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FDA JURISDICTION: A MATTER OF DEFINITIONS

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CHAPTER II

FDA JURISDICTION: A MATTER OF DEFINITIONS

A. INTRODUCTION

The 1938 Act gave FDA authority over four broad categories of products, all of which the agency still regulates: food, drugs, cosmetics, and medical devices. In the ensuing decades, the agency assumed or was given responsibility for additional classes of products, some of which (human biological products, electronic radiation-emitting products) it continues to regulate today, while others (toys, pesticides) it later ceded to other agencies. In addition, Congress has repeatedly tweaked the FD&C Act definitions, in some instances establishing entire subcategories with their own definitions, such as “food additives” and “dietary supplements” (both subcategories of “food”).

The scope of FDA’s power is defined almost entirely by the list of product categories over which it has jurisdiction.* The statutory definitions of these categories thus delineate the outer boundaries of the arena within which the agency operates. The definitions are also important for another reason. FDA has different degrees of power over different categories of products. In general, the agency has greater authority over drugs, devices, and biological products than over food and cosmetics. The category to which FDA—or Congress—assigns an article thus largely controls the shape of the regulatory regime the agency will impose on it.

As the materials in this chapter show, the product definitions are strikingly broad and thus confer jurisdiction over a vast range of goods. Furthermore, the definitions which are not mutually exclusive, are remarkably plastic, providing the agency with great flexibility to decide whether and how to regulate products. Sometimes FDA has interpreted the definitions expansively, so as to expand its power. On other occasions, the agency has construed the definitions narrowly, so as to avoid taking responsibility for products it does not want to regulate or to minimize the burdensomeness of the requirements it does impose.

Occasionally, when FDA interprets the definitions flexibly so as to achieve particular policy objectives, the courts will rein in the agency, as the Supreme Court did with respect to FDA’s attempts in the 1990s to regulate cigarettes as medical devices. *FDA v. Brown & Williamson*, 529

* [The most important exception to this principle is the power FDA shares with the Centers for Disease Control under Section 361 of the Public Health Service Act (42 U.S.C. 264) to take measures to control the spread of communicable diseases.

U.S. 120 (2000), *infra* p. 82. In general, however, as the next case illustrates, courts have granted the agency considerable latitude in applying the product definitions.

United States v. An Article of Drug . . . Bacto-Unidisk

394 U.S. 784 (1969).

■ MR. CHIEF JUSTICE WARREN delivered the opinion of the court.

At issue here is the scope of the statutory definition of drug contained in the Federal Food, Drug, and Cosmetic Act and the extent of the Secretary of Health, Education, and Welfare's regulatory authority under that definition. The specific item involved in this definitional controversy is a laboratory aid known as an antibiotic sensitivity disc, used as a screening test for help in determining the proper antibiotic drug to administer to patients. If the article is a "drug" . . . then the Secretary can subject it to pre-market clearance regulations promulgated pursuant to § 507 of the Act. . . . If, on the other hand, the article is merely a "device" under the Act, it is subject only to the misbranding and adulteration proscriptions of the Act and does not have to be pretested before marketing; and, of course, if the disc does not fall under either definition, the Act itself is totally inapplicable. . . .

At the outset, it is clear from § 201 that the word "drug" is a term of art for the purposes of the Act, encompassing far more than the strict medical definition of that word. . . .

The historical expansion of the definition of drug, and the creation of a parallel concept of devices, clearly show, we think, that Congress fully intended that the Act's coverage be as broad as its literal language indicates and equally clearly, broader than any strict medical definition might otherwise allow. Strong indications from legislative history that Congress intended the broad coverage the District Court thought "ridiculous" should satisfy us that the lower courts erred in refusing to apply the Act's language as written. But we are all the more convinced that we must give effect to congressional intent in view of the well-accepted principle that remedial legislation such as the Food, Drug, and Cosmetic Act is to be given a liberal construction consistent with the Act's overriding purpose to protect the public health, and specifically, § 507's purpose to ensure that antibiotic products marketed serve the public with "efficacy" and "safety."

Respondent's alternative contention, that even if its product does fall within the purview of the Act, it is plainly a "device" and therefore by definition necessarily not a "drug," must also be rejected, we believe, in light of the foregoing analysis. At the outset, it must be conceded that the language of the statute is of little assistance in determining precisely what differentiates a "drug" from a "device": to the extent that both are intended for use in the treatment, mitigation and cure of disease, the former is an "article" and the latter includes "instruments," "apparatus," and "contrivances." Despite the obvious areas of overlap in definition, we are not entirely without guidance in determining the propriety of the

Secretary's decision below, given the overall goals of the Act and its legislative history.

More specifically, . . . the "natural way" to draw the line "is in light of the statutory purpose." Since the patient will tend to derive less benefit and perhaps some harm from a particular antibiotic if, though the drug itself was properly batch-tested, it was not the proper antibiotic to use, it was entirely reasonable for the Secretary to determine that the discs, like the antibiotics they serve, are drugs and similarly subject to pre-clearance certification under § 507. An opposite conclusion might undercut the value of testing the antibiotics themselves, for such testing would be a useless exercise if the wrong drug were ultimately administered, even partially as the result of an unreliable disc

Reversed.

B. FOOD

Section 201(f) of the FD&C Act defines "food" as follows: "The term 'food' means (1) articles used for food and drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article." Not surprisingly, this tautological definition ("food" means "food") leaves many open questions. The issue of the definition's precise meaning has sometimes arisen in disputes over whether a particular product is a food or falls outside FDA's authority altogether. On other occasions, as in the case excerpted below, the question has come up when FDA has tried to regulate as a drug a product that the manufacturer claims is only a food. Because new drugs are subject to premarket approval by the agency for safety and effectiveness, whereas foods are not, the resolution of such a dispute over application of the food definition frequently determines the fate of the product.

Nutrilab, Inc. v. Schweiker

713 F.2d 335 (7th Cir. 1983).

■ CUMMINGS, CHIEF JUDGE.

Plaintiffs manufacture and market a product known as "starch blockers" which "block" the human body's digestion of starch as an aid in controlling weight. On July 1, 1982, the Food and Drug Administration ("FDA") classified starch blockers as "drugs" and requested that all such products be removed from the market until FDA approval was received

The only issue on appeal is whether starch blockers are foods or drugs under the Federal Food, Drug, and Cosmetic Act. Starch blocker tablets and capsules consist of a protein which is extracted from a certain type of raw kidney bean. That particular protein functions as an alpha-amylase inhibitor; alpha-amylase is an enzyme produced by the body which is utilized in digesting starch. When starch blockers are ingested during a meal, the protein acts to prevent the alpha-amylase enzyme from acting,

thus allowing the undigested starch to pass through the body and avoiding the calories that would be realized from its digestion.

Kidney beans, from which alpha-amylase inhibitor is derived, are dangerous if eaten raw. By August 1982, FDA had received seventy-five reports of adverse effects on people who had taken starch blockers, including complaints of gastro-intestinal distress such as bloating, nausea, abdominal pain, constipation and vomiting. Because plaintiffs consider starch blockers to be food, no testing as required to obtain FDA approval as a new drug has taken place. If starch blockers were drugs, the manufacturers would be required to file a new drug application pursuant to 21 U.S.C. § 355 and remove the product from the marketplace until approved as a drug by the FDA.

The statutory scheme under the Food, Drug, and Cosmetic Act is a complicated one. Section 321(g)(1) provides that the term "drug" means

... (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any article specified in clauses (A), (B), or (C) of this paragraph; but does not include devices or their components, parts, or accessories.

The term "food" as defined in Section 321(f) means

(1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article.

Section 321(g)(1)(C) was added to the statute in 1938 to expand the definition of "drug." The amendment was necessary because certain articles intended by manufacturers to be used as drugs did not fit within the "disease" requirement of Section 321(g)(1)(B). Obesity in particular was not considered a disease. Thus "anti-fat remedies" marketed with claims of "slenderizing effects" had escaped regulation under the prior definition...

It is well established that the definitions of food and drug are normally not mutually exclusive; an article that happens to be a food but is intended for use in the treatment of disease fits squarely within the drug definition in part B of Section 321(g)(1) and may be regulated as such. Under part C of the statutory drug definition, however, "articles (other than food)" are expressly excluded from the drug definition (as are devices) in Section 321(g)(1).^{*} In order to decide if starch blockers are drugs under Section 321(g)(1)(C), therefore, we must decide if they are foods within the meaning of the part C "other than food" parenthetical exception to Section 321(g)(1)(C). And in order to decide the meaning of "food" in that parenthetical exception, we must first decide the meaning of "food" in Section 321(f).

^{*} [Authors' Note: the definition of "drug" at 21 U.S.C. § 321(g)(1) no longer explicitly excludes devices.]

Congress defined "food" in Section 321(f) as "articles used as food." This definition is not too helpful, but it does emphasize that "food" is to be defined in terms of its function as food, rather than in terms of its source, biochemical composition or ingestibility. Plaintiffs' argument that starch blockers are food because they are derived from food—kidney beans—is not convincing; if Congress intended food to mean articles derived from food it would have so specified. Indeed some articles that are derived from food are indisputably not food, such as caffeine and penicillin. In addition, all articles that are classed biochemically as proteins cannot be food either, because for example, insulin, botulism toxin, human hair and influenza virus are proteins that are clearly not food.

Plaintiffs argue that 21 U.S.C. § 343(j) specifying labeling requirements for food for special dietary uses indicates that Congress intended products offered for weight conditions to come within the statutory definition of "food." Plaintiffs misinterpret that statutory section. It does not define food but merely requires that if a product is a food and purports to be for special dietary uses, its label must contain certain information to avoid being misbranded. If all products intended to affect underweight or overweight conditions were *per se* foods, no diet product could be regulated as a drug under Section 321(g)(1)(C), a result clearly contrary to the intent of Congress that "anti-fat remedies" and "slenderizers" qualify as drugs under that Section.

If defining food in terms of its source or defining it in terms of its biochemical composition is clearly wrong, defining food as articles intended by the manufacturer to be used as food is problematic. When Congress meant to define a drug in terms of its intended use, it explicitly incorporated that element into its statutory definition. For example, Section 321(g)(1)(B) defines drugs as articles "intended for use" in, among other things, the treatment of disease; Section 321(g)(1)(C) defines drugs as "articles (other than food) intended to affect the structure or any function of the body of man or other animals." The definition of food in Section 321(f) omits any reference to intent. . . . Further, a manufacturer cannot avoid the reach of the FDA by claiming that a product which looks like food and smells like food is not food because it was not intended for consumption. In *United States v. Technical Egg Prods., Inc.*, 171 F. Supp. 326 (N.D. Ga. 1959), the defendant argued that the eggs at issue were not adulterated food under the Act because they were not intended to be eaten. The court held that there was a danger of their being diverted to food use and rejected defendant's argument.

Although it is easy to reject the proffered food definitions, it is difficult to arrive at a satisfactory one. In the absence of clearcut Congressional guidance, it is best to rely on statutory language and common sense. The statute evidently uses the word "food" in two different ways. The statutory definition of "food" in Section 321(f) is a term of art and is clearly intended to be broader than the common-sense definition of food, because the statutory definition of "food" also includes chewing gum and food additives. Food additives can be any substance the intended use of which results or may reasonably [be expected to] result in its becoming a component or otherwise affecting the characteristics of any food. See 21 U.S.C. § 321(s). Paper food-packaging when containing polychlorinated biphenyls

(PCB's), for example, is an adulterated food because the PCB's may migrate from the package to the food and thereby become a component of it. Yet the statutory definition of "food" also includes in Section 321(f)(1) the common-sense definition of food. When the statute defines "food" as "articles used for food," it means that the statutory definition of "food" includes articles used by people in the ordinary way most people use food—primarily for taste, aroma, or nutritive value. To hold as did the district court that articles used as food are articles used solely for taste, aroma or nutritive value is unduly restrictive since some products such as coffee or prune juice are undoubtedly food but may be consumed on occasion for reasons other than taste, aroma, or nutritive value.

This double use of the word "food" in Section 321(f) makes it difficult to interpret the parenthetical "other than food" exclusion in the Section 321(g)(1)(C) drug definition. As shown by that exclusion, Congress obviously meant a drug to be something "other than food," but was it referring to "food" as a term of art in the statutory sense or to foods in their ordinary meaning? Because all such foods are "intended to affect the structure or any function of the body of man or other animals" and would thus come within the part C drug definition, presumably Congress meant to exclude common-sense foods. Fortunately, it is not necessary to decide this question here because starch blockers are not food in either sense.* The tablets and pills at issue are not consumed primarily for taste, aroma, or nutritive value under Section 321(f)(1); in fact, as noted earlier, they are taken for their ability to block the digestion of food and aid in weight loss. In addition, starch blockers are not chewing gum under Section 321(f)(2) and are not components of food under Section 321(f)(3). To qualify as a drug under Section 321(g)(1)(C), the articles must not only be articles "other than food," but must also be "intended to affect the structure or any function of the body of man or other animals." Starch blockers indisputably satisfy this requirement for they are intended to affect digestion in the people who take them. Therefore, starch blockers are drugs under Section 321(g)(1)(C) of the Food, Drug, and Cosmetic Act.

Affirmed.

NOTES

1. *Dual Classification.* It is indisputable that a product fitting the common sense definition of a "food" in section 201(f) is also subject to regulation as a drug

* The FDA urges an interpretation of the statute that would allow drug regulation of a product if, for example, an appetite suppressant were added to a recognized food. According to the FDA, addition of the drug might make it a "component" and therefore subject to regulation as a statutory "food". As such, the literal language of Section 321(g)(1)(C) would preclude regulation as a drug because the product would qualify as a statutory "food". Even if Section 321(g)(1)(C) meant only to exclude common-sense foods, an article might still be considered food unless addition of an appetite suppressant so changed its

nature that it was no longer used primarily for taste, aroma or nutritional value. The FDA submits that a drug manufacturer could easily escape drug regulation by simply adding the drug to a food.

It is not necessary to resolve this problem in order to resolve this case. We merely note the possibility that the word "component" might be interpreted to exclude substances specifically added to a food to avoid bringing the substance within the drug definition, and, as noted above, a food may lose its food character if a drug is added.

under section 201(g)(1)(B) if the manufacturer makes a therapeutic claim for it. See Senate Rep. No. 361, 74th Cong. 1st Sess. 4 (1935). In *American Health Products Co., Inc. v. Hayes*, 574 F. Supp. 1498 (S.D.N.Y. 1983), a case brought about the same time as *Nutrilab* by a different starchblocker manufacturer, the government advanced a bolder argument. It contended that a food is subject to dual classification, even in the absence of a therapeutic claim, if there is a claim regarding a specific physiological effect (that is, a structure or function claim). The United States asserted that a product making such a claim falls outside the food exclusion from section 201(g)(1)(C)'s definition of "drug," even if it is also a common sense food under section 201(f). Although the District Court held for the government on the same grounds as the Seventh Circuit in *Nutrilab*, it rejected FDA's argument as to dual classification.

