No. 98-1152

IN THE SUPREME COURT OF THE UNITED STATES

FOOD AND DRUG ADMINISTRATION, ET AL.,
Petitioners

v.

BROWN AND WILLIAMSON TOBACCO CORPORATION, ET AL.,
Respondents

BRIEF OF RESPONDENT UNITED STATES TOBACCO COMPANY

Filed September 10, 1999

This is a replacement cover page for the above referenced brief filed at the U.S. Supreme Court. Original cover could not be legibly photocopied

QUESTION PRESENTED

Whether the Food and Drug Administration ("FDA") has jurisdiction to regulate the continued marketing of tobacco products, even though (1) its governing statute provides authority to regulate only products with a medical purpose, which tobacco products lack, and requires it to ban those that are "unsafe," and (2) Congress has enacted tobacco-specific statutes, which are premised on the continued marketing of tobacco products and which provide no role for FDA.

RULE 29.6 STATEMENT

Pursuant to Supreme Court Rule 29.6, Respondents submit the following corporate information:

1. Central Carolina Grocers, Inc., is a North Carolina corporation which is owned by one hundred ten (110) individuals and entities, none of whom individually own ten percent (10%) or more of the capital stock of the corporation. Central Carolina Grocers, Inc., has no nonwholly owned subsidiaries.

2. The parent companies of Conwood Company, L.P., are Conwood LLC; Conwood LLC-1; Conwood LLC-2; D. Aviation Services, Inc.; and Woodcon Holdings, Inc. Conwood Company, L.P., has no nonwholly owned subsidiaries.

3. J.T. Davenport, Inc., has no parent companies and has no nonwholly owned subsidiaries.

4. The parent company of National Tobacco Company, L.P., is North Atlantic Trading Company, Inc. National Tobacco Company, L.P., has no nonwholly owned subsidiaries.

5. North Carolina Tobacco Distributors Committee, Inc., has no parent companies and has no nonwholly owned subsidiaries.

6. The parent companies of The Pinkerton Tobacco Company are Swedish Match AB and Swedish Match North America Inc. The Pinkerton Tobacco Company has no nonwholly owned subsidiaries.

7. The parent company of Swisher International, Inc., is Swisher International Group, Inc. Swisher International Group, Inc., is wholly owned by Hay Island Holding Corporation, which is privately held. Swisher International, Inc., has no nonwholly owned subsidiaries.

8. The parent company of United States Tobacco Company is UST Inc. United States Tobacco Company has no nonwholly owned subsidiaries.

TABLE OF CONTENTS

TABLE OF CONTENTS—Continued

TABLE OF AUTHORITIES

CASES

TABLE OF AUTHORITIES—Continued

TABLE OF AUTHORITIES—Continued

TABLE OF AUTHORITIES—Continued

TABLE OF AUTHORITIES—Continued

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On Writ of Certiorari to the United States Court of Appeals for the Fourth Circuit

BRIEF FOR RESPONDENTS UNITED STATES TOBACCO COMPANY, *ET AL.*

OPINIONS BELOW

The opinions below are identified in the Brief for the Petitioners ("Pet. Br.") 1.

JURISDICTION

The basis for this Court's jurisdiction is set forth at Pet. Br. 1.

STATUTORY PROVISIONS INVOLVED

This case involves the Federal Food, Drug, and Cosmetic Act of 1938 ("FDCA" or "1938 Act"), Pub. L. No. 75-717, 52 Stat. 1040, codified as amended at 21 U.S.C. §§ 301-397; the Federal Cigarette Labeling and Advertising Act ("FCLAA"), Pub. L. No. 89-92, 79 Stat.

282 (1965), codified as amended at 15 U.S.C. §§ 1331-1341; the Comprehensive Smokeless Tobacco Health Education Act of 1986 ("CSTHEA"), Pub. L. No. 99-252, 100 Stat. 30, codified as amended at 15 U.S.C. §§ 4401-4408; and the Alcohol, Drug Abuse, and Mental Health Administration Reorganization Act ("ADAMHA Reorganization Act"), § 202, Pub. L. No. 102-321, 106 Stat. 323, 394-95 (1992), codified at 42 U.S.C. § 300x-26.[1]

STATEMENT

Nature of the case. This is a lawsuit to invalidate FDA regulations that classify smokeless tobacco products and cigarettes as "drug delivery devices" under the FDCA. The respondents on this brief[2] are manufacturers of smokeless tobacco products, wholesale distributors whose products include smokeless tobacco, and an association of tobacco product wholesalers.[3] Smokeless tobacco includes chewing tobacco and moist and dry snuff.

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[1] The originally-enacted texts of the 1938 Act, and its predecessor, the Food and Drugs Act of 1906 ("1906 Act"), Pub. L. No. 59-384, 34 Stat. 768, are printed in the Appendix to this brief. Codified provisions of the FDCA as amended are in that Appendix and in the Appendix to Respondents' Brief in Opposition to Petition for a Writ of Certiorari ("Opp. Cert. App."). The originally-enacted and codified texts of the FCLAA and the CSTHEA and amendments, and the ADAMHA Reorganization Act, 42 U.S.C. § 300x-26, are set forth in the Opp. Cert. App.

[2] United States Tobacco Company; Conwood Company, L.P.; National Tobacco Company, L.P.; The Pinkerton Tobacco Company; Swisher International, Incorporated; Central Carolina Grocers, Incorporated; J.T. Davenport, Incorporated; North Carolina Tobacco Distributors Committee, Incorporated.

[3] This brief presents the arguments that smokeless tobacco products are outside FDA's jurisdiction because they have no medical purpose and are therefore not "drugs" or "devices" under the FDCA, and because the CSTHEA precludes any contrary interpretation of the FDCA. The smokeless tobacco respondents agree with, and hereby rely on, the arguments made in the briefs of the other respondents.

Smokeless tobacco has a long history. The Copenhagen brand of moist snuff has existed since 1822. The "Garrett" trademark, used for moist and dry snuff products, is the oldest trademark in continuous use in the United States. In addition to the CSTHEA, federal laws relating to smokeless tobacco have included excise taxes and agricultural controls. *See* Comments of the Smokeless Tobacco Council, Inc., *et al.*, at 6-8, 53 (Jan. 2, 1996) (FDA Docket Nos. 95N-0253, 95N-0253J).[4] Other restrictions have been imposed at the state or local level.

The FDCA of 1938. The FDCA replaced the Food and Drugs Act of 1906. The 1906 Act defined "drug" as "all medicines and preparations recognized in the United States Pharmacopoeia or National Formulary" (*i.e.*, "compendial" products) and "any substance or mixture of substances intended to be used for the cure, mitigation, or prevention of disease" (*i.e.*, "disease-treatment" products). Pub. L. No. 59-384, § 6, 34 Stat. at 769. Interstate commerce in adulterated or misbranded drugs was prohibited. §§ 2, 7, 8, 34 Stat. at 768, 769-71.

The 1906 Act was criticized because the "[d]efinition of drug does not include therapeutic devices, or drugs or devices intended to affect nonpathologic conditions of the body." 77 Cong. Rec. 5721 (1933). Consequently, the 1938 Act "drug" definition included a category for products "intended to affect the structure or any function of the body" (*i.e.*, "structure-or-function" products), Pub. L. No. 75-717, § 201(g)(3), 52 Stat. at 1041 (21 U.S.C. § 321(g)(1)(C)).[5] A separate "device" definition, simi-

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[4] Lodged with the Court is a compilation of materials containing the cited pages of this and other documents referenced herein that may not be readily accessible.

