1906, the implementing FDA regulation took the position that the exporter was not required to furnish evidence that exported products comply with the laws of a foreign country, (2) FDA attempted but failed to persuade Congress to change that statutory approach during the consideration of the legislation that became the FD&C Act of 1938, (3) Congress explicitly amended the pending legislation in 1937 to retain the burden of proving a violation of foreign law on FDA, and (4) Congress stated in 1938 that the new law made “no substantial change” from the export provision in the 1906 Act.

I. The Federal Food and Drugs Act of 1906

Although the first bill to establish comprehensive federal regulation of domestic commerce in food and drugs was introduced in 1879, final legislation was not enacted until 1906.¹ Section 2 of the 1906 Act explicitly prohibited the “shipment to any foreign country” of any adulterated or misbranded food or drug, subject to the following exception:

Provided. That no article shall be deemed misbranded or adulterated within the provisions of this Act when intended for export to any foreign country and prepared or packed according to the specifications or directions of the foreign purchaser when no substance is used in the preparation or packing thereof in conflict with the laws of the foreign country to which said article is intended to be shipped; but if said article shall be in fact sold or offered for sale for domestic use or consumption, then this proviso shall not exempt said article from the operation of any of the other provisions of this Act.

This provision remained unchanged throughout the entire life of the 1906 Act.

¹ 34 Stat. 768 (1906).

Some of the food and drug bills considered by Congress prior to 1906 would have banned the export of any product that did not meet the same requirements as domestic products.² The 1906 legislation, however, unambiguously exempted exported products. Prior to the Senate debate, there was no significant discussion of this export provision. The House Report did nothing more than relate the impact of the legislation on export of regulated products, and concentrated instead on other contested provisions.³ The Senate Report was less than a page long.⁴

The rationale for the export provision was the subject of extended discussion during the Senate debate on the legislation. Senator Lodge introduced an amendment designed to make certain that United States manufacturers could pack hams in borax for shipment to Great Britain, where this practice was lawful.⁵ Senator McCumber and Senator Heyburn responded that the proviso in Section 2 already permitted such export and that a further amendment was unnecessary.⁶ Senator Heyburn, the Chairman of the Committee on Manufactures which had reported out the legislation, explained the reasons for the export proviso as follows:

Mr. HEYBURN. Mr. President, if I may add to the suggestions of the Senator from North Dakota, I will state the provisions of the bill are sufficiently drastic and specific to prohibit the transportation from State to State of this class of articles that come within the exception as to the export trade. Then we were met with the proposition that we should not attempt to enforce upon other countries the same morals in this business that we thought sufficient for our own, provided that they themselves did not think these restrictions were necessary. So, having prohibited interstate commerce in this class of articles among our own States, for which we are responsible, we made the exception that if a foreign country entertained different views in regard to the desirability of this class of packing we would not run counter to them and shut out the export trade from doing business with them simply because they ought not to be compelled to comply with restrictions necessarily adopted for our own country. That was the reason for this exceptional provision.

The Senator will find in the body of the bill that the class of articles that are within the exception as applied to the export trade are absolutely prohibited as between our own States. We are protecting our own people,

² *E.g.*, S. 3342, 57th Cong., 1st Sess. (1902); S. Rep. No. 972, 57th Cong., 1st Sess. (1902).

³ H.R. Rep. No. 2118, 59th Cong., 1st Sess. 1 (1906).

⁴ S. Rep. No. 8, 59th Cong., 1st Sess. (1905).

⁵ 40 Cong. Rec. 1129 (January 16, 1906).

⁶ *Id.* at 1129-1130. A colloquy between Senator McCumber and Senator Spooner clarified that the requirement of the proviso that the exported article not “conflict with the laws of the foreign country” was satisfied if there was no foreign law covering the matter. *Id.* at 1130.

and then we are protecting the people of other countries from imposition at the hands of our own people only to the limit that they demand such protection. But we are applying the same rule to the people governed under the laws of other countries that we apply to people governed under our own laws. That is the reason for the exception.⁷

When Senator Spooner objected on the ground that this failed adequately to protect foreign consumers, Senator Heyburn offered these further views on the matter:

The committee spent weeks and months in the consideration of this measure at this and other sessions of Congress, and we have inquired into the conditions to which this legislation was directed. That provision was not incorporated into the bill until it became apparent that there was a certain class of our export trade that did business, with the consent of the laws of the countries under which those live with whom they did business, with people who do not entertain the same views as are entertained in this country in regard to what may be necessary to preserve human health.