The government's contention [in favor of dual classification] is untenable. Though most sections of the Act countenance dual classification, no other contains a parenthetical like that Congress inserted in part (C). Ignoring that parenthetical would render meaningless the distinctions Congress has attempted to delineate. Nevertheless, the government is correct in claiming that starchblocker pills are a "drug" under the Act, because the pills are not a "food" in any sense cognizable under the statute. . . .

In affirming the district court, the Second Circuit specifically stated that "we do not reach the issue whether dual classification is appropriate under section 321(g)(1)(C)." *American Health Prods. Co. v. Hayes*, 744 F.2d 912 (2d Cir. 1984) (per curiam).

2. *Caffeine*. FDA regulates over-the-counter stimulants in which caffeine is the active ingredient as drugs. 21 C.F.R. Part 340. However, when caffeine is added to food, such as a soft drink, the agency does not regulate the product as a drug even if the manufacturer promotes the food's high level of caffeine and its "energizing" qualities. Apparently, in FDA's view, such products fall within the food exception to the structure/function drug definition in section 201(g)(1)(C).

3. *The Impact of DSHEA*. The Dietary Supplement Health and Education Act of 1994 (DSHEA) amended the FD&C Act in a way that dramatically changed the categorization question for products such as starchblockers. A product that satisfies DSHEA's definition of a "dietary supplement" is now automatically classified as a food, regardless of whether it satisfies *Nutrilab*'s "common sense" test. Indeed, "starch-blocking" amylase inhibitors derived from kidney beans are currently marketed as dietary supplements, and thus as foods. Nonetheless, for products that do not qualify as dietary supplements under DSHEA, *Nutrilab*'s "common sense" definition of food still applies. DSHEA is addressed in detail below, *infra* p. 260.

4. *Structure/Function Claims Versus Disease Claims*. The line between structure/function claims and disease claims can be a maddeningly indistinct one. Nevertheless, FDA did not set forth a comprehensive analysis of the distinction until 2000. We consider the agency's assessment of the difference between the types of claims, *infra* p. 276.

COMMENT: OTHER APPLICATIONS OF THE DEFINITION OF "FOOD"

Food Additives. As explained by the *Nutrilab* court, the distinction between a food and a drug is critical because new drugs, unlike conventional foods, are subject to the requirement of premarket approval by FDA. The manufacturer of a new drug must establish to FDA that its product is safe and effective before the agency will approve it. Observe, however, that

there is a subcategory of foods, called "food additives," that are subject to a premarket safety approval by the agency. The definition of food in section 201(f) includes "articles used for components" of food or drink. As set forth in section 201(s) of the FD&C Act, "The term 'food additive' means any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food . . . if such substance is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety . . . to be safe under the conditions of its intended use." The exemption for foods that are generally recognized as safe (GRAS) frees most conventional food ingredients from the requirement of premarket approval. Section 201(s) also lists a number of specific exceptions to the definition of "food additive." This section is examined in detail *infra* Chapter III.

Migrating Food-Contact Materials. The statutory definition of food includes substances that migrate to food from food packaging and dinnerware, even before such migration takes place. *Natick Paperboard Corp. v. Weinberger*, 525 F.2d 1103 (1st Cir. 1975); *United States v. Articles of Food Consisting of Pottery . . . Labeled Cathy Rose*, 370 F. Supp. 371 (E.D. Mich. 1974).

Chewing Gum. Section 201(f)(2) of the FD&C Act specifically classifies chewing gum as food. As a result, FDA has taken the position that when snuff is included in a masticatory carrier base, which has the appearance of a piece of confectionary, it is properly regulated as a food. See Letter from FDA Associate Commissioner for Regulatory Affairs J.M. Taylor to S.M. Pape (Apr. 11, 1988).

No Longer "Fit" Food. A product is a food under the Act if it is generally regarded as food when sold in food form even if it is decomposed or otherwise unfit for food at the time FDA institutes legal action against it. See, e.g., *United States v. H.B. Gregory Co.*, 502 F.2d 700 (7th Cir. 1974); *Otis McAllister & Co. v. United States*, 194 F.2d 386 (5th Cir. 1952); *United States v. O.F. Bayer & Co.*, 188 F.2d 555 (2d Cir. 1951); *United States v. 52 Drums Maple Syrup*, 110 F.2d 914 (2d Cir. 1940); *United States v. Technical Egg Products, Inc.*, 171 F. Supp. 326 (N.D. Ga. 1959); *United States v. Thirteen Crates of Frozen Eggs*, 215 F. 584 (2d Cir. 1914). See also Annotation: *What is "Food" Within Meaning of Statute*, 17 A.L.R. 1282 (1922).

COMMENT: OTHER AGENCIES' ROLES IN REGULATING FOOD

Several categories of food products are subject to specific regulatory requirements.

Meat, Poultry, and Eggs. These products are regulated by the United States Department of Agriculture (USDA) under the Federal Meat Inspection Act (FMIA), 21 U.S.C. 601 *et seq.*, the Poultry Products Inspection Act, 21 U.S.C. 451 *et seq.*, and the Egg Products Inspection Act, 21 U.S.C. 1031 *et seq.* USDA has ceded to FDA jurisdiction over any food that is less than two percent meat or poultry. The jurisdiction of USDA and FDA over these three categories of food products is otherwise complex and uncertain. FDA

has exclusive regulatory jurisdiction over live animals intended to be used for food. *United States v. Tomahara Enterprises, Ltd.*, Food Drug Cosm. L. Rep. (CCH) ¶ 38,217 (N.D.N.Y. 1983). USDA has exclusive jurisdiction over the slaughter of food animals and over the subsequent processing of meat and poultry, except that USDA and FDA have joint jurisdiction over the use of food additives in meat and poultry. After processing, USDA and FDA have joint jurisdiction over the distribution of meat and poultry up to the retail establishment where it is sold. FDA has exclusive jurisdiction over retail food establishments. *D&W Food Centers, Inc. v. Block*, 786 F.2d 751 (6th Cir. 1986), held that a central kitchen making pizza containing meat was not subject to the continuous inspection requirements of the Federal Meat Inspection Act. See generally *Food Regulation: A Case Study of USDA and FDA*, in "Study on Federal Regulation: Regulatory Organization," Senate Comm. on Governmental Affairs, 95th Cong., 1st Sess., Vol. V, at Ch. 4 (Comm. Print 1977).

The FMIA has long applied to the meat of only five named species (cattle, sheep, swine, goats, and equines), and not to meat of other species such as rabbit, venison, or bison, which remained within FDA's purview. See, e.g., 21 U.S.C. 601(j) (definition of "meat food product"). In 2005, however, Congress, as part of the FY 2006 Agriculture Appropriations bill, 119 Stat. 2120, amended the FMIA to extend the USDA inspection system to all "amenable species," defined as the above species plus "any additional species of livestock that the Secretary considers appropriate." 21 U.S.C. 601(w)(2).

FDA has primary responsibility for the safety and labeling of shell eggs, although the voluntary grading of shell eggs is done under USDA supervision. Egg processing plants that wash, sort, break, and pasteurize eggs are under USDA jurisdiction, as are processed products known for their egg content.

Alcoholic Beverages. The Alcohol and Tobacco Tax and Trade Bureau (TTB) of the Department of the Treasury has jurisdiction over alcoholic beverages under the Federal Alcohol Administration Act, 49 Stat. 977 (1935), codified in 27 U.S.C. 201 *et seq.* The Bureau of Alcohol, Tobacco and Firearms in the Department of the Treasury formerly performed this function, but the Homeland Security Act of 2002 shifted certain law enforcement responsibilities of BATF to the Department of Justice and kept tax and trade regulation within a newly-named unit of the Treasury Department. TTB regulates all beer products regardless of their alcohol content. 51 Fed. Reg. 39666 (Oct. 30, 1986). In contrast, TTB regulates only those wine products that contain 7 percent alcohol or more, and FDA regulates all wine products containing less than 7 percent alcohol. FDA Compliance Policy Guide No. 7101.05 (Oct. 1, 1980). Attempts to amend the Federal Alcohol Administration Act to extend the Department of the Treasury's jurisdiction to wine products containing as little as 0.5 percent alcohol have been unsuccessful. Accordingly, wine coolers, which have an alcohol content of less than 7 percent, are regulated by FDA rather than TTB.

One court has held that the labeling of alcoholic beverages (except for wine products containing less than 7 percent alcohol) is subject only to

BATF (now TTB) jurisdiction and is exempt from the labeling requirements of the FD&C Act. *Brown-Forman Distillers Corp. v. Mathews*, 435 F. Supp. 5 (W.D. Ky. 1976). In other respects, however, alcoholic beverages are regulated as food by FDA, although the two agencies have a memorandum of understanding that confirms TTB's primary responsibility for overseeing voluntary recalls of adulterated products. See FDA Compliance Policy Guide No. 7155.04 (Nov. 1987); Elaine T. Byszewski, *What's in the Wine? A History of FDA's Role*, 57 FOOD & DRUG L.J. 545 (2002); Iver P. Cooper, *The FDA, the BATF, and Liquor Labeling: A Case Study of Interagency Jurisdictional Conflict*, 34 FOOD DRUG COSM. L.J. 370 (1979); Mary Hancock, *Federal Jurisdictional Disputes in the Labeling and Advertising of Malt Beverages*, 34 FOOD DRUG COSM. L.J. 271 (1979); *Symposium on Alcoholic Beverage Control*, 7 LAW & CONTEMP. PROBS. 543 (1940). FDA has also adopted Compliance Policy Guide 7101.04, 54 Fed. Reg. 38559 (Sept. 19, 1989), governing the labeling of dealcoholized wine beverages.

Water and Ice. Under the Safe Drinking Water Act, 88 Stat. 1660 (1974), general responsibility for the purity of drinking water was placed in the Environmental Protection Agency (EPA), but section 410 was added to the FD&C Act to preserve FDA's jurisdiction over bottled drinking water. The agency also has jurisdiction over ice. See C.W. Felix, *Ice—the Forgotten Food*, 53 J. ASS'N FOOD & DRUG OFFICIALS 19 (July 1989). Water used to process food or as an ingredient in food is subject to the same requirements under the FD&C Act as any other food constituent.

C. COSMETICS

Section 201(i) of the FD&C Act defines "cosmetic" as "(1) articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and (2) articles intended for use as a component of any such articles; except that such term shall not include soap." Cosmetics are the least intensively regulated of all the product categories under FDA's jurisdiction. There is no premarket approval requirement for any cosmetic or cosmetic ingredient, with the exception of color additives. But, like foods, cosmetics may be simultaneously classified as drugs. Moreover, because the structure/function leg of the drug definition, section 201(g)(1)(C), does not contain an exception for cosmetics, as it does for food, a cosmetic may be dual-classified as a drug even if it is a nontherapeutic product intended only to affect the structure or any function of the body. The question of when a cosmetic is also a drug is addressed later in this chapter, *infra* p. 48.

Section 201(i)—the "cosmetic" definition itself—has raised relatively few interpretive questions. Even so, several features of this provision deserve further discussion.

NOTES

1. *Odors.* FDA considers products intended to mask or prevent body odors, such as mouthwashes and underarm deodorants, to be cosmetics.

2. *Soap Exemption.* The FD&C Act does not define “soap.” FDA has defined the scope of the soap exemption by regulation. According to the agency, the exemption applies only to articles that meet the following conditions: “(1) The bulk of the nonvolatile matter in the product consists of an alkali salt of fatty acids and the detergent properties of the article are due to the alkali-fatty acid compounds; and (2) The product is labeled, sold, and represented only as soap.” 23 Fed. Reg. 7483 (Sept. 26, 1958), codified at 21 C.F.R. 701.20. If a product is intended not only for cleansing but also for other cosmetic uses, such as beautifying, moisturizing, or deodorizing, FDA will regulate it as a cosmetic. The exemption is thus quite narrow, and most products on the soap shelves of stores are cosmetics. In *United States v. An Article of Cosmetic . . . Beacon Castile Shampoo*, 1969–1974 FDLI Jud. Rec. 149 (N.D. Ohio 1973), the court held that the claimant had the burden of proving the product fell within the soap exemption. The court acknowledged that a shampoo made from soap would fall within that exemption, but concluded that the claimant’s shampoo did not qualify because it contained a synthetic detergent.

A soap-like product may also be a drug if it is intended to cure, treat or prevent disease or to affect the structure or any function of the human body. It remains unclear whether simply calling a soap product “antibacterial” renders it a drug, *see infra* p. 57, but any explicit therapeutic claims indisputably place a soap product in the drug category.

3. *Tattoos.* FDA regulates the inks used in tattoos and permanent makeup as cosmetics and the pigments used in these inks as color additives. Office of Cosmetics & Colors Fact Sheet: *Tattoos & Permanent Makeup*, Nov. 29, 2000. FDA, however, does not regulate the actual practice of tattooing; instead, oversight is left to local laws and jurisdictions.

4. *Animal Cosmetics.* The FD&C Act’s definition of “cosmetic” is limited to articles intended to be applied to the “human body.” Products intended to cleanse or promote the attractiveness of animals thus fall outside FDA’s control. *Cf. United States v. Articles of Drug for Veterinary Use . . . Goshen Laboratories, Inc.*, Food Drug Cosm. L. Rep. (CCH) ¶38,174 (S.D.N.Y. 1982) (claimant argued that the veterinary products involved were “canine cosmetics” not subject to the FD&C Act, but court concluded the articles were animal drugs under FDA control). By contrast, the FD&C Act’s definitions of “food,” “drug,” and “device” (but not the definition of “biological product” in the Public Health Service Act) refer to “man or other animals.”

5. *Cosmetic Foods.* Because breath freshening is a cosmetic effect, the line between foods and cosmetics can sometimes be elusive. For example, some dissolvable “breath strips” have been labeled as foods, whereas most are now labeled as cosmetics. FDA apparently has not voiced its opinion on the proper categorization of these products.

COMMENT: ARE COSMETIC DEVICES “COSMETICS”?

Are combs, nail files, or razor blades “cosmetics”? The requirement that a cosmetic be “rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body” seems to exclude many common household implements from the definition, despite their cosmetic uses. Indeed, prior to the passage of the FD&C Act, a Senate report considering this language declared, “[T]he definition of the term cosmetic does not include devices. . . .” S. Rep. No. 361, 74th Cong., 1st Sess. 3 (1935). Nevertheless, until the early 1960s, FDA, on rare occasions, took legal action against household devices such as hair brushes, stockings, and toothpicks under the cosmetic provisions of the Act. In more recent decades, although the

agency has never explicitly disclaimed its authority to classify such products as cosmetics, it has declined to assert jurisdiction over them.