[5] When referring to early provisions of the FDCA or subsequent amendments to the FDCA in historical context, we cite the section

lar to the "drug" definition, was also added. § 201(h), 52 Stat. at 1041 (§ 321(h)(2)-(3)).

The structure-or-function category of the 1938 "drug" and "device" definitions filled a gap created by use of the word "disease" in the 1906 "drug" definition. FDA was uncertain of its legal authority over products that claimed to alleviate "nonpathologic" bodily conditions, such as obesity or short stature, that were undesirable but "that may not in themselves be diseases." *Food, Drugs, and Cosmetics: Hearings on S. 1944 Before a Subcomm. of the Senate Comm. on Commerce*, 73d Cong. 16 (1933) ("*1993 Hearings*") (statement of FDA Chief Walter G. Campbell). The structure-or-function category authorized FDA to regulate such medical products with respect to adulteration, misbranding, and safety. FDA did not ask for and was not given authority over non-medical products.

Congress amended the drug and device provisions of the FDCA many times. Uniformly, the amendments extended the FDCA framework to address additional issues raised by products with a medical purpose. Congress enacted separate laws to deal with health and safety issues of non-medical products, *e.g.*, the Consumer Product Safety Act, 15 U.S.C. §§ 2051-2084, the Federal Hazardous Substances Act, 15 U.S.C. §§ 1261-1278, and the Toxic Substances Control Act, 15 U.S.C. §§ 2601-2692.

Tobacco product legislation. Cigarettes and smokeless tobacco were among the non-medical products for which Congress enacted separate laws. In 1964, the Department of Health, Education, and Welfare ("HEW") issued

numbers of the law as enacted and provide a reference to the provision's section number as it currently appears in the United States Code ("U.S.C.") (1994 & Supp. III 1998). Otherwise, we cite the section numbers of the U.S.C. title in which the FDCA has been codified. Repetitive citations to the session laws are omitted.

the Surgeon General's Report on Smoking and Health. HEW, *Smoking and Health: Report of the Advisory Committee to the Surgeon General of the Public Health Service* (1964). Congress conducted hearings.[6] Despite the Surgeon General's conclusion that tobacco use was an "habituation" and that nicotine had "pharmacological actions . . . on the central nervous system" of a "stimulant or tranquilizing" nature, Report at 351, 354, HEW and FDA officials testified that the FDCA provided no jurisdiction over cigarettes. *1964 Hearings* 56; *1965 Hearings* 193. The Secretary of HEW cautioned that, if FDA had jurisdiction, it would have to ban cigarettes due to their adverse health effects. *1964 Hearings* 18. Congress then enacted the FCLAA, which allowed cigarettes to be sold but with a prescribed label warning. Pub. L. No. 89-92, § 4, 79 Stat. at 283.[7]

In 1986, Congress enacted the CSTHEA. Modeled on the FCLAA, it allowed the sale of smokeless tobacco products but required warnings and prohibited broadcast advertising. Pub. L. No. 99-252, § 3, 100 Stat. at 30-32. Congress understood, as it did with the FCLAA, that FDA had no authority to regulate tobacco products. *See Tobacco Issues: Hearings on H.R. 2835, H.R. 760, H.R. 2950, and H.R. 3078, Before the Subcomm. on Health and the Environment of the House Comm. on Energy and Commerce*, 99th Cong. 106 (1985) ("*1985 Hearings*")

[6] *Cigarette Labeling and Advertising Relative to Health Problems Associated With Smoking: Hearings Before the House Comm. on Interstate and Foreign Commerce*, 88th Cong. (1964) ("*1964 Hearings*"); *Cigarette Labeling and Advertising: Hearings on H.R. 2248, H.R. 3014, H.R. 4007, H.R. 7051, and H.R. 4244 Before the House Comm. on Interstate and Foreign Commerce*, 89th Cong. (1965) ("*1965 Hearings*").

[7] The brief of respondents Philip Morris Incorporated and Lorillard Tobacco Company more fully describes the FCLAA, including amendments to prohibit television and radio advertising.

("FDA claims it does not have the authority to regulate the sale of smokeless tobacco." (Statement of Rep. Mike Synar)).

The FDA tobacco proceeding. FDA regulates nicotine when marketed separately from tobacco for the medical purpose of helping smokers quit. However, FDA has never previously attempted to regulate nicotine in tobacco as a drug intended to "affect the structure or any function of the body" or suggested that cigarettes and smokeless tobacco have medical utility.

In 1995, FDA proposed regulations "restricting the sale and distribution of cigarettes and smokeless tobacco products." 60 Fed. Reg. 41,314 (1995). In an "analysis regarding jurisdiction," FDA determined that nicotine in tobacco products is a "drug" and that cigarettes and smokeless tobacco are "nicotine delivery devices" under the FDCA. *Id.* at 41,453.

The "objective of the proposed rule" was not to regulate tobacco products based on the supposed "drug" effects of nicotine, however, but "to reduce the death and disease caused by tobacco products," with "[t]he goal of . . . help[ing] the country achieve one of the objectives of 'Healthy People 2000,' . . . to reduce the number of children and adolescents who use tobacco products by roughly one half by the year 2000." *Id.* at 41,314.[8] The FDCA was not designed for tobacco control. Therefore, FDA explained, "[it] examined many domestic and foreign tobacco control statutes, regulations, and legislation, as well as numerous studies and reports." 60 Fed. Reg.

[8] "Healthy People 2000" is an annual report published by HEW's successor agency, the Department of Health and Human Services ("HHS"). The year 2000 target for smokeless tobacco use by minors—under 4 percent smokeless tobacco use by males age 12-17—has already been achieved. HHS, *Healthy People 2000 Review 1998-99* at 51, 54 (1999).

41,315. FDA concluded that "an effective program must address . . . (1) Restrictions on cigarette and smokeless tobacco sales that will make these products less accessible to young people; and (2) restrictions on labeling and advertising to help reduce the appeal of tobacco products to young people." *Id.* Accordingly, FDA proposed a federal 18-year minimum age requirement on retail tobacco sales and extensive restrictions on tobacco product advertising.

FDA's basis for regulating tobacco products was that the nicotine they contain is "intended to affect the structure or any function of the body," and is therefore a "drug" under 21 U.S.C. § 321(g)(1)(C) because nicotine has "foreseeable" physiologic effects, such as "addictiveness." *Id.* at 41,463-66. FDA did not find that these effects had, or were represented as having, a medical purpose in relieving undesirable "nonpathologic conditions" of the body. Nor did FDA explain how the physiologic effects of nicotine in tobacco products could be regulated under the FDCA's operative provisions relating to the "safety" and "effectiveness" of medical products.

FDA issued final regulations on August 28, 1996. 61 Fed. Reg. 44,396 (1996). Criticized for using the FDCA as an excuse for a tobacco control program, FDA pointed to such FDCA requirements as "good manufacturing practices" and "device listing," which it said could be applied to cigarettes and smokeless tobacco as if they were genuine "drugs" and "devices." *Id.* at 44,409-11. But FDA did not explain the basis for regulating these "dangerous" products, *id.* at 44,412, under the FDCA's "safety" provisions for devices, or how the "drug-like" effects of nicotine, on which jurisdiction was predicated, would be evaluated under the "effectiveness" provisions.

SUMMARY OF ARGUMENT

Two grounds for upholding the court of appeals are presented here: smokeless and other tobacco products are not "drugs" or "devices" under the FDCA, and a contrary interpretation is precluded by the CSTHEA.