In other words, we ship from this country vast quantities of horse meat to be used in certain foreign countries. We do not use it at home at all. A dealer in the State of Oregon told me, having been in the business, as he said, five years, that not one single pound of that commodity had been used or consumed in this country, but that he found a market for it in the countries of Europe.

Now, if those people want that kind of a commodity, if they are presumed to be intelligent enough to determine what they want and what is conducive to their health or destructive of it, and are convinced that they have no objection to that class of commerce or commodity, there is no reason why we should constitute ourselves the guardian of their health. It is not for us to say -- except it would not be permitted to go beyond a certain line, and neither do we in this bill -- that those people shall not, in the exercise of their judgment, consume a certain class of articles.⁸

After additional spirited discussion, the Lodge amendment did not proceed to a vote at that time.⁹ Following further attempts at a compromise between Senator Heyburn and Senator Lodge¹⁰ and still further discussion,¹¹ Senator Heyburn stated that he personally felt that "the standard of our

⁷ *Id.* at 1130.

⁸ *Id.* at 1131.

⁹ *Id.* at 1135; 40 Cong. Rec. 1216 (January 18, 1906).

¹⁰ 40 Cong. Rec. 2720-2721 (February 20, 1906).

¹¹ *Id.* at 2729.

products for export should be up to the standard of our products for home consumption”¹² but that the Committee on Manufactures had voted to include the export proviso in the bill. When the final votes were taken on the Senate amendments and bill, Senator Spooner offered no objection or amendment to the export proviso and the Lodge amendment as modified in conformance with the compromise colloquy with Senator Heyburn was accepted.¹³ The Lodge amendment was not discussed or presented during the House debate,¹⁴ however, and was dropped in conference.¹⁵ Thus, the proviso in Section 2 was the sole export provision in the 1906 Act.

The first publication analyzing the 1906 Act simply paraphrased the provisions relating to export of food and drugs and provided no additional insight.¹⁶ It suggested, however, that the export proviso:

appears to be to permit the use in certain food products for export to foreign countries, of preservatives which are considered deleterious under the strict rulings of the Department of Agriculture.¹⁷

The regulations promulgated by FDA immediately after enactment of the new law contained the following pertinent provisions:

Regulation 31. Preparation of Food Products for Export.

(Section 2.)

- (a) Food products intended for export may contain added substances not permitted in foods intended for interstate commerce, when the addition of such substances does not conflict with the laws of the country to which the food products are to be exported and when such substances are added in accordance with the directions of the foreign purchaser or his agent.
- (b) The exporter is not required to furnish evidence that goods have been prepared or packed in compliance with the laws of the foreign

¹² *Id.* at 2730.

¹³ 40 Cong. Rec. 2769 (February 21, 1906).

¹⁴ A simple amendment to permit one percent borax as a food preservative was defeated. 40 Cong. Rec. 9075 (June 25, 1906).

¹⁵ S. Doc. No. 521, 59th Cong., 1st Sess. (1906); H.R. Rep. No. 5056, 59th Cong., 1st Sess. (1906); H.R. Rep. No. 5096, 59th Cong., 1st Sess. 1906).

¹⁶ Arthur P. Greeley, *The Food and Drugs Act June 30, 1906: A Study* 9 (1907).

¹⁷ *Id.*

country to which said goods are intended to be shipped, but such shipment is made at his own risk.

- (c) Food products for export under this regulation shall be kept separate and labeled to indicate that they are for export.
- (d) If the products are not exported they shall not be allowed to enter interstate commerce.¹⁸

These regulations were not changed for the entire history of the 1906 Act.

In 1920, FDA issued a manual containing instructions to its employees about enforcement of the 1906 Act.¹⁹ The two pages relating to examination of export foods²⁰ were devoted to reconciling the annual appropriations for voluntary examination and certification of exported food in order to facilitate acceptance of United States food products abroad, with the proviso in Section 2 of the 1906 Act that permitted the export of adulterated and misbranded food. FDA determined that food found to be in violation of the 1906 Act would not be eligible for certification under the appropriations statute but would be permitted to be exported under the 1906 Act.