In 2003, FDA took regulatory action against a type of device under the cosmetics provisions of the Act, apparently for the first time in many years. FDA declared that noncorrective decorative contact lenses were not medical devices, *see infra* p. 61, but it simultaneously asserted that they qualified as cosmetics and would be regulated as such. The agency observed that “decorative contact lenses are articles intended to be introduced into the eye, which is a part of the body, to beautify the wearer, promote the attractiveness of the wearer, or alter the wearer’s appearance.” 68 Fed. Reg. 16520, 16521 (Apr. 4, 2003). In asserting that these products were cosmetics, the agency observed: “The fact that contact lenses are ‘devices’ in the colloquial sense does not preclude cosmetic status under the act. FDA has previously determined that section 201(i) of the act applies to appearance-enhancing devices such as wigs, hair brushes, stockings and toothpicks.” Later that year, FDA sent a warning letter to a distributor of decorative contact lenses, asserted that the lenses were adulterated cosmetics (because they were distributed without the involvement of a qualified eye care professional) and misbranded cosmetics (because their labeling failed to include sufficient instructions or warnings). Warning Letter from Timothy Ulatowski, Director, CDRH Office of Compliance, to BWild Inc. (Sept. 16, 2003). The agency has since sent similar letters to at least two other distributors of decorative contact lenses.

D. DRUGS AND DEVICES

In general, drugs and devices are subject to much more rigorous regulatory regimes than food or cosmetics. Most important, since 1938, “new drugs” have been subject to premarket approval, and since 1976, many medical devices have been subject to either premarket approval or to the requirement that their manufacturers demonstrate that they are substantially equivalent to products already on the market. Consequently, a determination that a product is a drug or device is often tantamount to a determination that the product cannot be sold at all until FDA approves it for marketing.

Section 201(g)(1) of the FD&C Act defines “drug” as follows:

The term “drug” means

(A) articles recognized in the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and

(B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and

(C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and

(D) articles intended for use as a component of any article specified in clause (A), (B), or (C)

Section 201(h) of the FD&C Act defines “device” as follows:

The term “device” . . . means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other

similar or related article, including any component, part, or accessory, which is—

- (1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,
- (2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
- (3) intended to affect the structure or any function of the body of man or other animals,

and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.

The Act's definitions of *drug* and *device* are parallel in many respects. This chapter focuses primarily on their common elements, while the distinctions between drugs and devices are considered in Chapter VII, which examines device regulation.

1. INCLUSION IN OFFICIAL COMPENDIA

Section 321(g)(1)(A) of the Act includes within the definition of “drug” any article “recognized in the official United States Pharmacopeia, official Homeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them.” The definition of “device” contains a parallel provision. See FD&C Act 321(h)(1).

The *United States Pharmacopeia and National Formulary (USP-NF)* is a compendium of standards for drug strength, quality, purity, packaging, labeling, and storage, published by the United States Pharmacopeia (USP), a nongovernmental organization more than a century old. The *National Formulary* was published separately by the American Pharmaceutical Association until 1975, when USP acquired the *NF* and combined the two publications under one cover. In addition to products universally viewed as drugs, the *USP-NF* also contains standards for most vitamins and minerals. The Homeopathic Pharmacopeia contains many herbal products.

Although section 321(g)(1)(A) appears on its face to give FDA the power to treat any item listed in these compendia as a drug, the agency generally has not viewed this provision so expansively. When FDA has attempted to regulate products as drugs based solely on their inclusion in the *USP* or *NF*, courts have usually thwarted these efforts. Compare *National Nutritional Foods Assoc. v. FDA*, 504 F.2d 761, 788–89 (2d Cir. 1974) (rejecting argument that vitamins and minerals are drugs because of their recognition in the official compendia); *National Nutritional Foods Association v. Mathews*, 557 F.2d 325, 337–38 (2d Cir. 1977) (rejecting the argument with regard to high potency vitamins); and *U.S. v. An Article of Drug . . . Ova II*, 414 F. Supp. 660 (D.N.J. 1975), *aff'd without op.* 535 F.2d 1248 (3d Cir. 1976) (rejecting the argument with regard to pregnancy test kit), with *U.S. v. Articles of Drug . . . Beuthanasia*, Food Drug Cosm. L.

Rep. (CCH) ¶ 38,265 (D. Neb. 1979) (accepting the argument with regard to animal euthanasia drug).

In *U.S. v. Ova II*, a federal district court considering the regulatory status of a pregnancy test concluded that the official compendia provision of the drug definition “cannot be taken literally,” because a literal interpretation would “run[] afoul of the principle that a legislative body may not lawfully delegate its functions to a private citizen or organization.” Nonetheless, the court observed that the inclusion of a product in such a compendium has real, if limited, legal significance.

[T]he first definition, *i.e.*, recognition in the U.S.P. or other named compendium must be read to mean that:

(a) an article put into the stream of interstate commerce with the intention that it be used for medicinal purposes, as evidenced by the label designation “U.S.P.,” “N.F.,” and the like, must meet the privately designated standards for quality and strength, or else be subject to appropriate action for misbranding or adulteration;

(b) the recognition of an item in the U.S.P., etc., by a monograph, coupled with a label indicating compliance with standards, constitutes evidence that the item is a “drug” as a matter of prima facie proof only, calling on the opposing party to come forward with contrary evidence or else risk an adverse ruling; . . .

(d) an item recognized in U.S.P., etc., such as sodium hydroxide, hydrochloric acid, or whatever, by name, is not a drug if it is put into the channels of interstate commerce without a label such as “U.S.P.,” “N.F.” and the like, to imply that it is intended for medicinal use.

414 F. Supp. at 665–66.

For a further analysis of the official compendia provision of the drug definition, see *National Nutritional Foods Ass’n v. Mathews*, *infra* p. 42.

2. “INTENDED USE” AND THE FOOD-DRUG SPECTRUM

The most important similarity between the definitions of “drug” and “device” is their common reference to “intended” use. In most instances, if a product is “intended for use in the diagnosis, cure, mitigation, treatment, or prevention” of disease or is “intended to affect the structure or function of the body,” it is either a drug or a device. Not surprisingly, there have been countless disputes over the meaning of “intent” and over the types of evidence required to establish intent.

For both drugs and devices, FDA has used the following regulatory definition of “intended use” since 1952:

The words *intended uses* or words of similar import . . . refer to the objective intent of the persons legally responsible for the labeling of drugs. The intent is determined by such persons’ expressions or may be shown by the circumstances surrounding the distribution of the article. This objective intent may, for example, be shown by labeling claims, advertising matter, or oral or written statements by such persons or their representatives. It

may be shown by the circumstances that the article is, with the knowledge of such persons or their representatives, offered and used for a purpose for which it is neither labeled nor advertised. The intended uses of an article may change after it has been introduced into interstate commerce by its manufacturer. If, for example, a packer, distributor, or seller intends an article for different uses than those intended by the person from whom he received the drug [device], such packer, distributor, or seller is required to supply adequate labeling in accordance with the new intended uses. But if a manufacturer knows, or has knowledge of facts that would give him notice, that a drug [device] introduced into interstate commerce by him is to be used for conditions, purposes, or uses other than the ones for which he offers it, he is required to provide adequate labeling for such a drug [device] which accords with such other uses to which the article is to be put.

21 C.F.R. 201.128 (drugs); 21 C.F.R. 801.4 (devices). This definition articulates an extremely broad view of the types of evidence the agency can rely upon to establish a product's intended use. However, FDA has rarely attempted to classify a product as a drug or device in the absence of relevant representations by the manufacturer or distributor. The following, seminal case concerns one of the rare instances in which the agency attempted to do so.

The case involves high-dose vitamin supplements. FDA traditionally classified vitamin and mineral products as foods unless therapeutic claims were made for them. In the early 1970s, however, the agency was confronted with reports of people experiencing toxic effects from large doses of vitamins A and D. Adelle Davis, a self-proclaimed nutritional expert who advocated a "natural" approach to good health, recommended megadoses of these vitamins in her books. Vitamins A and D are fat-soluble nutrients (which accumulate in fatty tissue), and FDA thus concluded that ingestion of excess quantities of these vitamins could lead to serious harm.

To meet this problem, FDA promulgated regulations, 37 Fed. Reg. 26618 (Dec. 14, 1972), 38 Fed. Reg. 20723 (Aug. 2, 1973), classifying preparations providing more than 10,000 international units (IU) of vitamin A or 400 IU of vitamin D per daily serving as drugs and requiring further that they be sold only on prescription. Vitamin manufacturers challenged these regulations in court. The District Court initially upheld the regulations, *National Nutritional Foods Ass'n v. Weinberger*, 376 F. Supp. 142 (S.D.N.Y. 1974), but the Court of Appeals concluded that the administrative record was incomplete. It remanded the case with instructions that the district court inquire into the FDA Commissioner's reasoning. 512 F.2d 688 (2d Cir. 1975). After conducting the mandated hearing, the District Court once again upheld the regulations, 418 F. Supp. 394 (S.D.N.Y. 1976), and the plaintiffs appealed for a second time.

National Nutritional Foods Ass'n v. Mathews

557 F.2d 325 (2d Cir. 1977).

■ ROBERT P. ANDERSON, CIRCUIT JUDGE:

... When this case was previously remanded by us to the district court, we said, "... a serious question is raised as to whether the

Commissioner, in concluding that the higher level dosage forms of Vitamins A and D are 'drugs,' acted 'in accordance with law.' " . . . In the statement announcing the proposal of the Vitamins A and D regulations and in the one accompanying their adoption, the Commissioner did not rely upon the recognition of these preparations in the [official compendia] as the basis of the drug classification. Rather, the Commissioner determined that the circumstances surrounding the use of Vitamins A and D at the regulated levels indicated an intended therapeutic use under § 201(g)(1)(B). The vendors' intent in selling the product to the public is the key element in this statutory definition.

In determining whether an article is a "drug" because of an intended therapeutic use, the FDA is not bound by the manufacturer's subjective claims of intent but can find actual therapeutic intent on the basis of objective evidence. Such intent also may be derived or inferred from labeling, promotional material, advertising, and "any other relevant source." [Case citations omitted.] In remanding this case, this court expressly indicated that evidence that Vitamins A and D at the regulated levels were used "almost exclusively for therapeutic purposes" when coupled with lack of a recognized nutritional use, would be sufficient to show that high dosage Vitamins A and D products were intended for use in the treatment of disease.

In proposing the regulations, the Commissioner emphasized the potential for toxicity and the widespread promotion of the intake of high doses of Vitamins A and D to cure a variety of ills. To show objective therapeutic intent, the Commissioner's affidavit submitted on remand relied upon three factors: (1) widespread promotion to the public in the use of high potency Vitamins A and D preparations for the treatment of various ailments; (2) lack of recognized nutritional usefulness; and (3) potential for toxicity from the ingestion of large doses of these vitamins over extended periods of time. . . .

Plaintiffs assert that toxicity is irrelevant to the issue of therapeutic intent and, although the key element in determining that a drug should be limited to prescription use under § 503(b) of the Act, it has no bearing upon whether an article is a drug. The Government argues, on the other hand, that toxicity is relevant to therapeutic intent and that the Commissioner must make the decision of whether there should be a regulation which classifies an article as a food or as a drug, for the purposes of the Act. Although an article may be recognized as a food, this does not preclude it from being regulated as a drug. The determination that an article is properly regulated as a drug, however, is not left to the Commissioner's unbridled discretion to act to protect the public health but must be in accordance with the statutory definition. Toxicity is not included as an element in the statutory definition of a drug. It is relevant as a factor supporting the Commissioner's classification under § 201(g)(1)(B), but only to the extent that it constitutes objective evidence of therapeutic intent. Toxicity is cited by the Commissioner as constituting objective evidence of "something more" than lack of nutritional usefulness. . . . Such evidence,

however, only presents a further indication that the excessive intake of Vitamins A and D may not be nutritionally useful and does not provide the objective evidence of therapeutic intent necessary to support these regulations.

There is no evidence in the administrative record that the manufacturers and vendors of Vitamins A and D preparations, at the regulated dosages, represent through labeling, promotional materials, or advertising that these products are effective in the cure or treatment of disease. They are sold as "dietary supplements." . . .

The main issue on this appeal is whether the evidence of the extensive use of large doses of Vitamins A and D to treat or prevent diseases and the promotion of such usage by persons not associated with the manufacturers or vendors establishes such widespread therapeutic use at the regulated levels as to overcome the plaintiffs' claim of the lack of an intended use to cure or prevent disease and thus justifies the Commissioner's determination.

The Commissioner admits that below the stated levels of potency, Vitamins A and D are foods. The evidence relied upon to show therapeutic intent, therefore, must be related to the potency level chosen to differentiate between the use of Vitamins A and D as foods and the use of these vitamins as drugs. The administrative record clearly establishes that the factors involved in choosing the levels at which Vitamins A and D become drugs were solely related to the Commissioner's fear of potential toxic effect and his belief that the ingestion of vitamins at levels above the U.S. RDA is not nutritionally useful. No further record evidence has been produced on the remand to show that the 10,000 IU and 400 IU levels were chosen because at those potencies, consumption of them is almost exclusively for therapeutic purposes. A sampling of the comments submitted to the FDA after publication of the proposed regulations reveals that people believe that a wide range of doses of these vitamins are therapeutically useful. A large group of individuals indicated that they ingested these vitamins at various dosages solely to supplement their daily diet in the belief that more Vitamins A and D were needed to maintain optimal health than the upper limits in the U.S. RDA.

In remanding this case, this court suggested that proof in the record demonstrating that, at the 10,000 IU and 400 IU levels, respectively, these vitamins were taken "almost exclusively" for therapeutic purposes, would tend to show that the regulations were not arbitrary or capricious. There was no evidence, however, supporting the Commissioner's conclusion that, when sold at the regulated, *i.e.* prescription, levels, therapeutic usage of these vitamins so far outweighed their use as dietary supplements, it showed an objective intent that these products were used in the mitigation and cure of diseases. This claim furnished no contradiction to the charge that the FDA's regulations are arbitrary and capricious and not in accordance with law

The Commissioner also seeks to justify the Vitamins A and D regulations on the basis of § 201(g)(1)(A), which defines as drugs, articles "recognized" in the United States Pharmacopoeia (USP) or National Formulary (NF) To construe § 201(g)(1)(A) so as to grant the Commis-

sioner the power to regulate as drugs every item mentioned in the USP and NF solely on the basis of such inclusion would give the FDA virtually unlimited discretion to regulate as drugs a vast range of items. . . . An administrator's decision under a regulatory statute, such as the Food, Drug, and Cosmetic Act, must be governed by an intelligible statutory principle. If § 201(g)(1)(A) defines as drugs every item included in the USP and NF, the FDA is not being consistent in its treatment of other items similarly recognized. The Commissioner, therefore, has not applied the § 201(g)(1)(A) definition to every item in the compendia. Rather he has singled out for drug classification items included in the USP and NF on the basis of factors, such as toxicity in this case, that are not relevant to the statutory criteria in § 201(g).