I. The FDCA's structure-or-function definitions complemented the 1906 Act's compendial-product and disease-treatment definitions, providing FDA with comprehensive jurisdiction to regulate medical products. Congress's intent to limit FDA's authority to medical products is evident in the operative provisions of the FDCA relating to safety, effectiveness, adulteration, and misbranding, as well as in the legislative history of the "drug" and "device" definitions. Tobacco products have no medical purpose, and the FDCA does not contain provisions suitable to their regulation. Tobacco products, therefore, are not "drugs" or "devices" within the meaning of those terms in the statute.

FDA's contrary interpretation fails to relate the structure-or-function definitions to the FDCA's operative provisions, thus violating the "fundamental canon of statutory construction that the words of a statute must be read in their context and with a view to their place in the overall statutory scheme." *Davis v. Michigan Dep't of Treasury*, 489 U.S. 803, 809 (1989). It also gives the FDCA an absurdly broad scope, subject to no legislatively-prescribed limitation on FDA's choice of products to regulate.

FDA's attempt to avoid the overbreadth problem by arguing that tobacco products are "quintessentially drug-like" is based on a false premise: that physiologic effects that "resemble" the effects of products intended for a medical purpose trigger FDCA "drug" and "device" jurisdiction even if the products producing those effects have no such purpose. If this premise were right, pepper spray would be a "drug" and an automobile seatbelt would be a medical "device."

II. The CSTHEA is Congress's program for addressing issues related to smokeless tobacco and health, and precludes FDA's interpretation of the FDCA as applicable to smokeless tobacco.

ARGUMENT

I. THE FDCA DOES NOT APPLY TO TOBACCO PRODUCTS.

A. The Structure Of The FDCA As A Whole Demonstrates That The "Drug" And "Device" Definitions Apply Only To Products With A Medical Purpose.

"In ascertaining the plain meaning of the statute, the court must look to the particular statutory language at issue, . . . [and] the language and design of the statute as a whole," *K Mart Corp. v. Cartier, Inc.*, 486 U.S. 281, 291 (1988) (citation omitted), as well as " 'its object and policy,' " *Dole v. United Steelworkers of Am.*, 494 U.S. 26, 35 (1990) (citations omitted). The "drug" and "device" definitions in chapter II of the FDCA serve the statute's operative provisions for "drugs" and "devices" in chapter V. The operative provisions enable FDA to evaluate, and take measures to assure the safety, effectiveness, and proper labeling of, products with a medical purpose. Therefore, the "drug" and "device" definitions are limited to products with a medical purpose.

As enacted (and as currently codified), chapter V provided that a drug was adulterated if "its strength differs from, or its quality or purity falls below, the standards set forth in" an official compendium (such as the *United States*

Pharmacopeia ("USP")), § 501(b) (21 U.S.C. § 351(b)), and that a noncompendial drug was adulterated if "its strength differs from, or its quality falls below, that which it purports or is represented to possess," § 501(c) (§ 351(c)). Chapter V provided that a drug with more than one ingredient was misbranded unless labeled with the "name of each active ingredient." §502(e)(2) (§ 352(e)(1)(A)(ii)). It provided that a drug or device was misbranded unless it had "adequate directions for use" and warnings "against unsafe dosage or methods or duration of administration," § 502(f) (§ 352(f)), or if it was "dangerous to health when used in the dosage, or with the frequency or duration prescribed, recommended, or suggested in the labeling," § 502(j) (§ 352(j)). New drugs had to be shown to be "safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling." § 505(d)(1) (§ 355(d)(1)).

Chapter V was designed only for medical products. It was medical products that raised concerns about "strength," "quality," and "purity," that required "adequate directions" and "warnings" against "unsafe dosages" and "methods of administration," and that had labeling that prescribed conditions of use under which a safety determination could be made as part of premarket review.

Amendments to chapter V have all related to medical products. In 1941 and 1945, Congress provided for FDA certification of insulin and penicillin drugs. Pub. L. No. 77-366, § 3, 55 Stat. 851; Pub. L. No. 79-139, § 3, 59 Stat. 463-64.[9] The 1951 Prescription Drug Amendments, Pub. L. No. 82-215, § 1, 65 Stat. 648-49, established the

[9] These provisions were repealed by the Food and Drug Administration Modernization Act of 1997 ("FDAMA"), Pub. L. No. 105-115, § 125, 111 Stat. 2296, 2325.

requirement that a drug not "safe for use" except under a physician's supervision be dispensed only on prescription, 21 U.S.C. § 353(b)(1). Physicians do not prescribe drugs for other than medical purposes. The Drug Amendments of 1962, Pub. L. No. 87-781, § 102(b), 76 Stat. 780, 781, added the requirement that there be adequate evidence of effectiveness, in addition to evidence of safety, of a new drug under its labeled conditions of use, § 355(b)(1)(A). Products without a medical purpose cannot be evaluated under this standard.

The Medical Device Amendments of 1976, Pub. L. No. 94-295, § 2, 90 Stat. 539, 540141, required that all devices be classified "to provide reasonable assurance of the safety and effectiveness of the device," 21 U.S.C. § 360c(a)(1), "with respect to the conditions of use prescribed, recommended, or suggested in the labeling of the device, and . . . weighing any probable benefit to health from the use of the device against any probable risk of injury or illness from such use," § 360c(a)(2)(B)-(C). Products without a medical purpose cannot be evaluated under this standard.

Recent amendments to chapter V also pertain to medical drugs, *e.g.*, pharmacy compounding of drugs, 21 U.S.C. § 353a; pediatric studies of drugs to generate information on how "the use of a new drug in the pediatric population may produce health benefits," § 355a; fast track products "intended for the treatment of a serious or life-threatening condition," § 356; and discontinuance by the sole manufacturer of a drug that is "life-supporting" or "life-sustaining," § 356c.

Chapter V is the core of the FDCA's authority for drugs and devices; the definitions are the means for implementing chapter V and "must be understood against the backdrop of what Congress was attempting to accom-

plish." *Reves v. Ernst & Young*, 494 U.S. 56, 62-63 (1990). Chapter V is designed and intended for products with a medical purpose.

B. FDA Improperly Focused On The "Drug" And "Device" Definitions In Isolation From The FDCA As A Whole.

FDA explained at length how the FDCA's drug and device provisions relating to manufacturing procedures, recordkeeping, and product listing could be applied to tobacco products, 61 Fed. Reg. at 44,409-11—as, indeed, they could be applied to any manufactured product, including ballpoint pens and automobiles—but it did not explain how the FDCA's safety and effectiveness requirements could rationally be used to regulate cigarettes and smokeless tobacco as medical products having the physiologic effects FDA relied on as the basis for its exercise of jurisdiction.

The Agency's inability to articulate a rational relationship between the FDCA's core operative provisions for assuring the safety and effectiveness of drugs and devices and the purported "structure-or-function" effects of tobacco products that supposedly subject them to FDCA jurisdiction demonstrates that there is none. FDA did not view the "drug" and "device" definitions as integral parts of chapter V's program for regulating medical products, but as a source of language useful for rationalizing its pursuit of tobacco control.

FDA's strategy is improper. "[T]he words of a statute must be read in their context and with a view to their place in the overall statutory scheme." *Davis*, 489 U.S. at 809. The definitions of "drug" and "device" are not grants of jurisdiction to regulate anything within their literal language. Rather, they explain what the defined terms refer to when used in the operative provisions of

the FDCA. FDA's "jurisdiction" consists of its authority to administer those provisions.