During the thirty-two-year history of the 1906 Act, two court opinions were published relating to the export of adulterated and misbranded food and drugs. In the first case,²¹ adulterated tomato paste was shipped from New Jersey to Philadelphia to be examined to determine whether, although it was illegal under the 1906 Act, it could nonetheless meet the English standard and thus could be exported to a customer in London. The court recognized that, if the English standard had been satisfied, the food could have been exported lawfully. Because the adulterated product was initially shipped in interstate commerce rather than directly abroad, however, the condemnation was upheld.

In the second case,²² FDA seized sacks of dried figs that were about to be loaded aboard a ship for export, on the ground that they consisted partly of filthy, decomposed, or putrid vegetable matter and thus were adulterated. In a split decision, the court of appeals held that the adulterated figs could properly be exported under the proviso in Section 2 of the 1906 Act. FDA introduced in evidence the provisions of the Austrian law prohibiting some types of impure food materials. The majority of the court concluded, however, that this was inadequate to show that the ultimate use of the product abroad would conflict with the laws of the foreign country,

¹⁸ USDA, *Rules and Regulations for the Enforcement of the Food and Drugs Act*, Office of the Secretary Circular No. 21 at 12-13 (October 16, 1906), reprinted in S. Doc. No. 252, 59th Cong., 2d Sess. (1907).

¹⁹ Bureau of Chemistry, *The Food and Drug Manual* (1920).

²⁰ *Id.* at 136-137.

²¹ *Philadelphia Pickling Co. v. United States*, 202 Fed. 150 (3d Cir. 1913).

²² *United States v. Catz American Co., Inc.*, 53 F.2d 425 (9th Cir. 1931).

because the manufacturer might well cull out the deleterious matter before using the remaining material for food or, if that were not possible, might divert the shipment to other proper uses. The dissent argued that the proviso in Section 2 should not be interpreted to apply to decayed food in its natural condition.

In an unreported district court case,²³ FDA seized adulterated apple chops after they had been shipped from the state of Washington to California for export to France. FDA argued that the requisite interstate commerce had been shown, but the court held that the shipment fell within the proviso of Section 2.

Thus, the courts as well as FDA unequivocally placed the burden of showing a violation of foreign law on FDA.

II. The Federal Food, Drug, and Cosmetic Act of 1938

As early as the 1917 Annual Report,²⁴ FDA identified deficiencies in the 1906 Act that required legislative correction. The proviso in section 2, however, was not mentioned as a problem.

A. The Export Provision

In 1933, when Senator Royal S. Copeland introduced the first bill, S. 1944, that was to become the Federal Food, Drug, and Cosmetic Act (FD&C Act) of 1938, the legislation contained no exemption for exported articles.²⁵ During hearings on S. 1944, several industry representatives objected to this omission. Testimony on behalf of the Pacific Northwest fruit and vegetable industry suggested that the definition of interstate commerce be amended to exclude exports:

The reason for this change is that it is unreasonable to require American manufacturers and processors of food products to meet standards and tolerances which are not requirements of the countries to which the food is exported. In the field of international competition, the American exporter would be greatly handicapped by this unreasonable restriction. The present act amply covers this point by the provision that such commerce shall not be in violation of the laws of foreign countries of destination.²⁶

²³ FDA, *1935 Report of Food and Drug Administration* 19, reprinted in Food Law Institute, *Federal Food, Drug, and Cosmetic Law Administrative Reports 1907-1949* 825, 843 (1951).

²⁴ Bureau of Chemistry, *1917 Report of Bureau of Chemistry*, reprinted in Food Law Institute, note 75 *supra*, at 355, 366.

²⁵ S. 1944, 73d Cong., 1st Sess. (1933). The lack of any provision regarding exports was not mentioned when the bill was introduced. 77 Cong. Rec. 5721 (June 12, 1933).

²⁶ "Food, Drugs, and Cosmetics," *Hearings Before a Subcommittee of the Committee on Commerce, United States Senate*, 73d Cong., 2d Sess. 426 (1933) (1933 Senate Hearings).