The Commissioner admitted in his affidavit that mere inclusion in the USP and NF is an insufficient basis for drug classification after the decision in *National Nutritional Foods Ass'n v. FDA* [504 F.2d 761 (2d Cir. 1974)]. He attempts to distinguish that case on the ground that Vitamins A and D are recognized at therapeutic dosages in the compendia and are regulated as drugs in this case only at levels in excess of the recognized food levels in the USP. Other articles, however, are recognized in the compendia at therapeutic levels and not regulated as drugs, for example Vitamin C. The Commissioner must, therefore, show that the conflicting treatment in the regulations of items similarly classified in the USP and NF is not arbitrary under the applicable criteria. The FDA regulates Vitamin C preparations at the USP's therapeutic level as food. To justify the regulation of Vitamins A and D as drugs by relying on § 201(g)(1)(A) the Commissioner would have to distinguish his treatment of Vitamin C as food.

In proposing and adopting these regulations for Vitamins A and D, the Commissioner did not rely upon or cite the recognition of these vitamins in the USP and NF. He may not at this late hour on appeal rely upon them as the basis for his drug classification because it is sheer *post hoc* rationalization. . . .

NOTES

1. *Subsequent Proceedings.* Following this decision, FDA revoked the challenged regulations. 43 Fed. Reg. 10551 (Mar. 14, 1978).

2. *Dual Classification.* There is no doubt that a product can be classified simultaneously as both a therapeutic drug under section 201(g)(1)(B) and as a food. Indeed, a product currently marketed as a food may at the same time undergo clinical investigation for drug uses (in compliance with the FDA investigational drug requirements, discussed *infra* p. 624). See, e.g., "Nutrition Education—1973: Phosphate Research and Dental Decay," Hearings before the Senate Select Comm. on Nutrition and Human Needs, 93d Cong., 1st Sess. 549 (1973).

On various occasions, courts have upheld FDA's reliance on the Act's broad definition of "drug" to regulate products that were concededly also subject to the food provisions of the Act. In the following cases, courts held that products ordinarily regarded as foods were properly classified as drugs because of the claims made for them: *United States v. 250 Jars* . . . "Cal's Tupelo Blossom U.S. Fancy Pure Honey", 344 F.2d 288 (6th Cir. 1965); *United States v. 24 Bottles* . . . "Sterling

Vinegar and Honey", 338 F.2d 157 (2d Cir. 1964); *United States v. Hohensee*, 243 F.2d 367 (3d Cir. 1957) (tea); *United States v. 500 Plastic Bottles . . . "Wilfley's Bio Water,"* Food Drug Cosm. L. Rep. (CCH) ¶38,143 (D. Or. 1989) (water); *United States v. Kollman*, Food Drug Cosm. L. Rep. (CCH) ¶38,342 (D. Or. 1985 & 1986) (blue-green algae harvested from Klamath Lake, Oregon). In each instance, the agency invoked the drug definition in order to demand premarket testing and approval. As discussed *infra* p. 49, a product can also be simultaneously both a drug and a cosmetic.

3. *Once a Drug?* In *United States v. Articles of Drug . . . Neptone*, Food Drug Cosm. L. Rep. (CCH) ¶38,240 (N.D. Cal. 1983), FDA contended that the seized product was a drug and was granted summary judgment based on the following reasoning:

. . . Claimant Aquaculture Corporation markets in the United States a product called Neptone, which is freeze-dried, homogenized, powdered New Zealand green mussel (*Perna canaliculus*) in capsule form. In 1976, claimant received from the Food and Drug Administration ("FDA") an Investigational Exemption for New Drug ("IND") for Neptone. The purpose of this exemption is to permit claimant to conduct clinical investigations into Neptone's safety and effectiveness.

Neptone is sold in health food stores and by mail order. Claimant advertises in various health food magazines. Since 1980, claimant has also promoted Neptone through several brochures, magazine reprints, and a scientific paper. These were available on request and were sent to mail order customers. FDA Consumer Safety Officer Paul J. Sage was one such customer. In general, claimant's advertising extols the green mussel (and Neptone) as being high in mucopolysaccharides, which are claimed to help prevent diseases commonly associated with aging, such as arthritis and hardening of the arteries. . . .

. . . The Court finds that the claimant's promotional claims clearly show that it intended Neptone to be used "in the diagnosis, cure, mitigation, treatment, or prevention of disease in man." The so-called "brown brochure" is the most flagrant example, but even the so-called "blue brochure" claims, among other things, that Neptone helps to repel infection, prevent blood clots, and maintain the elasticity of the arteries. . . .

The Court does not view this opinion as establishing for all time that Neptone is a drug. The determination that Neptone is a drug rests entirely on the pattern of promotion used by claimant in the several years immediately preceding the instant seizure. Should Neptone again be marketed after some hiatus and a change in labelling, this order will not necessarily work an estoppel on whether that batch of Neptone is a drug.¹ The answer will turn on the relationship between the future sales and the offensive labelling. Clearly, this opinion cannot work any estoppel on the issues of misbranding and safety and effectiveness. . . .

The Court recognizes that not applying collateral estoppel to future batches of Neptone might allow it to be marketed without its having been established as safe and effective. Fault for this lies with the drafters of this statute for conditioning the safety and effectiveness requirements on

1. This reasoning does not apply to any Neptone now in existence that is not currently under the *in rem* jurisdiction of this Court. The Court has found that claimant's promotions over the past few years reveal Nep-

tone's intended use as a drug. These promotional claims presumably apply to the Neptone that was effectively seized as well as to the Neptone that was [not] effectively seized.

labelling. As noted above, claimant brought the regulatory scheme down upon itself through its labelling and promotional brochures; this Court will not take the further step of saying that now claimant can never get out from under the regulatory scheme.

See also *In the Matter of Property Seized from International Nutrition*, Food Drug Cosm. L. Rep. (CCH) ¶ 37, 177 (D. Nev. 1997).

4. *Commentary.* For discussion on food and drug classifications, see Roseann B. Termini, *Product Classification Under the Federal Food, Drug, & Cosmetic Act: When a Food Becomes a Drug*, 2 J. PHARMACY & L. 1 (1993). For a discussion of the regulatory boundaries between foods and drugs throughout the world, see Peter Mansell, *Battling Over the Boundaries*, SCRIP MAGAZINE, Oct. 2000, at 71.

COMMENT: "INTENDED USE" IN THE ABSENCE OF CLAIMS

Since the decision in *Mathews*, FDA has rarely asserted its drug or device jurisdiction over a product unless the manufacturer or distributor has made representations about product's disease or structure/function effects. But neither has the agency unequivocally disclaimed its authority to establish intended use based on the "circumstances surrounding the distribution of the article." 21 C.F.R. 201.128, 21 C.F.R. 801.4.

The most famous instance in which FDA attempted to declare a product to be a drug (or device) in the absence of relevant manufacturer claims was its 1996 rulemaking on cigarettes and smokeless tobacco. 61 Fed. Reg. 44396 (Aug. 28, 1996). FDA argued that tobacco products were "intended" to affect the structure/function of the body based solely on evidence concerning the foreseeable and actual use of the products for stimulation, tranquilization, weight control, and satisfaction of nicotine addiction and on internal company statements confirming the manufacturers' awareness of these uses. The Supreme Court ultimately denied FDA jurisdiction without reaching the "intended use" issue. *FDA v. Brown & Williamson Tobacco*, 529 U.S. 120 (2000), excerpted *infra* p. 82.

Throughout the *Brown & Williamson* litigation, the tobacco industry asserted that no court had ever found that a product was "intended for use" or "intended to affect" absent manufacturer claims regarding that product's use. This assertion would no longer be true if made today. In 2001, the United States brought criminal charges against a number of individuals for selling unlabeled balloons containing nitrous oxide ("laughing gas") in a parking lot outside a rock concert. The government alleged the defendants were unlawfully distributing misbranded prescription drugs, in violation of the FD&C Act. In *U.S. v. Travia*, 180 F. Supp.2d 115, 119 (D.D.C. 2001), the District Court rejected the defendants' argument that the nitrous oxide they sold was not a "drug" under the FD&C Act because they made no representations about its use. Judge Thomas Hogan stressed that intent could be determined not only by labeling, promotional claims, and advertising, but also by "any other relevant source." He observed, "This case is obviously unique in that . . . the sellers did not need to label or advertise their product, as the environment provided the necessary information between buyer and seller. In this context . . . the fact that there was no labeling may actually bolster the evidence of an intent to sell a mind-altering article without a prescription—that is, a misbranded drug."

COMMENT: DISEASE CLAIMS FOR FOOD AND STRUCTURE/FUNCTION CLAIMS FOR DIETARY SUPPLEMENTS

The definition of “drug” in section 201(g)(1) of the FD&C Act concludes with the following proviso:

A food or dietary supplement for which a claim, subject to sections 403(r)(1)(B) and 403(r)(3) of this title or sections 403(r)(1)(B) and 403(r)(5)(D) of this title, is made in accordance with the requirements of 403(r) of this title is not a drug solely because the label or the labeling contains such a claim. A food, dietary ingredient, or dietary supplement for which a truthful and not misleading statement is made in accordance with section 403(r)(6) of this title is not a drug under clause (C) solely because the label or the labeling contains such a statement.

This language reflects dramatic changes in the relationship between food and drugs made by two important statutes passed in the 1990s: the Nutrition Labeling and Education Act of 1990 (NLEA) and the Dietary Supplement and Health Act of 1994 (DSHEA). The first sentence refers to the fact that under the NLEA, a food may, with approval by FDA (or in accordance with an authoritative statement by a federal scientific body or the National Academy of Sciences), make a claim “which expressly or by implication . . . characterizes the relationship of any nutrient . . . to a disease or a health-related condition.” FD&C Act 403(r)(1)(B). The second sentence refers to the fact DSHEA establishes a new subcategory of food called “dietary supplements” and allows such products (many of which are not “common sense” foods) to make structure and function claims.

FDA began to permit explicit disease claims (termed “health claims” by the agency) on food labels in the 1980s, following the lead of the Federal Trade Commission, which started to allow such claims in food advertisements in the 1970s. *See infra* p. 272. By establishing the NLEA health claims regime in 1990, Congress was thus authorizing a lenient regulatory approach that FDA had, in broad terms, already embraced. By contrast, before the passage of DSHEA, FDA demonstrated a willingness to regulate dietary supplements aggressively, particularly through the imposition of the FD&C Act’s premarket approval requirements for drugs and food additives. In short, DSHEA represented an effort by Congress to rein in the agency. The regulatory regimes for disease claims and dietary supplements are discussed at length, *infra* p. 284 and p. 246. At this early stage, however, it is important to recognize that the desire to subject certain classes of products to more or less regulation not only shapes FDA’s interpretation of the statutory definitions, but sometimes leads Congress to revise the definitions.

3. “INTENDED USE” AND THE COSMETIC-DRUG SPECTRUM

An article may fall under the FD&C Act’s definitions of “drug” or “medical device” even if it has no therapeutic purpose, so long as it is “intended to affect the structure or any function of the body.” FD&C Act 201(g)(1)(C) and 201(h). The definitions thus raise the question of how

much, and in what way, a nontherapeutic product must be intended to alter the body to be considered a drug or device.

Just as an article may be both a "food" and a "drug," a product may simultaneously fall within the definitions of "cosmetic" and "drug" and be subject to the requirements of both categories. Cosmetics are the least intensively regulated of any of the products under FDA's jurisdiction. The agency thus has sometimes reached for greater authority over particular cosmetic products by trying to categorize them as new drugs subject to premarket review for safety and effectiveness.

Peter Barton Hutt, *Reconciling the Legal, Medical, and Cosmetic Chemist Approach to the Definition of a "Cosmetic"*

3 CTFA COSMETICS JOURNAL, No. 3 (1971).

The first principle is that the intended use of the product, rather than its inherent properties, control[s] its classification. . . . [T]he controlling representations made by the manufacturer may appear in labeling, in advertising, or in any other form of oral or written communication. And an implicit representation is as controlling as an explicit one. . . .

The second general principle is that the representations made for a product may properly classify it in more than one product category under the Act. If a product were represented both to treat a disease and to promote attractiveness, it would properly be classified as both a drug and cosmetic, and must meet the legal requirements for both categories. . . .

The third, and final, general principle is that it is the initial and primary responsibility of the manufacturer or distributor of a product to determine the proper classification of his product, and to make certain that it meets all applicable legal requirements. . . .

Attempting to formulate a hard and fast rule differentiating between cosmetic claims and drug claims is virtually impossible. Some cosmetics are intended merely to color some part of the body, in order to promote attractiveness, and present no problem of proper classification. And on the other end of the scale, some products are represented to effect a physiological change in the body, and these would clearly fall into the drug category as well as the cosmetic category. But in between these two extremes is the difficult area of judgment—the cosmetics that claim to promote attractiveness through a slight, and usually temporary, physical but not physiological, effect upon the skin.

The Food and Drug Administration attempted to deal with the proper legal classification of some of these various types of products in the advisory opinions contained in its Trade Correspondence during 1938–1946. The difficulty in resolving these matters on a purely rational basis is readily demonstrated by just three of those opinions. FDA stated that mercury preparations used to bleach or remove tan are drugs because they are intended to affect the structure and function of the body. On the other hand, an article represented solely to produce an even tan is regarded by

FDA as a cosmetic. And a product intended not just to produce an even tan, but also to prevent sunburn, is a drug. . . .

A further indication of the distinction between a product that does and does not affect a bodily structure or function may be found in the area of deodorants. A product that absorbs perspiration, or masks its odor, or prevents odor by germicidal or bacteriostatic agents that act upon odor-producing bacteria, is classified by the Food and Drug Administration as a cosmetic and not a drug. A product that is designed to reduce perspiration odor by reducing the perspiration itself, through a change in the sweat glands, is considered by the Food and Drug Administration to be a drug.

A cosmetic may properly be represented for use to mask or cover up the physical manifestations of a disease, without becoming a drug. Acne and dandruff are regarded as disease conditions, and any product represented to treat those conditions is classified as a drug. But products that claim merely to cover up manifestations of acne, or to wash away loose dandruff flakes, would properly be classified solely as cosmetics.

An analogous question is presented by "hypoallergenic" cosmetic products, which claim to have "screened out" most irritants. Since hypoallergenic foods have not been regarded as drugs it would appear that hypoallergenic cosmetics would similarly not be regarded as drugs absent specific claims that certain diseases will be treated or relieved by the product. . . .

A question frequently asked is whether any inclusion of an active ingredient in a cosmetic automatically classifies it as a drug. The answer is that classification depends upon the claims made, not upon the inclusion of the ingredient itself. . . .