As the court of appeals recognized, *see* Appendix to Petition for a Writ of Certiorari 18a-30a, "drugs" and "devices" in chapter V are products that can sensibly be regulated by applying statutory provisions that require "adequate directions" for use, labeling disclosure of "active ingredients," and determinations of "safety" and "effectiveness" based on the "weighing [of] any probable benefit to health from the use of the device against any probable risk of injury or illness from such use," 21 U.S.C. § 360c(a)(2)(C). The "drugs" and "devices" referred to in chapter V are products with a medical purpose. Because tobacco products, including the nicotine they contain, have no medical purpose, they are not "drugs" and "devices" within the meaning Congress intended those terms to have.

The Government contends that "the structure of the Act as a whole" does not "detract[ ] from" FDA's interpretation of the definitions. Pet. Br. 8. The quoted statement refers to FDA's explanation (*see* 61 Fed. Reg. 44,412-13) for why classifying "dangerous" tobacco products as "drug delivery devices" would not require them to be banned under the operative provisions of the FDCA. *see* Pet. Br. 30-37. This is not a "whole act" analysis but its antithesis: an attempt to explain away a paradox created by FDA's interpretation of the "drug" and "device" definitions in isolation from the "whole act," which includes the operative provisions of chapter V. The Government's misleading attempt to suggest that FDA considered the "structure of the Act as a whole," *id.* at 30, underscores both the importance of that interpretational methodology and the significance of FDA's failure to apply it in this case.

C. The Legislative History Of The 1938 Act Confirms That The Structure-Or-Function Definition Applies Only To Medical Products.

The legislative history of the 1938 Act demonstrates that the only problem Congress addressed by adding the structure-or-function category to the "drug" definition, and by adding a parallel "device" definition, was that FDA's authority did not reach all medical products.

The first bill, S. 1944, 73d Cong. (1933), was introduced on June 12, 1933, by Senator Royal S. Copeland, who became the FDCA's principal Senate sponsor. The bill defined "drug" as in the 1906 Act, but added a structure-or-function category. § 2(b). Devices were included within the "drug" definition. *Id.* Senator Copeland placed a memorandum in the record comparing S. 1944 with the 1906 Act. It noted that (unlike S. 1944) the 1906 Act's "drug" definition "does not include therapeutic devices, or drugs or devices intended to affect nonpathologic conditions of the body." 77 Cong. Rec. 5721. FDA Chief Campbell stated at hearings on S. 1944 that the purpose of the structure-or-function definition was to authorize regulation of antifat remedies, which "cannot be alleged to be treatments for diseased [sic] conditions," and devices to "correct physiological or anatomical defects that may not in themselves be diseases." *1933 Hearings* 16.[10]

S. 1944 was replaced by S. 2800, 73d Cong. (1934). The drug definition was the same as in S. 1944, but, consistent with the legislators' understanding that the definition identified medical products, clarified that "drug"

[10] To the same effect, see *Food, Drugs, and Cosmetics: Hearings on S. 2800 Before the Senate Comm. on Commerce*, 73d Cong. 516 (1934) (*"1934 Hearings"*); *Food, Drugs, and Cosmetics: Hearing on H.R. 6906, H.R. 8805, H.R. 8941 and S. 5 Before a Subcomm. of the House Comm. on Interstate and Foreign Commerce*, 74th Cong. 55-56 (1935).

was defined for purposes of the Act and " 'not to regulate the legalized practice of the healing art,' " S. Rep. No. 73-493, at 2 (1934).

During the floor debate, Senator Copeland criticized the 1906 "drug" definition:

> The present [1906] law defines drugs as substances or mixtures of substances intended to be used for the cure, mitigation, or prevention of disease. This narrow definition permits escape from legal control of all therapeutic or curative devices like electric belts, for example. It also permits the escape of preparations which are intended to alter the structure or some function of the body, as, for example, preparations intended to reduce excessive weight.

78 Cong. Rec. 8960 (1934).

A revision of S. 2800, introduced as S. 5, 74th Cong. (1935), created separate but similar definitions for "drugs" and "devices," S. Rep. No. 74-646, at 1 (1935). When S. 5 was reported out of committee, the definitions were unchanged, except that the clause relating to "the healing art" had been removed as "unnecessary," H.R. Rep. No. 74-2755, at 5 (1936). The definitions would address such problems as "[d]eadly drugs intended for reducing purposes or otherwise to affect the structure or function of the body, which do not fall within the narrow definition of drug in the present [1906] law" and "[d]angerous and worthless therapeutic devices." *Id.* at 3.

Further proceedings in 1936 and 1937 produced a slightly modified bill, reported in the House on April 14, 1938, 83 Cong. Rec. 5465 (1938). The House Report stated that the bill would close "serious loopholes" in the 1906 Act, in that, among other things, "[t]herapeutic devices are brought under control" and "[d]rugs . . . for remedying underweight or overweight or for otherwise

affecting bodily structure or function are subjected to regulation." H.R. Rep. No. 75-2139, at 1-2 (1938). The bill was signed into law on June 25, 1938. Pub. L. No. 75-717, 52 Stat. 1040 (1938).

This legislative history demonstrates that the problem Congress perceived and addressed was that non-compendial products intended for medical purposes, but not for "diseases," escaped regulation under the 1906 Act. Congress closed that "loophole" by adding the structure-or-function category to the "drug" and "device" definitions.

The Government relies on some of the same legislative history as "additional support" for FDA's conclusion that tobacco products are drugs and devices under the FDCA. Pet. Br. 20-21. It contends that "Congress understood" that the expanded "drug" definition "would reach well beyond weight-loss products and cover other products intended to affect the structure or function of the body." *Id.* at 20 (citing the House Report reference to drugs "for remedying underweight or overweight or for otherwise affecting bodily structure or function," H.R. Rep. No. 75-2139, at 2). As the Government's own explanation makes clear, however, the word "otherwise" refers to products for different *medical* purposes: shoulder braces, radium belts, crutches. Pet. Br. 21. Congress regarded the structure-or-function definition as "an inclusive, . . . wide definition," *id.*, but the definition "inclusively" covered medical products, not all products that, literally, are intended to "otherwise" affect the structure or function of the body.

D. The Structure Of The Definitions Is Contrary To FDA's Interpretation.

The Government contends that the "structure" of the definitions supports the conclusion that they encompass products with no medical purpose, such as cigarettes and

smokeless tobacco. *Id.* at 17-19. It notes that several FDCA definitions exempt products that would otherwise be included, but tobacco products are not exempt from the "drug" and "device" definitions. *Id.* at 18-19.

This misconceives the issue. The issue is whether the "drug" and "device" definitions apply to tobacco products in the first instance. They do not. The structure of the FDCA as a whole and its legislative history demonstrate that Congress intended the "drug" and "device" definitions to apply only to products with a medical purpose. There was therefore no need for the definitions to exempt tobacco products. Moreover, neither when the definitions were enacted nor thereafter did Congress have the slightest inkling that FDA would consider tobacco products to be within the definitions. FDA itself, on numerous occasions after 1938, interpreted the definitions as inapplicable to tobacco products, obviating the need for Congress to add an exemption when federal regulation of tobacco and health began in 1965.