A representative of the National Canners Association offered a similar amendment,²⁷ and the California Fruit Exchange also argued against applying United States restrictions to the export trade.²⁸

At the conclusion of the 1933 hearings, Senator Copeland revised the proposed legislation in response to some of the issues raised by witnesses.²⁹ Section 20(d) of the revised bill, S. 2000,³⁰ provided that:

- (d) A food, drug, or cosmetic intended for export which is not adulterated within the meaning of section 3, paragraph (a); section 4, paragraph (a); or section 5 shall not be deemed to be adulterated or misbranded under this Act if it (1) accords to the specifications of the foreign purchaser, (2) complies with the laws of the country to which it is intended for export, and (3) is labeled on the outside of the package with the words, "For Export." But if such article is sold or offered for sale in domestic commerce, this paragraph shall not exempt it from any of the provisions of this Act.

Compared to the 1906 Act, which permitted the export of any food or drug that accorded to the specifications of the foreign purchaser and was not in conflict with the laws of the receiving country, this bill and its successor, S. 2800,³¹ exempted food, drugs, and cosmetics only from the misbranding provisions and selected adulteration provisions of the bill. Section 20(d) of S. 2800 would have barred the export of a food bearing or containing a poisonous or deleterious substance or consisting of any filthy, decomposed, or putrid substance. A drug that was dangerous to health under the conditions of use prescribed in its labeling could not be exported. A cosmetic containing a poisonous or deleterious substance in such quantity as to render it injurious to the user under its labeled conditions of use could not be exported.

A representative of the California State Chamber of Commerce, Agriculture and Industry, the Dried Fruit Association of California, and the Northwest Dried Fruit Association, testified against this export provision, arguing that it would severely hamper the position of United States producers in international trade.³² Instead of the restrictive export provision contained in Section 20(d) of S. 2800, it was suggested³³ that the Committee adopt the language

²⁷ *Id.* at 389.

²⁸ *Id.* at 477.

²⁹ *Id.* at 494.

³⁰ 73d Cong., 2d Sess. (1934). See 78 Cong. Rec. 59 (January 4, 1934).

³¹ 73d Cong., 2d Sess. (1934). See 78 Cong. Rec. 2728 (February 19, 1934).

³² "Food, Drugs, and Cosmetics," *Hearings Before the Committee on Commerce, United States Senate*, 73d Cong., 2d Sess. 454-455 (1934) (1934 Senate Hearings).

³³ *Id.* at 455.

in Section 16(b) of the competing McCarran-Jenckes bill, which provided that the law would not apply:

to any food, drug, or cosmetic shipped or delivered for shipment for export to a foreign country, in a form complying with the laws of such country and acceptable to the foreign consignee: Provided, That if such article is diverted for domestic use and remains in commerce it shall become subject to this Act.³⁴

Alternatively, it was urged that the export language of Section 2 of the 1906 Act be retained because "It has the benefit of court decisions, making it understood and accepted in export trade, under which a very large export business has been built up in agricultural commodities."³⁵

FDA Commissioner Walter G. Campbell argued for strict export standards:

My thought is this: Without undertaking any undue solicitude about the welfare of consumers in other nations, it would be inhuman not to restrict the shipment of products that would be deleterious to health to the foreign consumers, products that we would not permit to be marketed in this country; also products which are filthy, putrid, or decomposed. If that practice is permitted on the part of a few who might desire to do it, it would compromise the standing and the reputation of American food and drug producers.³⁶

Senator Herbert observed that protecting the reputation of United States manufacturers was not the purpose of the bill, and Mr. Campbell conceded that "There can be no brief held for that provision if it is the purpose of the Congress to have us confine ourselves to the food and drugs that are to be consumed by Americans."³⁷

When S. 2800 was reported out of the Commerce Committee in 1934,³⁸ the export provision was revised to drop the requirement that foods, drugs, or cosmetics intended for export not be adulterated. The new provision, substantially the same as the one ultimately enacted, provided that:

- (d) A food, drug, or cosmetic intended for export shall not be deemed to be adulterated or misbranded under this act if it (1) accords to the specifications of the foreign purchaser, (2) complies with the laws of the country to which it is intended for export, and (3) is labeled on the

³⁴ S. 2858, 73d Cong., 2d Sess. (1934).