United States v. An Article . . . Sudden Change

409 F.2d 734 (2d Cir. 1969).

■ ANDERSON, CIRCUIT JUDGE:

This is an appeal in a seizure action from an order of the United States District Court for the Eastern District of New York . . . granting summary judgment for the claimant. The seizure concerned 216 bottles of a cosmetic product called "Sudden Change" which is a clear liquid lotion consisting primarily of two ingredients: bovine albumen (15%) and distilled water (over 84%). It is meant to be applied externally to the surface of the facial skin, and it is claimed, *inter alia*, in its labeling and advertising that it will provide a "Face Lift Without Surgery." The court below described the effects of the product as follows:

Allowed to dry on the skin, it leaves a film which (1) masks imperfections, making the skin look smoother and (2) acts mechanically to smooth and firm the skin by tightening the surface. Both effects are temporary. There is apparently no absorption by, or changes in, skin tissue resulting from its applications; it washes off.

The central issue presented in this appeal is whether Sudden Change is, within the meaning of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 321(g)(1), a “drug.” . . .

It is well settled that the intended use of a product may be determined from its label, accompanying labeling, promotional material, advertising and any other relevant source. Regardless of the actual physical effect of a product, it will be deemed a drug for purposes of the Act where the labeling and promotional claims show intended uses that bring it within the drug definition. . . .

The mere statement of this rule poses a crucial issue: by what standards are these claims to be evaluated? Or, to put it another way, what degree of sophistication or vulnerability is to be ascribed to the hypothetical potential consumer in order to understand how these claims are understood by the buying public? . . . [W]e conclude that the purposes of the Act will best be effected by postulating a consuming public which includes “the ignorant, the unthinking and the credulous. . . .” . . .

While it is not altogether clear what standard the court below applied, the reasoning appears to assume something like a “reasonable woman” standard. Thus, the District Court assumes that the “constant exposure to puffing and extravagant claims” has induced “some immunity in the beautifiers’ hyperbole” which is such that the court “cannot believe” that the potential consumer of Sudden Change “expects anything other than a possibility that she may look better.” We agree that certain claims which arguably would bring the product within § 321(g)(1)(C) have so drenched the potential consumer that even the “ignorant, the unthinking and the credulous” must be presumed able to discount their promises as typical of cosmetic advertising puffery. We cannot agree, however, with the conclusion that such immunity or skepticism somehow transfers to the promise to “lift out puffs” or give a “face lift without surgery.” The references to “face lift” and “surgery” carry distinctly physiological connotations, suggesting, at least to the vulnerable consumer that the product will “affect the structure . . . of the body . . .” in some way other than merely temporarily altering the appearance. We do not accept the concept that skepticism toward familiar claims necessarily entails skepticism toward unfamiliar claims; the theory of the legislation is that someone might take the claim literally.

In other words, with the exception of those claims which have become so associated with the familiar exaggerations of cosmetics advertising that virtually everyone can be presumed to be capable of discounting them as puffery,¹⁰ the question of whether a product is “intended to affect the structure . . . of the body of man . . .” is to be answered by considering,

10. . . . We agree that the legislative history and the language of the Act require rejection of any rule which would convert all cosmetics into drugs. We believe, however, that the test which we have applied draws the necessary line while at the same time protecting the public. For example, promises that a product will “soften” or “moisturize”

a woman’s skin are so thoroughly familiar that constant exposure can be presumed to have induced sufficient immunity even in our hypothetical vulnerable consumer (this assumes, *arguendo*, that these promises have exactly the same degree of drug-type connotations as the “face lift without surgery” claim—an assumption which we reject).

first, how the claim might be understood by the “ignorant, unthinking or credulous” consumer, and second, whether the claim as so understood may fairly be said to constitute a representation that the product will affect the structure of the body in some medical—or drug-type fashion, *i.e.*, in some way other than merely “altering the appearance.”

We hold, therefore, that so long as Sudden Change is claimed to give a “face lift without surgery” and to “lift out puffs” it is to be deemed a drug within the meaning of 21 U.S.C. § 321(g)(1)(C). It should be understood, however, that if the claimant ceases to employ these promotional claims and avoids any others which may fairly be interpreted as claiming to affect the structure of the skin in some physiological, though temporary, way, then, assuming *arguendo* that no actual physical effect exists, the product will not be deemed a drug for purposes of the Act. While there may be merit in the cause of those who seek to require pretesting of new cosmetics, it is not for the courts to legislate such a requirement; rather it must rest in the hands of Congress to decide whether such an amendment to the statute should be enacted or not. . . .

■ MANSFIELD, DISTRICT JUDGE (dissenting): . . .

In view of the existence of ample authority for regulation of cosmetics, it strikes me as unnecessary, in the absence of some imminent danger to public health—and none is suggested here—for the Court to adopt new standards of construction for the purpose of determining whether an article is intended as a “drug” rather than to follow time-proven rules. Yet that is exactly what the Court does here, with the result that it opens up a new—and in my view, unnecessary—avenue for regulation of cosmetics as drugs. If Congress believes that protection of the public requires pretesting and clearance of cosmetics by the Food and Drug Administration . . . and that their components be listed on the label, it has the power to act. I do not think the Court should do so by a process of tortuous construction. . . .

It may well be that the existence of fraud upon consumers of such products (whether drugs or cosmetics) should depend upon whether “the ignorant, the unthinking and credulous” would be deceived. The issue before us, however, is not whether consumers may be defrauded by the labelling and enclosures used in connection with the sale of “Sudden Change.” The issue is whether the product must be classified as a “drug” which must be pre-tested, cleared and bear a label listing its components. Since that issue turns upon whether the article is “*intended* to affect the structure of the body” (emphasis added), it seems to me that the “gullible” woman standard is both irrelevant and unnecessary, and that the standard should be whether a reasonable person would construe the labeling and advertising as showing that the product was so intended. . . .

NOTES

1. *Parallel Cases.* In *United States v. An Article . . . “Line Away,”* 415 F.2d 369 (3d Cir. 1969), the court concluded that the promotional material for a similar product attributed drug characteristics to it:

. . . [T]he repeated statements that Line Away is made in a “pharmaceutical laboratory” and packaged under “biologically aseptic conditions”

imply that the product itself is a pharmaceutical. Characterizing the lotion as “super-active” and “amazing,” creating a “tingling sensation” when “at work,” “tightening” the skin and “discouraging new wrinkles from forming” strongly reinforces the impression that this is a therapeutic product, the protein content of which has a tonic or otherwise wholesome physiological effect on the skin itself.

... Even the denial that Line Away is a “hormone” or a “harmful drug,” read in the context of the other representations, suggests that it is a harmless drug.

Some “puffery” may not amount to representation of a cosmetic as a drug, but when “puffery” contains the strong therapeutic implications we find in the Line Away promotional material, we think the dividing line has been crossed.

But *United States v. An Article ... “Helene Curtis Magic Secret ...”*, 331 F. Supp. 912 (D. Md. 1971), held that Helene Curtis’s very similar wrinkle smoother was a cosmetic and not a drug:

... The only two claims made for “Magic Secret” which even approach the magnitude of the claims made in *Line Away* and *Sudden Change* are that “Magic Secret” is a “pure protein” which causes an “astringent sensation.” The promotional material does not emphasize these two claims and even the “ignorant, unthinking and credulous” consumer would not be led by these references to believe that “Magic Secret” would do other than alter their appearance. It is apparent that the promotional claims made for “Magic Secret” are less exaggerated than those reported in *Line Away* and *Sudden Change*. It cannot be said that they carry the same drug connotations as found by the Second and Third Circuits.

The court concluded that the product’s promotional material would lead a prospective purchaser only to expect that she may look better, and not that the structure of the body would be affected. See also *FTC v. Pantron I Corp.*, 33 F.3d 1088, 1105 (9th Cir. 1994) (endorsing *Magic Secret* analysis, but concluding that a baldness remedy claiming new hair growth was a drug).

2. *Subsequent FDA Actions Regarding Antiwrinkle Products.* Beginning in April 1987, FDA sent regulatory letters to dozens of cosmetic manufacturers alleging that products with “wrinkle remover” claims were illegal new drugs. “‘Antiaging’ Creams Challenged,” FDA Talk Paper No. T87-24 (May 14, 1987). A series of meetings and correspondence between an industry coalition and FDA on this matter was abruptly terminated on November 19, 1987 by the following statement in a letter by the FDA Associate Commissioner for Regulatory Affairs.

We consider a claim that a product will affect the body in some physiological way to be a drug claim, even if the claim is that the effect is only temporary. Such a claim constitutes a representation that the product is intended to affect the structure or function of the body and thus makes the product a drug under 21 U.S.C. 321(g)(1)(C). Therefore, we consider most of the anti-aging and skin physiology claims that you outline in your letter to be drug claims. For example, claims that a product ‘counteracts,’ ‘retards,’ or ‘controls’ aging or the aging process, as well as claims that a product will ‘rejuvenate,’ ‘repair,’ or ‘renew’ the skin, are drug claims because they can be fairly understood as claims that a function of the body, or that the structure of the body, will be affected by the product. For this reason also, all of the examples that you use to allege an effect within the epidermis as the basis for a temporary beneficial effect on wrinkles, lines, or fine lines are unacceptable. A claim such as ‘molecules absorb ... and

expand,' exerting upward pressure to 'lift' wrinkles 'upward' is a claim for an inner, structural change.

The Associate Commissioner did offer some guidelines for cosmetic claims:

While we agree with your statements that wrinkles will not be reversed or removed by these products . . . we would not object to claims that products will temporarily improve the appearance of such outward signs of aging. The label of such products should state that the product is intended to cover up the signs of aging, to improve the appearance by adding color or a luster to skin, or otherwise to affect the appearance through physical means. . . .

. . . [W]e would consider a product that claims to improve or to maintain temporarily the appearance or the feel of the skin to be a cosmetic. For example, a product that claims to moisturize or soften the skin is a cosmetic.

An attempt by one manufacturer to obtain clarification of the dividing line between cosmetic and drug claims for these products through a declaratory judgment action was thwarted when the court agreed with FDA's contention that the matter was not ripe for judicial review. *Estee Lauder, Inc. v. FDA*, 727 F. Supp. 1 (D.D.C. 1989). Individual companies eventually resolved their issues with FDA, and the agency ultimately did not bring formal action against any of these products.

After a lull, FDA has recently resumed taking action against antiwrinkle products. It issued warning letters to two manufacturers of skin creams, stating that the companies were selling unapproved drugs. See *Warning Letters Address Claims Made for Topical Skincare Preparations*, Office of Cosmetics and Colors Press Release (Mar. 1, 2005). The objectionable claims cited by FDA with respect to one of these products, Collagen5, included: "Collagen5" is proven to reduce deep wrinkles up to . . . 70%," "Stimulates your skin's own collagen building network," "Reduces deep wrinkles from within the skin's surface," and "Visible results that won't fade away." Warning Letter from Alonza E. Cruse, Director, Los Angeles District, FDA, to University Medical Products USA, Inc. (Jan. 22, 2004). The other warning letter cited (among many other statements) the manufacturers' reference to "Pal-KTTKS solution's effectiveness at reducing the appearance of fine lines and wrinkles." Warning Letter from B. Belinda Collins, Director, Denver District Office, FDA, to Basic Research, LLC (Jan. 14, 2005). It is unclear why FDA took issue with this particular claim; perhaps it objected to the manufacturer's failure to declare that the effects were only "temporary."

3. *Thigh Creams*. The warning letters discussed above in Note 2 also informed companies that products claiming to combat cellulite, stretch marks, and breast sag and shrinkage and to reduce thigh circumference and overall weight were unapproved drugs. Warning Letter from Alonza E. Cruse, Director, Los Angeles District, FDA, to University Medical Products USA, Inc. (Jan. 22, 2004); Warning Letter from B. Belinda Collins, Director, Denver District, FDA, to Basic Research, LLC. FDA has suggested that it views all thigh creams promoted for cellulite reduction as drugs. See *Thigh Creams*, Office of Cosmetics and Colors Fact Sheet (Feb. 24, 2000) ("Thigh creams may more appropriately be classified as drugs under the Food, Drug, and Cosmetic Act since removal or reduction of cellulite affects the 'structure or function' of the body.")

4. *Hair Care Products*: In *United States v. Kasz Enterprises, Inc.*, 855 F. Supp. 534 (D.R.I. 1994), the U.S. District Court found that the distributor's two hair care products were drugs. Although the defendant stated that it never labeled or promoted its products as cures for baldness or to prevent hair loss, the court found the company was aware that its products were being offered by others to prevent

baldness. "The promotional materials accompanying Solutions 109 are replete with claims (testimonials) that hair growth has occurred and hair loss prevented with use of these products. Therefore, Solutions 109 are intended by Kasz for use in the mitigation, treatment, or prevention of hair loss and are thus drugs"

In a series of warning letters that FDA began issuing in April 2003, it reminded manufacturers that hair care products marketed with claims such as restoration of hair growth, hair loss prevention, and treatment of dandruff are considered drugs, not cosmetics. Office of Cosmetics and Colors, *Warning Letters Address Hair Care Products*, Apr. 3, 2003.

5. *FDA's Persistence*. FDA continues to challenge, as unapproved drugs, numerous products portrayed if not expressly labeled as providing health benefits. *E.g.*, *United States v. Eighteen Units, More or Less, of "Sports Oxygen,"* Food Drug Cosm. L. Rep. (CCH) ¶ 39,025, 5 F.3d 1491 (3d Cir. 1993); *United States v. Ten Cartons, More or Less, of an Article . . . Ener-B,* Food Drug Cosm. L. Rep. (CCH) ¶ 39,518, 72 F.3d 285 (2d Cir. 1995) (nasal gel containing vitamin B12); Letter from Ronald G. Chesemore, FDA Associate Commissioner for Regulatory Affairs, to Walter E. Byerley (Dec. 26, 1990)(facial tissue impregnated with antibiotic).

COMMENT: "COSMECEUTICALS"

FDA scientists recognized very early that all cosmetics penetrate the skin and thus affect the body. As one wrote: "[T]here are few if any substances which are not absorbed through the intact skin, even though the idea is prevalent that the skin is a relatively effective barrier to its environment." H.O. Calvery, *Safeguarding Foods and Drugs in Wartime*, 32 AM. SCIENTIST No. 2, at 103, 119 (1944). There are some skin care products marketed as cosmetics, however, that clearly have more significant effects on the body than do traditional cosmetics. These products are often referred to as "cosmeceuticals." Although the FDA does not itself use the term "cosmeceutical," it recognizes that cosmetic manufacturers use this word "to refer to cosmetic products that have medicinal or drug-like benefits." Office of Cosmetics & Color Fact Sheet, (rev. Feb. 24, 2000).

When defining "cosmeceutical," the FDA remarked, "If a product has drug properties, it must be approved as a drug." *Id.* This statement is one of several instances in which the agency has suggested that the presence of an ingredient with pharmacological effects may render a product a drug, regardless of the claims made by the manufacturer. In 1996, John Bailey, the Director of FDA's Office of Cosmetics and Colors, stated, "If an active ingredient is present in a therapeutic concentration, the product is a drug, even if that product does not claim to produce the effect that will result from the action of the therapeutically effective ingredient." Anita H. Shaw, *The News in Skin Care*, SOAP-COSM.-CHEM. SPECIALTIES, Oct. 1, 1996, at 72.