There is a pertinent structural aspect of the "drug" and "device" definitions that the Government ignores. Each definition includes three categories: compendial products, disease-treatment products, and structure-or-function products. The compendial-products category has always been interpreted as including only products with a medical purpose, even though the designated compendia include substances that may have no such purpose. *See 1934 Hearings* 514-15;[11] *National Nutritional Foods Ass'n ("NNFA") v. Mathews*, 557 F.2d 325, 337 & n.11 (2d Cir. 1977). The disease-treatment category has never

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11 According to FDA Chief Campbell, whiskey was listed in the USP. *1934 Hearings* 514. Mr. Campbell disagreed with a suggestion to add "medicinal use" to the compendial-product definition because FDA did not interpret it as applicable unless a compendial substance was to be "used for drug purposes." *Id.* at 514-15.

been viewed as applying other than to products with a medical purpose. It follows (and the legislative history confirms) that the third category was for products with similar characteristics, *i.e.*, products whose intended structure-or-function effects have a medical purpose. *See, e.g., Gustafson v. Alloyd Co.*, 513 U.S. 561, 575-76 (1995); *id.* at 586-87 (Thomas, J., dissenting) (*noscitur a sociis*).

FDA's alternative interpretation is that the structure-or-function category includes all products that, literally, are "intended to affect the structure or any function of the body." So interpreted, the category includes a vast universe of manufactured goods, such as thermal pajamas, exercise equipment, and home air conditioners. The Government has conceded that FDA's interpretation would subject such products to the drug and device provisions of the FDCA, but its only response to this untenable result is that (as it stated to the lower court) "FDA may, in its discretion, decline to regulate them." Appellee and Reply Brief for Food and Drug Administration, *et al.* 20.

This response does not acknowledge, much less identify, any legislatively-sanctioned principle for distinguishing between products FDA may and those it may not regulate. Without such a principle, it will be FDA instead of Congress that determines the scope of the FDCA. This is not a role FDA may play. *See, e.g., Bureau of Alcohol, Tobacco & Firearms v. Fed. Labor Relations Auth.*, 464 U.S. 89, 97 (1983) (agencies may not make " 'major policy decisions properly made by Congress' ") (citation omitted).

FDA's response also misses the point. That FDA's interpretation would allow it to regulate the "safety" and "effectiveness" of home air conditioners demonstrates that the interpretation is flawed, *cf. Green v. Bock Laundry Mach. Co.*, 490 U.S. 504, 509-10 (1989) (rejecting a

"literal reading [that] would compel an odd result"), not that FDA needs to be wise in selecting which products to regulate.[12]

The Government relies on *United States v. An Article of Drug . . . Bacto-Unidisk*, 394 U.S. 784 (1969). Pet. Br. 22-23. There, the Court said, "Congress fully intended that the Act's coverage [under the "drug" definition] be as broad as its literal language indicates—and equally clearly, broader than any strict medical definition might otherwise allow." 394 U.S. at 798.

Bacto-Unidisk is not precedent for an interpretation of the structure-or-function definitions that, like FDA's for tobacco products, ignores the context of the FDCA. Indeed, the case supports our argument here.

The product at issue was an antibiotic sensitivity disk, used by physicians to choose the most effective antibiotic for medical treatment. *Id.* at 784. The disk was exposed to fluids taken from, but did not physically contact, the patient. *Id.* at 787. FDA classified the disk as a "drug" in order to require premarket review. *Id.* at 788. Except for its physical form, the disk was a conventional "disease-treatment" drug. Its function and purpose were within the traditional scope of FDA's regulatory responsibilities for assuring the safety and effectiveness of medical prod-

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12 Compare *United States v. Sullivan*, 332 U.S. 689, 694 (1948): "The scope of the offense [of misbranding under the FDCA] which Congress defined is not to be judicially limited by envisioning extreme possible applications. . . ." In *Sullivan*, there was no question as to the proper interpretation of the statutory text, only an issue as to whether FDA could be trusted not to misapply it to petty offenses. Here, the issue is whether FDA has properly interpreted the drug and device provisions to determine which products are properly subject to them. Whether FDA has correctly concluded that tobacco products are "drugs" and "devices" does not depend on whether its use of discretion can be defended, but on what the statutory text means.

ucts. Unlike tobacco products, the disk raised no issue of extending the FDCA into new product areas. It presented a "gap-filling" issue of the sort agencies are entrusted to resolve.

The lower courts held that the disk was not a "drug" within the disease-treatment definition, because "the commonly accepted view of physicians generally" was that a substance not "taken into or applied to the body" was not considered "medically" to be a drug. *See United States v. An Article of Drug . . . Bacto-Unidisk*, 392 F.2d 21, 22-23 (6th Cir. 1968). It was that limitation this Court found unjustified by the language of the "drug" definition. 394 U.S. at 792-93. But the Court looked beyond the "drug" definition's "literal language." It examined the legislative history of the FDCA, and the "fit" between the operative provision FDA wished to use—requiring premarket review—and the problem it wished to solve—assuring the "safety" and "efficacy" of a medical product. *Id.* at 793-98. The Court did not imply—much less say—that the "drug" definition encompasses nonmedical products. Indeed, it was because the sensitivity disk *was* a medical product that the Court upheld FDA's interpretation. *Bacto-Unidisk* supports our interpretation that the structure-or-function definition, read in the context of the FDCA and in light of its legislative history, includes only products with a medical purpose, which tobacco products lack.

E. On FDA's Own Findings, Tobacco Products Are Not Structure-Or-Function Drugs Or Devices.

FDA "found" that nicotine "causes and sustains addiction," "causes other psychoactive . . . effects, including tranquilization and stimulation," and "controls weight." 61 Fed. Reg. 44,661; Pet. Br. 3-5. However, FDA did not find that any of these effects, if caused by nicotine in

tobacco, serves a medical purpose. FDA's findings show only that nicotine "affects the structure or any function of the body" in the literal sense.[13]

The Government insists that the effects of nicotine in tobacco are similar to the effects of some medical products: "FDA found that those effects on the structure and function of the body are quintessentially drug-like, identical to those FDA has found in numerous other products that it regulates under the Act, including stimulants, tranquilizers, appetite suppressants, nicotine replacement products, and narcotics used to treat addiction." Pet. Br. 3-4. These effects "mirror" those of the medical products alluded to, *id.* at 23, and have the "classic characteristics of drugs and devices subject to regulation under the Act," *id.* at 24. As a consequence, tobacco products have a "resemblance" to "products regulated as drugs and devices by the FDA." *Id.*

It is not an accepted principle of interpretation that, if a statute specifies a thing or activity an agency is to regulate, the agency has authority to regulate all things and activities that are "found" to have a "resemblance" to it. Many manufactured products are similar to drugs and devices, but the similarity does not bring them within FDA's jurisdiction. Automobile seatbelts are, using FDA's vocabulary, "quintessentially device-like," in that they have the same physical effect as, for example, patient "protective restraints," which are regualted by FDA as medical devices, 21 C.F.R. § 880.6760 (1999). Under

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13 Under the FDCA's "drug" and "device" definitions, any effects must also be "intended" by the manufacturer or other vendor. 21 U.S.C. §§ 321(g)(1), 321(h). The brief of respondent Brown and Williamson Tobacco Corporation demonstrates that FDA has failed to show that the effects it has identified are "intended." This brief demonstrates that, even if those effects were "intended," they would be outside the definitions because they do not serve a medical purpose.

FDA's theory, seatbelts, which are regulated under laws administered by the National Highway Traffic Safety Administration,[14] would be subject to concurrent jurisdiction as devices under the FDCA. Chemical Mace similarly would be subject to FDA jurisdiction because it has the "classic characteristics" of topical irritant drugs, *e.g.*, capsicum oleoresin, which have been regulated by FDA for decades. *See* 48 Fed. Reg. 5852, 5868 (1983) (listing "capsicum oleoresin," among other chemicals, as a safe and effective "counterirritant" ingredient in topical analgesic over-the-counter drugs). Capsicum oleoresin is the ingredient in Mace-like personal protection "pepper sprays." [15]

The Government's decision to play up the "drug-like" effects of nicotine in tobacco products betrays its recognition that to interpret the structure-or-function definition in accordance with its "plain language" and without regard to medical purpose would extend its boundaries too far. The Government therefore analogizes the effects of nicotine in tobacco products to the effects produced by

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[14] *See* 49 U.S.C. § 30102(a)(7) (defining "motor vehicle equipment"). The National Traffic and Motor Vehicle Safety Act does not explicitly exclude "devices" from the definition of "motor vehicle equipment," and the FDCA does not explicitly exclude motor vehicle equipment from the "device" definition.