³⁵ 1934 Senate Hearings at 455.

³⁶ *Id.* at 522.

³⁷ *Id.*

³⁸ 78 Cong. Rec. 4567 (March 15, 1934).

outside of the shipping package with the words "For Export." But if such article is sold or offered for sale in domestic commerce, this paragraph shall not exempt it from any of the provisions of this act.³⁹

The Senate Report explained this provision as follows:

Section 2 of the existing law contains a proviso setting up exemptions for articles offered for export to foreign countries. This provision would be continued in substantially the same form by paragraph (d) of this section. It should be noted that this paragraph would require only those goods to be marked "For export" which did not conform with the requirements of the law applicable to domestic trade.⁴⁰

Thus, Congress rejected FDA's request for a narrower export policy and adopted instead the 1906 Act policy that permitted the export of any article that complied with applicable foreign law.

That this language was a substantial liberalization of the export provision was clearly understood by witnesses who addressed the issue during hearings on S. 5, the successor to S. 2800 in the following year.⁴¹ A representative of the National League of Women Voters, for example, testified that:

As this is drawn up, the United States manufacturer may export foods, drugs, and cosmetics to any country; provided, as I understand it, the laws of that country would permit the acceptance of those exports. That, as we feared, would permit this country to export adulterated foods, drugs, and cosmetics. I am afraid I still shudder over the testimony that appeared before you last year in the question of the wormy figs. I think about those every once in a while. We realize that most of the European countries do have food and drug laws, and that a good many South American countries have, but many of the eastern countries and the oriental countries have laws which do not protect the people who would buy, and we should like very much to see this clause strengthened so that the reputation of American goods may not be injured by the exporting to other countries of distinctly inferior products.⁴²

Similarly, the Association of Dairy, Food, and Drug Officials of the United States explained its understanding of the export provision that it "exempts from the act any food, drug, or cosmetic

³⁹ *Id.* at 4571.

⁴⁰ S. Rep. No. 493, 73d Cong., 2d Sess. 22 (1934).

⁴¹ S. 5, 74th Cong., 1st Sess. § 714(d) (1935).

⁴² "Foods, Drugs, and Cosmetics," *Hearings Before a Subcommittee of the Committee on Commerce, United States Senate, 74th Cong., 1st Sess. 39-40 (1935) (1935 Senate Hearings).*

intended for export and so labeled, so long as it complies with the law of the country to which it is intended for export.”⁴³

The Dried Fruit Association of California sought a further change in the provision. Instead of stating in subsection (d)(2) that a product could be exported “if it complies with the laws of the country to which it is intended for export,” they asked to:

have that put the other way around and to have it read: “Provided it does not violate the law of the country to which it is exported”.⁴⁴

In a supplemental submission to the Subcommittee, the Association explained that:

Our sole purpose in suggesting this present amendment is to preserve the existing court decisions on this point and not word the act in such a way as the burden of proof in compliance might be placed upon the shipper rather than the burden of proof in violation being placed upon the Government.⁴⁵

The language of the export provision remained substantially the same during the various revisions of the bill that followed the close of formal hearings. But in 1937, the revision of the export provision suggested by the Dried Fruit Association of California became part of Committee Print No. 3 of S. 5 during its consideration in the House of Representatives. It remained this way through final enactment of the 1938 Act⁴⁶ and has not been substantively amended since.

This review of the legislative history of the export provision demonstrates that Congress began by considering a bill that would have substantially tightened the export provision, and then revised the provision continuously so that it would preserve in substantially the same form the export exemption contained in the 1906 Act. Indeed, the House Report on the final 1938 Act explained that section 801 made “no substantial change from the provisions of the present law.”⁴⁷ In so doing, Congress rejected legislation that would have barred the export of adulterated food, drugs, and cosmetics or placed the burden of demonstrating compliance with foreign law on the exporter.

⁴³ *Id.* at 177.

⁴⁴ *Id.* at 202.

⁴⁵ *Id.* at 205.

⁴⁶ 52 Stat. 1040 (1938).

⁴⁷ H.R. Rep. No. 2139, 75th Cong., 3d Sess. 13 (1938).