The validity of Bailey's statement hinges on whether the agency must, in determining "intent," always depend at least in part on claims by the manufacturer. As will be discussed *infra* p. 81, when FDA asserted jurisdiction over tobacco products as medical devices in the 1990s, it vigorously maintained that evidence from "other relevant sources" could, on its own, establish objective intent. In the world of "cosmeceuticals," this question has been raised most frequently with regard to two types of topically

applied products: cosmetics containing hormones and cosmetics containing alpha hydroxy acids.

In 1993, FDA proposed a rule declaring that any cosmetic product containing more than a specified amount of the hormones pregnenolone acetate or progesterone was an unapproved drug, regardless of manufacturer claims. The agency observed that, above these amounts, the ingredients affected the structure or function of the body. 58 Fed. Reg. 47611 (Sept. 9, 1993). The agency also proposed banning "natural estrogens" from cosmetics altogether, unless manufacturers provided adequate data on the safety and exact chemical identity of such estrogens. "[T]he agency concludes at this time that any use of natural estrogens in cosmetic products makes the product an unapproved new drug. The conclusion is based on available data stating conclusively that at some levels the ingredients affect the structure or function of the body, and a concomitant lack of data establishing at what level, if any, the drug effect ceases." Finally, FDA also proposed that the use of the word "hormone" in the labeling or ingredient statement of any cosmetic product was an implied drug claim. In 2004, the agency withdrew this proposed rule but remarked that "this withdrawal neither affirms nor rejects statements contained in the preamble [to the proposed rule]." 69 Fed. Reg. 68833 (Nov. 26, 2004). Although the rule was never finalized, FDA did finalize a drug regulation, proposed simultaneously, providing that the use of the word "hormone" in the labeling or ingredient statement of any topically applied product is an implied drug claim. 58 Fed. Reg. 47610 (Sept. 9, 1993), codified at 21 C.F.R. 310.530(a).

Alpha hydroxy acids (AHAs) are chemicals that cause the skin to lose its outer layer. Manufacturers of cosmetics containing AHAs claim their products will smooth fine lines, reduce spots, and improve skin condition in general. In a 1994 speech, FDA official John Bailey stated: "In the final analysis, it is well established that AHAs exert an effect on the skin. I don't think that there is any doubt that, under some conditions of formulation and use, AHA containing products are affecting the structure and function of the body and that they should be regulated as drugs." *Quoted in* Jacqueline A. Greff, *Regulation of Cosmetics that are also Drugs*, 51 FOOD DRUG COSM. L.J. 243, 257 (1997). Nonetheless, FDA has not, to this point, charged a manufacturer with selling an unapproved drug based solely on the fact that the product contains AHAs. It has addressed safety issues raised by AHA-containing skin care products based solely on its authority over cosmetics. *See* 70 Fed. Reg. 1721 (Jan. 10, 2005) (announcing availability of final guidance advising manufacturers of AHA-containing cosmetics to label them so as to alert consumers of the need to limit sun exposure and apply sunscreen). For further discussion on AHAs, see Laura A. Heymann, *The Cosmetic/Drug Dilemma: FDA Regulation of Alpha-Hydroxy Acids*, 52 FOOD & DRUG L.J. 357 (1997).

NOTES

1. *Approved Cosmetic Drugs and Devices*. In recent years, FDA has approved new drug applications (NDAs) and device premarket approval applications (PMAs) for antiwrinkle products. Renova (tretinoin) is a prescription drug approved to reduce fine wrinkles, discoloration, and roughness on facial skin. BOTOX Cosmetic

(Botulinum Toxin Type A) is a prescription drug approved to treat frown lines between the eyebrows. The agency has approved collagen and hyaluronic acid gel, both injectable antiwrinkle products, as medical devices, as well as lasers making antiwrinkle claims.

The agency has approved NDAs for two types of hair regrowth products: Rogaine (minoxidil), a topical solution, and Propecia (finasteride), a drug in pill form.

2. *OTC Drug Review.* As discussed in Chapter IV, the Over-the-Counter (OTC) Drug Review is the primary process by which the agency has assessed the safety and effectiveness of active ingredients in OTC drug products. In this context, the relationship between the Act's definitions of "cosmetic" and "drug" has frequently been at issue. The agency has frequently evaded the question of whether a particular use of a substance is solely a cosmetic use or also a drug use by simply restricting the use of the substance in both cosmetics and drugs. *E.g.*, 21 C.F.R. 250.250(d) & (c) (limiting the use of hexachlorophene in OTC drugs and cosmetics). *Cf.* 21 C.F.R. 310.545(a)(17) (skin-bleaching OTC drug products containing ammoniated mercury are not generally recognized as safe and effective) & 700.13 (mercury-containing skin-bleaching agents are drugs as well as cosmetics and are misbranded and adulterated). For discussions of the various OTC drug monographs in which the cosmetic/drug distinction has been considered, see William E. Gilbertson, *FDA OTC Drugs Standards Versus Cosmetic Standards*, 21 DRUG INFO. J. 379 (1987); Stephen H. McNamara, *The Food and Drug Administration Over-the-Counter Drug Review—Concerns of the Cosmetic Industry*, 38 FOOD DRUG COSM. L.J. 289 (1983).

COMMENT: DEODORANT PRODUCTS

FDA's policy for products that deal with body odors seems to have evolved recently. Describing a product as a deodorant is indisputably a cosmetic claim, and deodorant products that merely mask odor with perfumes are clearly cosmetics and not drugs. But what of products that attack odors with antimicrobial ingredients? It was long assumed that a mouthwash or deodorant soap could make a claim like "kills germs that cause odor" without becoming a drug for regulatory purposes. In the early 1990s, however, the preambles to the tentative final monographs for various types of OTC antiseptic drug products firmly stated that claims of this sort would subject a product to regulation as a drug. 56 Fed. Reg. 33644, 33648-49 (July 22, 1991) (first aid antiseptics); 59 Fed. Reg. 6084, 6088-89 (Feb. 9, 1994) (oral antiseptics); 59 Fed. Reg. 31402, 31440 (health care antiseptics). Importantly, in these preambles, FDA disclaimed any intention to regulate deodorant products without such claims as drugs merely because they contained antimicrobial ingredients. 56 Fed. Reg. at 33648; 59 Fed. Reg. at 6088.

About the same time, FDA initiated a seizure action against a product called Pets Smellfree. The agency contended that the product, a pet food additive containing a subtherapeutic dose of an antibiotic, was an adulterated and misbranded animal drug. The manufacturer claimed the product "stops those awful odors associated with feces, urine, gas and BAD BREATH." One advertisement added that Pets Smellfree "will neutralize the undesirable mercaptans in the digestive tract without affecting the desirable bacterial flora." *U.S. v. Undetermined Quantities of Bottles of . . .*

“*Pets Smellfree*”, 1991 WL 11666517 (D. Utah 1991). (Mercaptans are sulfur-containing organic compounds.) The District Court accepted the company’s argument that the product was not a drug, but the court of appeals reversed. *U.S. v. Undetermined Quantities of Bottles of . . . “Pets Smellfree”*, 22 F.3d 235 (10th Cir. 1994). Interestingly, the Court of Appeals did not refer to even one instance in which the manufacturer mentioned the product’s antibacterial properties. Instead, the court seemed to hold that *Pets Smellfree* could properly be deemed a drug simply because of common knowledge that bacterial contamination causes those odors the product claimed to stop. *Id.* 239–40. The *Pets Smellfree* analysis of the drug status of a deodorant product was thus even more expansive than the principles FDA enunciated in the human antiseptic drug monographs discussed above. *But see E.R. Squibb & Sons v. Bowen*, 870 F.2d 678, 682 (D.C. Cir. 1989) (a claim that a product suppresses the growth a fungus in the body does not implicate the drug definition’s structure-function provision, in part because “it is questionable whether a drug that acts only upon non-human organisms that happen to reside within the human body can properly be understood as affecting the ‘body of man.’ ”)

NOTES

1. *Other Products on the Cosmetic–Drug Line.* There are a variety of common claims that can turn a product with cleansing or beautifying uses into a drug in addition to, or instead of, a cosmetic. A recent article included a list of some important examples of this phenomenon, based on decades of FDA literature and practice:

A suntan product is a cosmetic but a sunscreen product is a drug.

A deodorant is a cosmetic but an antiperspirant is a drug.

A shampoo is a cosmetic but an antidandruff shampoo is a drug.

A toothpaste is a cosmetic but an anticaries toothpaste is a drug.

A skin exfoliant is a cosmetic but a skin peel is a drug.

A mouthwash is a cosmetic but an antigingivitis mouthwash is a drug.

A hair bulking product is a cosmetic but a hair growth product is a drug.

A skin product to hide acne is a cosmetic but an antiacne product is a drug.

An antibacterial deodorant soap is a cosmetic but an antibacterial anti-infective soap is a drug.

A skin moisturizer is a cosmetic but a wrinkle remover is a drug.

A lip softener is a cosmetic but a product for chapped lips is a drug.

Peter Barton Hutt, *The Legal Distinction in the United States Between a Cosmetic and a Drug*, in *COSMECEUTICALS: DRUGS VS. COSMETICS* 223, 228 (Peter Elsner & Howard I. Maibach, eds., 2000).

Recent developments have reinforced many of these traditional positions taken by the agency. With regard to some of these products, however, FDA has manifested an inclination to categorize articles containing pharmacologically active ingredients as drugs even when their manufacturers make only cosmetic claims. As discussed above, the agency has made some moves in this direction with regard to AHA and hormone-containing skin care products. Moreover, when issuing its tentative final monograph for sunscreen drug products, FDA stated unambiguously that “a prod-

uct containing a sunscreen ingredient, even when labeled solely as a tanning aid, is both intended and understood to be a sunburn preventative. Such a product, therefore, is a drug under the act." 58 Fed. Reg. 28194, 28204 (May 12, 1993). At the same time that it issued its final sunscreen monograph, 64 Fed. Reg. 27666 (May 21, 1999), the agency revoked a 1940 official trade correspondence declaring that products promoted solely for tanning purposes (as opposed to products intended to be used as sunburn preventatives) are cosmetics and not drugs. 64 Fed. Reg. 27798 (May 21, 1999).

2. *Intercenter Agreement.* To facilitate oversight of products claiming to be cosmetics but that also fulfill the statutory definition of a drug, CDER and CFSAN entered an agreement affording either center the jurisdiction to bring regulatory actions relating to such products. See *Intercenter Agreement Between the Center for Drug Evaluation and Research and the Center for Food Safety and Applied Nutrition to Assist FDA in Implementing the Drug and Cosmetic Provisions of the Federal Food, Drug, and Cosmetic Act for Products that Purport to be Cosmetics but Meet the Statutory Definition of a Drug* (June 2002).

3. *Commentary.* For additional discussion of the cosmetic-drug spectrum, see Arlene Erlebacher, *When Is a "Cosmetic" Also a "Drug" Under the Federal Food, Drug and Cosmetic Act*, 27 FOOD DRUG COSM. L.J. 740 (1972); Jacqueline A. Greff, *Regulation of Cosmetics that are also Drugs*, 51 FOOD & DRUG L.J. 243 (1996); *The Legal Distinction in the United States Between a Cosmetic and a Drug*, Peter Barton Hutt, in COSMECEUTICALS: DRUGS VS. COSMETICS 223 (Peter Elsner et al., eds. 2000); Vincent A. Kleinfeld, "Cosmetic" or "Drug"—*The Minotaur's Labyrinth*, 22 FOOD DRUG COSM. L.J. 376 (1967); Bryan A. Liang and Kurt M. Hartman, *It's Only Skin Deep: FDA Regulation of Skin Care Cosmetics Claims*, 8 CORNELL J.L. & PUB. POL'Y 249 (1999); Stephen H. McNamara, *Performance Claims for Skin Care Cosmetics*, 41 FOOD DRUG COSM. L.J. 151 (1986); *Symposium on the Cosmetic-Drug Distinction*, 21 DRUG INFO. J. 377 (1987).

COMMENT: OTHER TYPES OF DRUGS WITH NONTHERAPEUTIC USES

Lethal Products. In *United States v. Beuthanasia D Regular*, Food Drug Cosm. L. Rep. (CCH) ¶ 38,265 (D. Neb. 1979), the court upheld an FDA seizure of products intended for euthanasia of animals, rejecting the company's argument that the products were not drugs and thus were outside the jurisdiction of the FD&C Act. Two years later, FDA rejected a petition to assert jurisdiction over the use of approved pharmaceuticals by state prison officials to execute prisoners sentenced to death. Letter from FDA Commissioner A.H. Hayes, Jr., to D.E. Kendall, FDA Dkt No. 80P-0513 (July 7, 1981). The Supreme Court ultimately held that the agency's refusal to take enforcement action in this instance was unreviewable. *Heckler v. Chaney*, 470 U.S. 821 (1985).

Drugs of Abuse. Prior to 1970, federal control of narcotic drugs, marijuana, and other drugs used for recreational and nonmedical purposes was shared among several agencies and rested on a haphazard cluster of laws enacted since 1900. For example, FDA was responsible for enforcement of the Drug Abuse Control Amendments of 1965, 79 Stat. 226, to prevent abuse of depressant and stimulant drugs that also have legitimate medical uses, such as amphetamines and barbiturates.

In 1970, Congress repealed the earlier statutes and enacted a new comprehensive law, the Controlled Substances Act, 84 Stat. 1236, 1242, codified in 21 U.S.C. 801 *et seq.* The CSA establishes five “schedules” of substances with strong potential for abuse, calibrated according to their degree of danger. Responsibility for enforcement of the distribution controls of the Controlled Substances Act rests with the Drug Enforcement Administration (DEA) of the Department of Justice. DEA has the obligation to consult with FDA on the scheduling of controlled substances. FDA’s recommendations on scientific and medical matters are binding, and DEA may not schedule a drug if FDA recommends against it. Moreover, FDA regulates the legitimate medical uses of scheduled substances the same way it regulates other drugs. Schedule I drugs—that is, illegal drugs with no approved medical use, such as heroin, cocaine, and marijuana—are under the exclusive jurisdiction of DEA.

Street Drug Alternatives. The FDA considers products manufactured, marketed, or distributed as alternatives to illicit street drugs to be unapproved new drugs. FDA, CENTER FOR DRUG EVALUATION AND RESEARCH, GUIDANCE FOR INDUSTRY; STREET DRUG ALTERNATIVES (2000). Street drug alternatives are often labeled as dietary supplements containing botanicals, vitamins, and minerals. They are marketed with claims implying that they mimic the effects of controlled substances. In *United States v. Undetermined Quantities of Articles of Drug*, 145 F. Supp. 2d 692 (D. Md. 2001). The district court concluded that the defendants’ products, comprising a variety of herbs, were not dietary supplements. Instead, it found them to be unapproved new drugs because the labeling and promotional claims, including a catalog explicitly stating the products were “for mood enhancement,” showed that the manufacturers intended these products to affect the function of the mind.