[15] *See Public Sale of Protective Chemical Sprays: Hearing Before the Consumer Subcomm. of the Senate Comm. on Commerce*, 91st Cong. 3 (1969). A witness at the hearing said that, because Mace "is a chemical which goes into the body and can alter the structure or function of the body," it should be regulated as a drug. *Id.* at 7. FDA's Chief Counsel agreed that Mace fit the literal language of the structure-or-function "drug" definition, just as "pistols and bullets are intended to affect the function or structure of the body in the same way." *Id.* at 37. However, he "concluded that the products [Mace and other self-protection chemical sprays] could not properly be classified as drugs under the definition in the Food, Drug, and Cosmetic Act." *Id.*

drugs that *do* have a medical purpose. The analogy is false. Whether a product is "quintessentially" a "drug" or a "device" does not depend on what it does, but on what it is intended to accomplish. Both a bayonet and a scalpel cut flesh, but only one of them is a medical device.

Conversely, FDA has the authority to regulate products intended to be used for medical purposes as "drugs" and "devices" without regard to the nature, or even the existence, of their actual physical effects. *See, e.g., United States v. 23 . . . Articles*, 192 F.2d 308 (2d Cir. 1951) (phonograph record a "device"); *Bradley v. United States*, 264 F. 79 (5th Cir. 1920) (water a "drug" under 1906 Act "disease-treatment" drug definition).

Under the FDCA there is no such thing as an inherently, or "quintessentially," drug-like or device-like effect that, standing by itself, triggers FDA jurisdiction. "[T]he statutory definition of a substance under the Act does not depend on any inherent properties of the substance, but rather, it depends on how the vendor of the substance intends the substance to be used." *United States v. Two Plastic Drums*, 791 F. Supp. 751, 753 (C.D. Ill. 1991) (citation omitted), *aff'd*, 984 F.2d 814 (7th Cir. 1993). The effects of nicotine in tobacco FDA characterizes as quintessentially drug-like do not have inherently medical purposes that transform tobacco products into FDA-regulated "drug delivery devices."

"*Addictiveness.*" FDA found that nicotine in tobacco products "causes and sustains addiction." 61 Fed. Reg. 44,661. Indeed, FDA went so far as to suggest that

> [t]here is . . . a basis for finding that these products are "effective" for adults who are addicted to tobacco products because such products sustain with great efficacy the individual's continued need for the active ingredient nicotine . . . [and] are effective for

> preventing withdrawal symptoms in individuals addicted to nicotine in much the same way that methadone is effective in preventing withdrawal.

Id. at 44,413.[16]

Drugs such as morphine have addictive properties. These drugs are not within the FDCA "drug" definition because they are addictive, however, but because their other pharmacological properties have a medical purpose (*e.g.* analgesia). Indeed, addictiveness is a toxic side effect,[17] and toxicity is not a basis for categorizing a product as a "drug." *NNFA v. Mathews,* 557 F.2d at 334-35. The medical benefits of an addictive drug must outweigh the risk of addiction to warrant approval under the FDCA. *See* 21 U.S.C. § 355(d).

FDA's result-oriented argument that tobacco products might somehow be considered "effective" under the FDCA due to their "addictiveness" is nonsensical and perverse. The only recognized medical use of nicotine is in FDA-approved smoking-*cessation* drugs, such as Nicorette gum. Those products provide nicotine in a form that does not involve the use of tobacco, ultimately to stop nicotine use altogether, including the nicotine in the drug products. It is not reasonable for FDA to contend that a cigarette might be considered a "drug delivery device" for treating cigarette smoking, or that nicotine in tobacco products might be considered "effective" for "sustaining" the very

[16] FDA did not convert this "basis" into a "finding," and its use of quotation marks around "effectiveness" signals that it was using that word with a meaning other than the statutory meaning.

[17] Methadone is approved as a drug under the FDCA for use in treating heroin addiction because it is a safer source of the addictive properties of heroin, and therefore can be used in place of heroin to improve the patient's medical status. However, neither FDA nor any other government agency recommends the use of methadone for the purpose of experiencing its addictiveness when there is no heroin addiction for methadone addiction to replace.

"addiction" it supposedly causes, and which drugs like Nicorette are intended to combat. If FDA were correct, methadone would be unnecessary because heroin could be considered an "effective" drug for the treatment of heroin addiction.

When it comes to tobacco, FDA views the FDCA not as a legislative charter but as a compendium of exploitable terminology. Just as the Agency interprets the structure-or-function definition in isolation from the operative provisions for drugs and devices, it interprets drug "effectiveness" without regard to the requirement that a drug be "effective" for a beneficial purpose, and that it also be "safe." This "words and phrases" approach allows FDA to apply a veneer of plausibility to an absurd proposition—nicotine in tobacco is an effective "drug" because it sustains "addiction" to nicotine in tobacco. But it cannot hide the Agency's failure to interpret the FDCA as a coherent legislative program for regulating medical products.

"*Tranquilization and stimulation.*" FDA's finding that nicotine in tobacco products has the structure-or-function properties of "tranquilization and stimulation," 61 Fed. Reg. 44,661—an observation made by the Surgeon General in 1964—is opportunistic. FDA has no intention of regulating cigarettes and smokeless tobacco as medically useful tranquilizers and stimulants, and would never permit them to be labeled for those purposes. Rather, FDA describes physiological effects using evocative terms to make them sound "drug-like." [18]

[18] FDA purported to analyze the "safety" of banning tobacco products used by "addicted" adults, taking into account the effects on adult users, treatment demands on the health care system, and possible smuggling, *id.* at 44,413. That is not a proper "safety" analysis under the FDCA, *see* Brief For Respondent R.J. Reynolds Tobacco Company, Part I.B.1; but, even if it were, FDA did

"Tranquilization" and "stimulation" are medical uses of some FDA-regulated drugs. But a medical use cannot be inferred solely from a physiological effect, *e.g.*, the cutting of flesh. The effects FDA found nicotine to have were "arousal-reducing" and "arousal-increasing" effects. 60 Fed. Reg. 41,536. Considered solely as effects, properties that cause drowsiness or agitation are not inherently medical. FDA obscures this fact by using "tranquilizer," "sedative," and "stimulant," words used to refer not just to effects but also to categories of FDA-regulated drugs. It is circular to use words that imply a medical purpose to describe an effect that is, according to FDA, inherently a "drug" effect without regard to its purpose.

"*Weight control.*" FDA found that "[n]icotine in cigarettes and smokeless tobacco controls weight." 61 Fed. Reg. 44,661. This finding, too, is tautological: the word "control" implies the very medical purpose FDA contends is inherent in the effect. Although an effect on body weight can be given a medical purpose by incorporating a substance that has that effect in a product labeled for "weight control" or "slenderizing," an effect on body weight in the abstract has no purpose, medical or otherwise.

