

I. CIGARETTES AND SMOKELESS TOBACCO PRODUCTS "AFFECT THE STRUCTURE OR ANY FUNCTION OF THE BODY" BECAUSE THEY HAVE PHARMACOLOGICAL EFFECTS AND LEAD TO ADDICTION

The definition of drug in the Food and Drugs Act of 1906 included only articles "intended to be used for the cure, mitigation, or prevention of disease." Pub. L. No. 59-384, 34 Stat. 768 § 6. Congress added section 201(g)(1)(C)² when it enacted the Federal Food, Drug, and Cosmetic Act of 1938 in order to expand the reach of the drug definition to encompass products that escaped regulation under the 1906 act. Section 201(g)(1)(C) and the parallel section 201(h)(3), governing devices, reach products that do not have therapeutic uses but have, or are promoted as having, significant pharmacological or physiological effects. As House Report 2139 explained:

[t]he definition of drug is expanded to include . . . articles other than food intended to affect the structure or any function of the body of man or other animals. These expansions are needed to give jurisdiction over a great number of drugs which are not amenable to control under the present law.

H.R. Rep. No. 2139 at 3, reprinted in 6 Legislative History 300, 302 (emphasis added). The principal example given in the legislative history of products "intended to affect the structure or any function of the body" is weight management products. The "structure or any function" language was needed because obesity and extreme thinness were not considered diseases. Congress was concerned with both the egregious nature of the claims for some of these products as well as the health risks associated with their use. See 78 Cong. Rec. 8960 (73d Cong., 2d Sess., May 16, 1934) (prepared statement of Senator Copeland), reprinted in 2 Legislative History at 831.

² Section 201 of the Federal Food, Drug, and Cosmetic Act is now codified at 21 U.S.C. § 321.

While Congress' primary focus in 1938 was on products intended for weight management, it adopted language that included all products that affect the structure or function of the body. This expansion of the drug definition was "needed to protect the consumer . . . against a multiplicity of abuses not subject to the [1906 act]." S. Rep. No. 646, 74th Cong. 1st Sess. 1, reprinted in 4 Legislative History at 93. As one court explained:

The legislative history of the 1938 Act discloses that . . . the law which broadened the drug definition was enacted in part, and perhaps in important part, to control fraudulent remedies for obesity and leanness. But it also discloses that the expansion of the drug definition was not aimed solely at these remedies. They were merely illustrative of a comprehensive class of preparations which were intended to affect the structure or function of the body to which the legislation was directed.

United States v. Article Consisting of 36 Boxes . . . "Lineaway, Temporary Wrinkle Smoother", 284 F. Supp. 107, 110 (D. Del. 1968), aff'd, 415 F.2d 369 (3d Cir. 1969) (emphasis added) (citations omitted).

Consistent with the statutory language and Congress' intent to insure that FDA has the authority to regulate products with non-therapeutic, but pharmacological effects, FDA has interpreted the provisions to encompass products that intrinsically have pharmacological or physiological effects, even though they are not promoted for therapeutic purposes. Examples of such products are topical hormones, sunscreens, and tanning booths. See Appendix to Legal Analysis. Judicial constructions of sections 201(g)(1)(C) and 201(h)(3) are consistent with this interpretation. See, e.g., E.R. Squibb & Sons, Inc. v. Bowen, 870 F.2d 678, 683 (D.C. Cir. 1989) (summarizing cases); United States v. Undetermined Quantities of Cal-Ban 3000, 776 F. Supp. 249, 253 (E.D.N.C. 1991) ("[T]he term 'drug' should be interpreted broadly and not limited to only products which are commonly known as drugs.").

Courts have been careful to distinguish between remote physical effects which arguably might fall within the literal language of section 201(g)(1)(C) or section 201(h)(3) and significant effects on structure or function which clearly fall within the provisions' ambit. "[R]emote physical effect[s] on the body" are not covered by the structure or function provision. E.R. Squibb & Sons, 870 F.2d at 682. On the other hand, products intended to prevent pregnancy, thus affecting the reproductive function of the human body, fall within that definition. Id. at 682-83.

For example, a product intended to reduce the number of bacteria in an animal's digestive system and oral cavity is a drug within the meaning of section 201(g)(1)(C) because it "was intended to alter a function of the animal's body." United States v. Undetermined Quantities . . . "Pet Smellfree", 22 F.3d 235, 240 (10th Cir. 1994). Similarly, liquid solutions intended to cause hair growth and prevent hair loss are drugs within the meaning of section 201(g)(1)(C) because the hair growth process is a function of the human body. United States v. Kasz Enterprises, Inc., 855 F. Supp. 534, 540 (D.R.I. 1994), judgment modified on other grounds, 862 F. Supp. 717 (D.R.I. 1994). Likewise, an apparatus containing oxygen that is intended to improve athletic performance by increasing a tired athlete's intake of oxygen falls within sections 201(g)(1)(C) and 201(h)(3) because enhanced oxygen absorption alters a bodily structure or function. United States v. Eighteen Units, More or Less Of An Article of Drug . . . "SPORTS OXYGEN . . .", Civ. No. 89-2085 (D.N.J. October 27, 1992), reprinted in Food, Drug, and Cosmetic Act Judicial Record, 1991-92 115. Cocaine and similar substances with parallel addictive and psychoactive effects also fall within the drug definition because

they "affect the structure or any function of the body."³

In each of these cases, a significant pharmacological effect on the body can bring a substance within the drug definition, even when the product has no therapeutic effect. On numerous other occasions, the Agency has reached similar conclusions and has taken regulatory action. See Appendix to Legal Analysis for examples. As is discussed at p. 22, et seq., it is now widely accepted that nicotine has pharmacological effects on both the structure and function of the central nervous system, particularly the brain. Addiction is a direct result of nicotine's effects on the structure and function of the body. Id. Based on the record before the agency, cigarettes and smokeless tobacco products "affect the structure or any function of the body" within the meaning of sections 201(g)(1)(C) and 201(h)(3).

³ In fact, the Controlled Substances Act, 21 U.S.C. §§ 801-904, which prohibits the sale of drugs such as cocaine, defines "drug" by reference to section 201(g)(1) of the FDCA. 21 U.S.C. § 802(12).