Oxygen Bars. Establishments known as “oxygen bars” first became popular in the late 1990s. These businesses offer customers the opportunity to sniff purified oxygen through a plastic hose inserted into their nostrils. The oxygen is sometimes “flavored” with aromatic solutions. Oxygen bar patrons variously believe that this practice reduces stress, increases energy and alertness, reduces headaches and hangover symptoms, and generally relaxes the body. Oxygen has legitimate uses as a medical gas, of course, and FDA regulates it as a prescription drug. Although oxygen bar proprietors are careful not to make medical claims, FDA has declared that any type of oxygen administered for breathing is a prescription drug, regardless of its labeling. Nevertheless, the agency has chosen to exercise its administrative discretion and leave the regulation of oxygen intended for recreational use to the states. See *Oxygen Bars: Is a Breath of Fresh Air Worth It?*, FDA CONSUMER MAG., Nov.–Dec. 2002, at 9.

4. THE “DEVICE” DEFINITION

a. COSMETIC DEVICES

The section above on the cosmetic-drug spectrum discussed the categorization of products intended to cleanse, beautify, or promote attractiveness. Some articles intended for cosmetic use operate through physical,

rather than chemical, action and thus raise similar issues with respect to the device definition. As with cosmetic drugs, the question of whether a cosmetic device is a “device” under the FD&C Act hinges on how much, and in what way, the article is “intended to affect the structure or any function of the body.” FD&C Act 201(h)(3).

FDA does not consider most nonmechanical household cosmetic implements to be “devices” under the Act. The following products, for example, fall outside the device requirements unless they make medical claims: toothpicks, hair brushes, combs, nail files, nail clippers, nail scissors, razors, tweezers, and loofah sponges (used to exfoliate the skin). On the other hand, FDA regulates breast implants and chin prostheses as medical devices, regardless of whether they are intended to be used for reconstructive or cosmetic purposes. 21 C.F.R. 878.3530, 3540, 3550. In addition, the agency treats collagen used to correct wrinkles and acne scars as a medical device, defined as “dermal collagen implants for aesthetic use.” See PMA Approval for CosmoDerm 1 Human-Based Collagen, CosmoDerm 2 Human-Based Collagen, and CosmoPlast Human-Based Collagen (Mar. 11, 2003). FDA also treats tanning lamps, epilators (used for hair removal), and tongue scrapers (used to treat bad breath) as medical devices. 21 C.F.R. 878.5350 (“needle-type epilator”); 878.5360 (“tweezer-type epilator”); 868.4635 (“ultraviolet lamp for tanning”); 872.6855 (“manual toothbrushes,” which is how FDA categorizes tongue scrapers).

Decorative contact lenses are products that do not correct vision but change the apparent color of the iris, seem to add a design to it, or give the eye a nonhuman or otherwise abnormal appearance. They present the same significant risks of eye injury that corrective contact lenses do. Corrective contact lenses are regulated as prescription medical devices, and it had long been assumed that noncorrective lenses were devices, as well. In 2002, however, Daniel Troy, the FDA Chief Counsel, informed the agency’s Center for Devices and Radiological Health (CDRH) that he was considering declaring that noncorrective decorative contact lenses are not medical devices. Megan Garvey, *Health Concerns Tinge Use of Cosmetic Lenses*, L.A. TIMES, Aug. 26, 2002, at 1. This information motivated California Congressman Henry Waxman, the ranking minority member of the House of Representatives Committee on Government Reform, to write the following letter to Tommy Thompson, the Secretary of Health and Human Services.

Letter from Rep. Henry A. Waxman to Tommy Thompson, Secretary of Health and Human Services

August 26, 2002.

... I am writing to alert you to a plan apparently set in motion by the Chief Counsel of the Food and Drug Administration (FDA) to reclassify colored contact lenses that do not correct vision as cosmetics instead of medical devices, essentially deregulating these products. Under current law, manufacturers of colored lenses must meet federal standards of hygiene and sterility and can sell their products only with a prescription. FDA’s new plan, however, would eliminate these rules, make colored lenses available over-the-counter without adequate directions for safe use, and

depend on an underfunded cosmetics enforcement division with limited safety authority to protect consumers. It would also establish a precedent that could lead to the deregulation of many more potentially hazardous prescription drugs and devices.

Because poor-quality or misused contact lenses can cause severe eye infections, painful corneal disease, and even blindness, the FDA plan virtually guarantees serious medical complications. . . . Ophthalmologists and optometrists find no justification to treat colored lenses differently from corrective contact lenses. I urge you to intervene personally and stop what is a legally unsound and medically dangerous policy. . . .

Contact lenses all qualify as medical devices under the third part of the [medical device definition at section 201(h)], as a product that is "intended to affect the structure or any function of the body of man." Lenses unavoidably alter the structure of the body by profoundly altering the biology of the eye. As one leading ophthalmology textbook states:

A contact lens may be considered to be an optical patch and bandage. As a patch it reduces the availability of oxygen to and the dissipation of carbon dioxide from the cornea. As a bandage it creates pressure on the underlying tissues and reduces wetting of the ocular surface and dissipation of material from between the contact lens and the cornea.

These effects are unavoidable and foreseeable. Any manufacturer of contact lenses that intends for users to place the products in the eye must also intend for these effects to occur.

This longstanding and fair reading of the law, however, has apparently been rejected by the Chief Counsel of FDA, Daniel Troy. Mr. Troy appears to believe that a product is only a "medical device" if it is marketed expressly as something that will affect the structure or function of the body. His argument seems to be that since colored noncorrective contact lenses are not marketed as something to correct a problem (like poor vision), these products cannot be classified as medical devices.

This reasoning is both wrong and dangerous. It is wrong because of legislative history, administrative precedent, and legal precedent, including cases in which courts have acknowledged FDA's ability to regulate products on the basis of evidence other than express marketing claims. Indeed, two such cases have expressly found that colored noncorrective contact lenses are medical devices. It is dangerous because of its logical consequence. If a medical device or a drug (which is defined using similar terms) must be expressly marketed as a treatment to fall under the FDCA, then manufacturers can simply use their marketing claims to evade regulation altogether. Breast implants and collagen injections marketed for aesthetic appeal and condoms marketed for pleasure would not be medical devices. Botox marketed for cosmetic purposes would not be a drug. A company might even attempt to market valium as "fun" to evade drug regulation. . . .

NOTES

1. *Subsequent Events*. In April 2003, FDA officially stated that it considered noncorrective decorative contact lenses to be cosmetics, but not devices. See GUID-

ANCE FOR FDA STAFF ON SAMPLING OR DETENTION WITHOUT PHYSICAL EXAMINATION OF DECORATIVE CONTACT LENSES (Import Alert 86-10); 68 Fed. Reg. 16520, 16521 (Apr. 4, 2003). Subsequently, Rep. Waxman—with support from the major manufacturers of colored lenses, advocacy organizations dedicated to eye health and safety, and eye health professionals—cosponsored legislation requiring FDA to regulate decorative contact lenses as medical devices. In November 2005, Congress amended the FD&C Act by adding new subsection 520(n), “Regulation of Contact Lens [sic] as Devices.” This new provision provides: “All contact lenses shall be deemed to be devices under section 201(h).” 119 Stat. 2119. It also, however, declares: “Paragraph (1) shall not be construed as bearing on or being relevant to the question of whether any product other than a contact lens is a device as defined by section 201(h) or a drug as defined by section 201(g).”

2. *Are Contact Lenses “Cosmetics”?* As discussed above, *supra* p. 39, there are valid questions as to whether contact lenses fit the definition of “cosmetic.”

b. DIAGNOSTIC DEVICES

The device definition includes articles (including “in vitro reagents”) “intended for use in the diagnosis of disease or other conditions.” FD&C Act 201(h). This provision raises its own interpretive problems.

United States of America v. 25 Cases, More or Less, of an Article of Device . . . “Sensor Pad for Breast Self-Examination”

942 F.2d 1179 (7th Cir. 1991).

■ CUDAHY, CIRCUIT JUDGE:

In this case we are called on to interpret the word “device” as used in the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 321(h)(2) (1988) (the Act). The government brought this action to seize the appellant’s inventory, believing it to consist of adulterated devices in interstate commerce. The district court granted summary judgment for the government. . . .

In the mid-1980s, Earl Wright developed a product which he believed would aid women in conducting self-examinations for the early detection of breast cancer. This product, descriptively named the “Sensor Pad,” consists of a flat, circular latex bag filled with a layer of silicone lubricant. It is intended to be placed over the breast during self-examinations to improve the woman’s ability to feel abnormalities beneath the skin. Wright and his associates believed the Pad was not a “device” under the Act. . . .

According to the Act, the term device “means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is . . . (2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease. . . .” 21 U.S.C. § 321(h). . . . Although agreeing that its Pad aids in the detection and screening of breast cancer, Inventive Products nevertheless argues that the word diagnosis does not encompass the function of the Sensor Pad. Diagnosis, the appellant suggests, includes only examinations to “determine the nature and circumstances of a diseased condition.” Because the Sensor Pad merely helps the woman in detecting abnormalities

that could be symptoms of a disease, strictly speaking it is used *before* actual diagnosis.

The distinction appellant attempts to draw between screening and diagnosis is an untenable one. In its opening brief, Inventive Products appears to argue that diagnosis occurs only at the last step in the process of discovering a disease, that step which ultimately determines the nature and circumstances of a diseased condition. Thus, because the Sensor Pad only detects irregularities which may or may not be cancerous growths, it does not diagnose the disease. Indeed appellant agrees with one of its expert physicians, who averred that “biopsy is the only means of diagnosing breast cancer.” By proposing that medical inquiries change from screening to diagnosis only at the final determination, the appellant’s theory would apparently exclude even a mammography unit from being classified as diagnostic, because it too cannot confirm the presence of cancer. . . .

The obscurity of the line appellant would draw between diagnosis and screening . . . well illustrates the arbitrariness of the line-drawing. Pursuing this fruitless inquiry is irrelevant in any event since we believe Congress had no such screening/diagnosing distinction in mind when it wrote section 321(h).

The current description of “device” in the Act was adopted essentially in the original version of the Federal Food, Drug and Cosmetic Act, 52 Stat. 1040 (1938), the development of which is discussed in *United States v. Article of Drug . . . Bacto-Unidisk*, 394 U.S. 784, 793–98 (1969). The bill emerged from committee in the Senate with several amendments, one of which proposed broadening the definition of “device” to include tools used in diagnosis of disease. At that time one senator, with the voiced approval of the bill’s sponsor, summarized the amendment on the floor of the chamber: “the word ‘diagnosis’ merely adds to their uses, namely, their use in looking into a situation prior to the time when the cure or mitigation shall begin.” 79 Cong. Rec. 4843 (1935) (statement of Sen. Barkley). Another senator meanwhile offered the view that weight scales used during the diagnosis of a patient would come within the bill’s regulation. *Id.* (statement of Sen. Clark).

Moreover, even if Congress’ intentions with regard to the scope of “diagnosis” were not clear from its debate, the FDA’s position in this matter would still prevail. It would be entirely plausible to suggest that Congress intended the FDA to decide for itself which devices are used for diagnosing disease. One senator opined on the floor of the Senate that “the language [of the bill] is broad enough to cover any device of which the Food and Drug Bureau of the Agricultural Department chooses to take jurisdiction.” *Id.* at 4841. Such a delegation to the FDA would require a court to give considerable deference to the agency’s decision. . . .

Second, even had Congress never considered the question before us, we might allow the FDA room to decide the question itself. Courts often will defer to an agency’s reasonable interpretation of an ambiguous provision within the agency’s own organic statute. *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 843 (1984). . . .

Our approach in this case has been further reinforced by the Supreme Court, which reminded litigants that “remedial legislation such as the Food, Drug and Cosmetic Act is to be given a liberal construction consistent with the Act’s overriding purpose to protect the public health . . .” *Bacto-Unidisk*, 394 U.S. at 798. A broad definition of “diagnosis” allows for greater authority in the agency to oversee developments in health care, and thus to better protect the public health.

For each of the above reasons, the district court was correct to grant the government’s motion for summary judgment in this case. . . .

NOTES

1. *Diagnostic Drugs*. The definition of “drug” at FD&C Act 201(g)(1) includes “articles intended for use in the diagnosis . . . of disease.” Unlike the definition of “device,” this provision does not embrace products intended for the diagnosis of “conditions” other than diseases. Since 1976, FDA has regulated almost all diagnostic products (whether for diseases or “other conditions”) as medical devices. See *infra* p. 983.

2. “*Diagnosis*” for What Purpose? FDA regulates as devices “OTC test sample collection systems for drugs of abuse testing.” These products, according to the regulation, are intended to “[c]ollect biological specimens (such as hair, urine, sweat, or saliva), outside of a medical setting and not on order of a health care professional (e.g., in the home, insurance, sports, or workplace setting); maintain the integrity of such specimens during storage and transport in order that the matter contained therein can be tested in a laboratory for the presence of drugs of abuse or their metabolites; and provide access to test results and counseling.” 21 C.F.R. 864.3260. When it finalized this regulation, FDA rejected a comment which asserted that kits for detecting drugs of abuse in hair are not medical devices under section 201(h) of the FD&C Act because they are not for medical diagnosis and treatment. 65 Fed. Reg. 18230, 18232 (Apr. 7, 2000).

In *U.S. v. Undetermined Number of Unlabeled Cases*, 21 F.3d 1026 (10th Cir. 1994), the Tenth Circuit held that containers used to collect urine and saliva specimens for HIV testing were devices, even though the laboratory-defendant that distributed the containers performed the testing for insurance risk-assessment purposes rather than for medical treatment.

c. LIMITS OF THE DEVICE DEFINITION

COMMENT: COMMON SENSE LIMITATIONS ON THE DEFINITION OF “DEVICE”?

FDA’s 1996 tobacco rulemaking raised fascinating issues concerning the definitions of “device” and “drug,” which were explored at length in the preambles to the proposed and final rules. See 60 Fed. Reg. 41314 (Aug. 16, 1995); 61 Fed. Reg. 44396 (Aug. 28, 1996). We have already mentioned FDA’s expansive approach to establishing the “intended use” of cigarettes and smokeless tobacco in the absence of representations by the manufacturers. *Supra* p. 47. Another important interpretive issue was whether there are unstated common sense limitations on the categories of “drug” and “device” as defined by the FD&C Act.