Thus, FDA's finding that nicotine in tobacco "controls weight," even if true as a physiological matter, could at most support the argument that "actual consumer use" can be evidence of an "intended drug use" of a product. FDA makes an "actual use" argument, *see id.* at 44,662,

not apply it, or any other safety analysis, to the "tranquilization" and "stimulation" effects of tobacco products. If FDA believes that cigarettes and smokeless tobacco were "sufficiently safe" for continued marketing to adults, the Agency should be prepared to review and approve over-the-counter labeling for cigarettes and smokeless tobacco as tranquilizer and stimulant medical devices, including indications for use, dosage instructions, warnings, and contraindications.

but the underlying finding is legally inadequate. Even under judicial dicta, the only circumstance in which consumer use of a product is evidence of "intended drug use" is when a product is used "almost exclusively for therapeutic purposes," *NNFA v. Mathews,* 557 F.2d at 334, and there is a lack of a recognized non-drug use, *id.* If that is not the case, actual use does not determine "intended use." FDA made no finding of "almost exclusive" use of tobacco products for "weight control." [19] In this very proceeding, it concluded that weight control is merely one of "a variety of ancillary drug effects" for which "[c]onsumers also use tobacco." 60 Fed. Reg. at 41,581.

The Government argues that, if nicotine is known to control body weight (or sedate or tranquilize, or cause addiction), manufacturers of cigarettes and smokeless tobacco products should not be free from FDA regulation merely because "they refrain from making such claims." Pet. Br. 24-25. This argument underscores FDA's distortion of the FDCA. Under FDA's theory, the known "intended" uses of tobacco products are *required* to be "claimed" in the labeling of cigarettes and smokeless tobacco. *See id.* at 27 n.5. Thus, if "weight control" actually were an "intended" drug use of nicotine in tobacco products, its omission from their labeling would cause them to be "misbranded drugs." *See* 21 U.S.C. § 352(f)(1); 21 C.F.R. § 201.5. However, inclusion of "weight control" as an indication would cause them to be unapproved "new drugs" because nicotine is not "generally

19 FDA's "intended use" findings, 61 Fed. Reg. 44,661-62, do not distinguish among the three categories of physiologic effects the Agency characterizes as "quintessentially drug-like" ("addictiveness," "tranquilization/stimulation," "weight control"). Nothing in the administrative record even purports to constitute a finding of intended use of smokeless tobacco for weight control purposes; and, as to cigarettes, the record shows only that many people cite weight control as one reason for smoking. 60 Fed. Reg. 41,580.

recognized" as safe and effective for that use. *See* 21 U.S.C. § 321(p)(1). Following the logic of the FDCA, as FDA normally would, manufacturers would be forced to submit approval applications to establish that tobacco products are "safe and effective" slenderizers—or remove them from the market. *See United States v. 354 Bulk Cartons . . . Trim Reducing-Aid Cigarettes,* 178 F. Supp. 847, 852-53 (D.N.J. 1959).

But the Government does not extend this logic to its natural conclusion, because the effects of nicotine on body weight, if any, are not "drug" or "device" effects amenable to the standards and controls of chapter V. They are a pretext for FDA's assertion of jurisdiction.

F. FDA Does Not Regulate Non-Medical Products As Drugs And Devices.

In the 61-year history of the FDCA, FDA has taken hundreds of thousands of actions, formal and informal, against a diverse array of products.[20] FDA cannot deny that its consistent practice has been to apply the drug and device provisions only to products with a medical purpose.[21]

FDA implied in the rulemaking that it has routinely applied the structure-or-function definition to products "with cosmetic, recreational, economic, or other non-

20 The Agency has filed over 67,000 seizure actions since 1938 as demonstrated by its sequential numbering of all civil seizure actions. *See, e.g., FDA Consumer* (July-Aug. 1999), Summaries of Court Actions, at 38, 39 (*Acne Cream,* FDC No. 67,231). In fiscal year 1998, FDA issued 36,724 import detentions, 905 warning letters, and 8038 lists of adverse inspectional observations, and supervised 3532 recalls. HHS, *The Enforcement Story: Fiscal Year 1998* at 220 (undated).

21 Isolated examples, lacking factual context, of uncontested actions, *see* 60 Fed. Reg. 41,527-28 (khat, "caine"), are not precedent (Pet. Br. 29) for expanding the scope of FDA's jurisdiction to include non-medical products.

therapeutic purposes." 61 Fed. Reg. 44,677. The examples cited, however, were products with the immediate purpose of improving the physical condition of the body. For instance, FDA gave tanning booths as an example of a product "with non-therapeutic, but pharmacological effects," 60 Fed. Reg. 41,468, and "cosmetic, recreational . . . or other nontherapeutic purposes," 61 Fed. Reg. 44,677. Under the FDCA, FDA does not regulate "tanning booths," but "ultraviolet lamps for tanning." 21 C.F.R. § 878.4635. FDA created this category of convenience because "the various therapeutic uses for sunlamp products, including treatment of fungal diseases, vitamin D production, treatment of psoriasis, and treatment of acne, cannot be readily separated from the tanning function," 44 Fed. Reg. 65,352, 65,353 (1979), and because the Agency has separate authority to regulate non-therapeutic sunlamps as radiation-emitting products under a different statute, *see id.* at 65,356. FDA also cited an animal euthanasia drug, on the ground that it was "intended to induce death in animals by humane means—an intended use that is indisputably not therapeutic." 61 Fed. Reg. 44,678. This is too narrow a view. From the perspective of the ethical treatment of animals, a drug that brings about the necessary or inevitable death of an animal in a humane fashion indisputably has a medical purpose.[22]

Consistent with the FDCA's objective of protecting the public health, *Bacto-Unidisk,* 394 U.S. at 798, FDA has taken a broad view of what constitutes a medical purpose so as to bring within the "drug" and "device" definitions

22 21 U.S.C. § 360b, for "new animal drugs," applies to products that have a medical purpose both in treating animals and in improving their growth or output (by making the animals healthier) for economic reasons.

a wide range of health-benefiting products. However, FDA cannot give those definitions a construction that has no limits at all. *See, e.g., Rodriguez v. United States,* 480 U.S. 522, 526 (1987). Nor is that necessary. Other agencies, with their own remedial statutes, also have the responsibility and authority to take action to protect the public health. In the improbable event, for example, that anyone tried to market a nicotine product for non-medical use—such as a nicotine inhaler promoted for "breathing pleasure," *see* Certiorari Reply Brief for the Petitioners 5—any safety issues could be promptly dealt with under appropriate federal laws, such as the Consumer Product Safety Act.

FDA's responsibilities are broad and vitally important, but they are nevertheless limited by the intent of Congress as embodied in the FDCA: "In our anxiety to effectuate the congressional purpose of protecting the public, we must take care not to extend the scope of the [FDCA] beyond the point where Congress indicated it would stop." *62 Cases . . . of Jam v. United States,* 340 U.S. 593, 600 (1951).

II. THE CSTHEA PRECLUDES FDCA JURISDICTION OVER SMOKELESS TOBACCO PRODUCTS.

In addition to being invalid on its own terms, FDA's new interpretation of the FDCA has been precluded by specific laws relating to tobacco and health—the FCLAA and the CSTHEA. The history of these laws, set forth at pp. 4-6, *supra,* and in the brief of respondents Philip Morris Incorporated and Lorillard Tobacco Company, demonstrates that Congress acted to do what FDA told Congress it had no authority to do: establish health-related requirements for tobacco products.[23]

[23] *See 1965 Hearings* 193 ("[FDA] has no jurisdiction under the [FDCA] over tobacco, unless it bears drug claims." (Statement of FDA Deputy Comm'r Winton B. Rankin)); *1985 Hearings* 106 ("FDA claims it does not have the authority to regulate the sale of smokeless tobacco." (Statement of Rep. Mike Synar)).

FDA cannot now override Congress's tobacco-specific statutes by reversing its position. The "proper inquiry is how best to harmonize" the FDCA with those later-enacted statutes. *United States v. Estate of Romani,* 118 S. Ct. 1478, 1486 (1998). "Th[e] classic judicial task of reconciling many laws enacted over time, and getting them to 'make sense' in combination, necessarily assumes that the implications of a statute may be altered by the implications of a later statute." *United States v. Fausto,* 484 U.S. 439, 453 (1988).

The Government trivializes the FCLAA and CSTHEA as "several statutes that deal with tobacco in certain specific respects." Pet. Br. 44. "Like FCLAA, the Smokeless Tobacco Act simply requires certain warnings on packages and precludes federal agencies, including FDA, from requiring different ones." *Id.* at 46. The FCLAA and CSTHEA are far more than that. They constitute Congress's enacted judgments about how tobacco products should be regulated at the federal level in relation to health issues.[24]

The CSTHEA, modeled on the FCLAA, bans broadcast advertising of smokeless tobacco products, 15 U.S.C. § 4402(f); requires health warnings on packages and in most advertising, § 4402(a); establishes a mandatory warning format, § 4402(b); authorizes the Federal Trade Commission, not FDA, to issue regulations, § 4402(c); requires ingredient reporting to HHS, § 4403; requires

[24] Congress encouraged the States to develop programs to curtail underage tobacco use. 42 U.S.C. § 300x-26. As explained in the brief of respondents National Association of Convenience Stores and Acme Retail Incorporated, Congress intended that States take the lead in this area, an objective thwarted by FDA's assertion of jurisdiction.

HHS to "establish and carry out a program to inform the public of any dangers to human health resulting from the use of smokeless tobacco products," by, among other things, making "programs, materials, and announcements available to States, local governments, school systems, [and] the media," § 4401(a)(1); and requires HHS to report biennially to Congress, including any "recommendations for legislation and administrative action that HHS considers appropriate," § 4407(a).

The CSTHEA was enacted to deal with the same issues FDA contends are the primary target of its own regulations under the FDCA: the use of smokeless tobacco by minors, and the supposed influence of advertising and promotion on minors' decision to use the product. "[A] major reason for the development of a legislative proposal is the alarming incidence of use by children." S. Rep. No. 99-209, at 4 (1985). A principal sponsor stated that the CSTHEA banned broadcast advertising "due to concern about the impact of such advertising upon youth," 132 Cong. Rec. 1330 (1986) (statement of Rep. Henry Waxman), and that the educational efforts "are especially critical at the primary and secondary school levels where young people are most vulnerable and the pressure to begin smokeless tobacco use is strong." *Id.* Congress was also well aware that nicotine in tobacco was considered to have "addictive properties," *id.* at 1331 (statement of Rep. Waxman), and, in particular, of the belief that "smokeless tobacco is addictive," *id.* at 1333 (statement of Rep. Synar).

The CSTHEA covers a wide range of issues relating to smokeless tobacco and health. The program was the result of congressional decisions both about what should be required (a ban on broadcast advertising, warnings in print advertising) and what should not be required

(limits on print advertising format, a ban on smokeless tobacco sales altogether). FDA's conclusion that its regulations are justified because "[t]he statutes enacted by Congress for regulation of tobacco products do not amount to a comprehensive scheme," 61 Fed. Reg. 44,547, is in truth an administrative repudiation of Congress's policy judgment as to how "comprehensive" federal regulation in this area should be. FDA believes it should be more comprehensive than the CSTHEA provides, but Executive Branch agencies may not second-guess Congress. Although, in FDA's view, its tobacco control regulations "may . . . be a better regime[, it] is not the one that Congress established," *MCI Telecomm. Co. v. AT&T*, 512 U.S. 218, 234 (1994), and therefore it cannot stand.

That FDA's regulations purport to be based on a separate law, the FDCA, does not insulate them from the choices Congress made in the tobacco-specific statutes. Congress's legislative judgments are those expressed in all relevant statutes " 'taken together, as if they were one law.' " *United States v. Stewart*, 311 U.S. 60, 64 (1940) (citation omitted). Even if the FDCA might once have been interpreted to apply to smokeless tobacco products, that possibility is now foreclosed: "We should be reluctant . . . to read an earlier statute broadly where the result is to circumvent the detailed remedial scheme constructed in a later statute." *Patterson v. McLean Credit Union*, 491 U.S. 164, 181 (1989) (citation omitted).

Moreover, the Government's portrayal of the FCLAA and the CSTHEA as irrelevant to FDA's regulations is contradictory. The "specific respects" in which the tobacco statutes principally "deal with tobacco products," Pet. Br. 44, are the identical "specific respects" in which FDA's regulations, supposedly based on the FDCA, prin-

cipally "deal with tobacco products": advertising and underage tobacco use. By contrast, FDA's regulations do *not* apply to tobacco products the very provisions of the FDCA that make that statute the nation's principal guarantor of the safety and effectiveness of true drugs and medical devices, most prominently, by requiring that drugs and devices be banned if they are not "safe."

Putting aside FDA's incongruous regulations, there is, contrary to the Government's brief, *id.*, an "irreconcilable conflict" between the FDCA and the tobacco-specific statutes. For instance, the CSTHEA provides that "[n]o statement relating to the use of smokeless tobacco products and health, other than the statements required by [the CSTHEA], shall be required by any Federal agency to appear on any package . . . of a smokeless tobacco product." 15 U.S.C. § 4406(a). But drug and device labeling regulations "are a fundamental part of FDA's regulatory scheme." *Zeneca, Inc. v. Shalala,* No. WMN-99-307, 1999 U.S. Dist. LEXIS 12327, at *30 (D. Md. Aug. 11, 1999).

The labeling provisions of the CSTHEA and the FDCA are at war. This is apparent from FDA's attempt to explain why it does not apply to smokeless tobacco products the FDCA's requirement for "adequate warnings against use [of a drug or device] . . . by children where its use may be dangerous to health," § 352(f)(2). *See* 61 Fed. Reg. 44,464-65. The purpose of FDA's tobacco regulations is to reduce tobacco use by children. FDA regards the FCLAA and the CSTHEA as inadequate for this purpose—they "do not amount to a comprehensive scheme . . . they address only a few specific aspects relating to regulation of tobacco products," *id.* at 44,547—and it views tobacco products as "dangerous," *id.* at 44,412. Nevertheless, to rationalize not applying the "adequate warnings" requirement of § 352(f)(2) to

"dangerous" smokeless tobacco (because the CSTHEA precludes FDA from doing so, 15 U.S.C. § 4406(a)), FDA says that the warnings required by the CSTHEA "satisfy this [FDCA] requirement," 61 Fed. Reg. at 44,465. In short, the CSTHEA is *inadequate* to address youth tobacco use, but it provides "*adequate* warnings" under the FDCA "against use . . . by children where [that] use may be dangerous to health." *See id.* (quoting 21 U.S.C. § 352(f)(2)) (emphasis added).

FDA's resort to such illogic with respect to one of the most important provisions of the FDCA, one that relates specifically to the safe use of "drugs" and "devices" by children, demonstrates that the CSTHEA cannot be reconciled with FDA's assertion of jurisdiction over smokeless tobacco products as "drug delivery devices" under the FDCA.

CONCLUSION

For the foregoing reasons, the decision of the court of appeals should be affirmed.

Respectfully submitted,

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