As discussed at the beginning of this chapter, courts use a “common sense” approach in interpreting the FD&C Act’s definition of “food.” The circular brevity of that definition leaves them with little other choice. By contrast, the more detailed definitions of “drug” and “device” are less obvious candidates for the imposition of implied limitations. However, the plain language of these definitions encompasses an enormous range of products not traditionally viewed as being within FDA’s authority. This is particularly true of the definition of “device,” which embraces products that do not act primarily through chemical action or metabolism. As the tobacco manufacturers pointed out repeatedly in attacking FDA’s jurisdiction over its products, the device definition, applied literally, would include guns and ammunition, thermal pajamas, air conditioners, scuba diving gear, automobile airbags, and roller coasters. The industry thus argued that a product could be treated as a device only if its intended effects on structure or function were “therapeutic,” “medical,” or “beneficial.” See 61 Fed. Reg. 44619, 44674–75 (Aug. 28, 1996). FDA emphatically opposed reading such limitations into the statute. The agency also observed that, in any event, tobacco products achieve their effects pharmacologically and are thus indistinguishable from products that the agency has traditionally regulated as drugs and devices. *Id.* at 44675–85.

The federal district court hearing the challenge to the tobacco rule rejected the industry’s argument that the structure/function provisions must be construed narrowly to avoid absurd implications for other types of products. The court remarked that a statute’s scope “is not to be judicially narrowed . . . by envisioning extreme possible applications.” *Coyne Beahm v. FDA*, 966 F. Supp. 1374, 1393 (M.D.N.C. 1997) (quoting *U.S. v. Sullivan*, 332 U.S. 689, 694 (1948)). Ultimately, however, the Supreme Court ruled for the tobacco industry without reaching the issue of the precise meaning of “affect the structure or any function of the body.” *FDA v. Brown & Williamson*, 529 U.S. 120 (2000) (*infra* p. 82). Consequently, whether there are any unstated limits on the definition of “device” remains an open question. In the following 2002 letter, FDA Chief Counsel Daniel Troy—who had represented Brown & Williamson in its challenge to the agency’s regulation of cigarettes—firmly embraced the notion that the device definition encompasses consumer products only if they are marketed with claims of therapeutic or medical utility. He also advanced a narrow interpretation of what types of evidence can establish “intended use.”

Letter from Daniel E. Troy, FDA Chief Counsel, to Jeffrey N. Gibbs

October 17, 2002.

. . . This responds to your letters concerning Applied Digital Solutions (ADS)’s two separate written requests submitted to the Center for Devices and Radiological Health under Section 513(g) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) requesting a determination that the VeriChip is not a medical device under the FD&C Act for the intended uses described in the requests. Your requests cover two different intended uses of the product. The first is for use of the VeriChip in health information

applications ("health information VeriChip"). The second is for security, financial, and personal identification\safety applications ("personal ID\security VeriChip"). For the reasons discussed below, FDA believes that the health information VeriChip is a medical device subject to FDA's jurisdiction. FDA agrees, however, that the personal ID/security VeriChip is not covered by the FD&C Act.

Background

Since 1986, Digital Angel Corporation, which is working with VeriChip Corporation, has sold more than 20 million implantable RFID transponders for animals. . . . The transponders provide access to information necessary to identify the animal.

In January of 1984, the Center for Veterinary Medicine (CVM) within FDA issued a letter to the manufacturer of this product stating: ". . . The device does not have a medical\therapeutic function. Therefore, we have no objection to marketing of this identification device for use in animals." . . .

ADS has determined to market in the United States a version of the microminiature transponder, known by the trade name "VeriChip," for a variety of uses in human beings. We understand from ADS that the VeriChip is a microminiature transponder that is encapsulated in medical grade glass that may be inserted by hypodermic needle under the skin of the upper arm in humans. The chip\transponder stores a unique identification number only. A small, handheld introducer is used to place the chip subcutaneously. A small, handheld battery-powered scanner can read the identification number on the chip. That number enables access to a database. . . . The personal\security VeriChip would allow access, via the database, to information related to security, financial, and personal safety applications only. You have represented that it will not contain any medical information. By contrast, ADS and its representatives have explained, the health information VeriChip would allow access, via the database, to medical history and other information to assist medical personnel in diagnosing or treating an injury or illness.

Regulatory Status of the VeriChip

We believe that the health information product, which facilitates access to information for use by medical professionals in treating the individual with the VeriChip embedded in his or her arm, is "intended for use in the diagnosis of disease or other conditions, or in the cure [or] mitigation of disease." The information in the database is meant to be used by medical professionals in diagnosing a disease or other condition. Indeed, the entire purpose of this product is for a medical professional to employ when treating a stricken individual. For example, information about whether the person is allergic to a particular medicine, or has an implanted pacemaker, which is accessed in connection with the VeriChip, is intended for use in treating the person. Accordingly, FDA has determined that the health information VeriChip is a medical device within the meaning of Section 201(h)(2) of the FD&C Act.

By contrast, as CVM recognized with respect to the use of the VeriChip predecessor in animals, it does not appear that the personal ID/security

VeriChip is a medical device, even though it is an “implant.” It is of course true that virtually any product that comes into contact with the body—and many that do not—could be said to have an effect on the structure or a function of the body. However . . . FDA’s medical device jurisdiction under Section 201(h)(2) extends only to such products that are marketed by their manufacturers or distributors with claims of effects on the structure or a function of the body. In the language of the statute itself, the product must be “intended to” affect the structure or a function of the body. It is well settled that intended use is determined with reference to marketing claims. . . .

In [its brief in] a 1994 case, FDA stated that it “does not claim that a device which has no *medical* application could ‘qualify as a device under the FD&CA.’” Courts have held that Section 201(h)(3) only encompasses products claimed to affect the body “in some *medical*—or drug-type fashion, *i.e.*, in some way other than merely altering the appearance.” *An Article . . . “Sudden Change,”* 409 F.2d at 742 (emphasis added).

The pertinent legislative history supports this interpretation. Specifically, the Senate Report accompanying the legislation that became the Federal Food, Drug, and Cosmetic Act of 1938 states:

The use to which the product is to be put will determine the category into which it will fall. . . . The manufacturer of the article, *through his representations in connection with its sale*, can determine the use to which the article is to be put.

S. Rep. No. 74–361, at 240 (1935) (emphasis added). . . .

Accordingly, assuming that no medical claims are made for the personal ID\security VeriChip, and the product marketed for that purpose contains no health information, FDA can confirm that it is not a medical device.

It is, of course, foreseeable that any implant, such as the personal ID\security VeriChip, will have an effect on the structure and function of the body; indeed, it will be permanently embedded under a person’s skin. However, as the Fourth Circuit recently held, a foreseeable effect on the structure or function of the body does not establish an intended use. If the foreseeability theory had been accepted by the courts, FDA would have won several cases that it lost. *See, e.g., National Nutritional Foods Ass’n v. Mathews*, 557 F.2d 325 (2d Cir. 1977).

Also, if foreseeability were a permissible basis for finding an intended use as that term is used in Section 201(h)(3), FDA’s jurisdiction would encompass many articles having foreseeable physical effects. Yet FDA only regulates products if they are marketed with claims of medical or therapeutic utility. For example, FDA only regulates exercise equipment as a medical device when it is marketed with claims to prevent, treat, or rehabilitate injury or disability. Otherwise, it is a consumer product.

In addition, if foreseeable effects were cognizable under Section 201(h)(3), FDA’s legal authority would intrude into consumer product regulation—an area of responsibility delegated by Congress to another federal agency. CPSC’s jurisdiction extends to “consumer products,” which means “any article, or component part thereof, produced or distributed (i)

for sale to a consumer for use in or around a permanent or temporary household or residence, a school, in recreation, or otherwise, or (ii) for the personal use, consumption or enjoyment of a consumer in or around a permanent or temporary household or residence, a school, in recreation, or otherwise. . . .” 15 U.S.C. § 2052(a)(1). The definition expressly excludes “drugs, devices, or cosmetics (as such terms are defined in sections 201(g), (h), and (i) of the Federal Food, Drug, and Cosmetic Act . . .).” *Id.* § 2052(a)(1)(H).

Similarly, if Section 201(h)(3) of the FD&C Act were interpreted to give FDA jurisdiction over any product foreseeably having an effect on the structure or a function of the body, then regulatory authority would shift from the CPSC to FDA for a host of non-health-related products. Hiking boots; shirts, pants, and coats; exercise equipment; insulated gloves; airbags; and chemical sprays can be said to affect bodily structure or function. Clothing and gloves, for example, keep the body warm. . . .

NOTES

1. *Subsequent Regulatory Treatment.* Because no product similar to the health information VeriChip was in commercial circulation prior to the 1976 enactment of the Medical Device Amendments, FDA automatically classified it into class III in 2004, when the agency received premarket notification under section 510(k). Immediately thereafter, however, FDA received a reclassification petition from Digital Angel, requesting that the device be placed in class II. FDA granted this petition in October 2004. Letter from Donna Bea-Tillman, FDA-CDER, to James Santelli (Oct. 12, 2004). Accordingly, the agency then promulgated a new classification regulation for the class II “Implantable radiofrequency transponder system for patient identification and health information.” 21 C.F.R. 880.6300. The rule identifies a guidance document as the special control for the device.

2. *“Behind-the-Wall” Medical Gas Pipeline Systems.* Most hospitals and many other health care facilities have permanently installed medical gas pipeline systems as part of their architectural infrastructure. These systems deliver medical gases such as oxygen and nitrous oxide from remote tanks to wall outlets throughout the facility. Medical gases are prescription drugs, and medical gas delivery products on the patients’ side of the wall (such as flowmeters, gauges, tubing, and masks) are indisputably devices. But what about the “behind-the-wall” pipes, manifolds, valves, and connectors, typically installed by plumbing contractors? FDA originally took the position that such systems were “part of the physical plant” rather than medical devices. See Letter from Franklin K. Coombs, P.E., Biomedical Engineering Branch, Division of Classification and Scientific Classification, FDA to Larry R. Pilot, Director of the Division of Compliance, FDA (Jan. 3, 1977); Memorandum from Pilot to Coombs (Jan. 10, 1977) (response confirming that oxygen supply systems “are not devices as that term is defined in the Act”). More recently, however, the agency has indicated that medical gas delivery distribution systems are in fact devices under the statute. Letter from Eugene M. Berk, Center for Devices and Radiological Health, FDA, to Howard Holstein (May 11, 1993). Nevertheless, FDA has said it will use its regulatory discretion to exempt such systems from the legal requirements for devices, with the exception of the general misbranding and adulteration regulations, which still apply.

3. *Leeches and Maggots.* FDA treats maggots and leeches marketed for medicinal purposes as medical devices. Maggots, or fly larvae, are normally associated with corpses and adulterated food, but they also help heal wounds and burns in living

patients' tissue by liquefying dead tissue. Leeches, the bloodsucking aquatic animals with cameo roles in the films *The African Queen* and *Stand By Me*, have been used in medicine for thousands of years. Today, doctors use them primarily to remove pooled blood in skin grafts and reattachment surgery. In 2004, FDA cleared separate 510(k) applications to market each of these products as a medical device substantially equivalent to a device sold prior to the enactment of the Medical Device Amendments in 1976. See FDA Talk Paper, No. T04-19 (June 28, 2004).

4. *Sterilizers*. Federal courts have held that machines used to sterilize other medical devices are themselves medical devices. See *United States v. 22 Rectangular or Cylindrical Devices . . . "The Ster-O-Lizer MD-200"*, 714 F. Supp. 1159 (D. Utah 1989) (surgical instruments); *United States v. Bowen*, 172 F.3d 682 (9th Cir. 1999) (dental handpieces).

COMMENT: DUAL USE PRODUCTS

FDA has set forth the following policy for products that have both medical and nonmedical uses.

FDA will regulate a multi-purpose product as a medical device if it is intended for a medical purpose . . . FDA will determine the intended use of a product based upon the expressions of the person legally responsible for its labeling and by the circumstances surrounding its distribution. The most important factors the agency will consider in determining the intended use of a particular product are the labeling, advertising, and other representations accompanying the product. Products that have medical uses only are clearly intended for medical purposes, and, therefore, will be regulated as medical devices whether or not medical claims are made for them.

45 Fed. Reg. 60576, 60579 (Sept. 12, 1980).

FDA has taken the position that exercise equipment used in recreational and sporting activities will be regulated as medical devices only where those products are intended for medical purposes and thus are properly classified as "therapeutic equipment." 48 Fed. Reg. 53032, 53043-44 (Nov. 23, 1983). Similarly, the agency has concluded that "electrostatic air cleaners are not inherently medical devices," because they have other uses as well, and that the fact that FDA regulates the emission of ozone from medical devices in 21 C.F.R. § 801.415 does not mean that all products emitting ozone are medical devices. Letter from FDA Chief Counsel R.M. Cooper to CPSC Assistant General Counsel S. Lemberg (May 14, 1979).

FDA considers magnets marketed with medical claims, including treatment of cancer or arthritis, to be medical devices. CDRH Consumer Information (Mar. 1, 2000). Similarly, the FDA website states that the agency considers clothes that are labeled or promoted as providing protection against the sun or limiting exposure to the sun's UVA/UVB rays to be medical devices. FDA imposed unapproved device status on an electric gas grill igniter advertised to relieve various kinds of pain when used to send an electric current into acupuncture points on the body. A federal appeals court upheld this determination. *U.S. v. Universal Management Services, Inc.*, 191 F.3d 750 (6th Cir. 1999).

d. FIRST AMENDMENT LIMITS

United States v. 23 . . . Articles

192 F.2d 308 (2d Cir. 1951).

■ WOODBURY, CIRCUIT JUDGE.

The United States of America filed a libel . . . seeking the seizure and condemnation of certain phonograph records, and various accompanying items of printed and graphic matter, all of which were moving or had moved in interstate commerce. The phonograph records were entitled in part "Time To Sleep," and their accompanying literature consists of (1) an album in part entitled, "De Luxe Records Presents Time To Sleep a Tested Method of Inducing Sleep Conceived and Transcribed by Ralph Slater," (2) a leaflet in part reading: "Sleep With This Amazing Record 'Time to Sleep,'" (3) a certificate entitled "Sleep Guaranteed," (4) display cards entitled "De Luxe Records Presents Time to Sleep," and (5) a poster headed "A 'Dream Girl' Shows a New Way to Dreamland." . . .

Section 201(h) of the Act under consideration provides in material part that "[t]he term 'device' . . . means instruments, apparatus, and contrivances, including their components, parts, and accessories, intended (1) for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; or (2) to affect the structure or any function of the body of man or other animals."

Certainly a phonograph record, if not itself an instrument or an apparatus, is a contrivance. And moreover, it is without question a component, part or accessory of a phonograph, or like record playing machine, which in its turn is without any doubt at all an instrument, apparatus or contrivance. The real question therefore is whether the libeled records were intended for either of the uses described in (1) or (2) of § 201(h), *supra*. Obviously the records were intended for use in the cure, mitigation, treatment or perhaps prevention of insomnia. But the medical experts who testified at the trial were agreed that insomnia is not a disease, but is a symptom of a disease, usually although not necessarily a neurological one, or of an emotional disturbance of some kind. Thus it may be argued that the records do not fall within the coverage of (1) above.

However, all the expert witnesses who testified on the point were unanimous that sleep is a function of the body, or body and mind, of man and other animals, and this testimony brings the records within the terms of (2), *supra*, for their intended use was to affect that function, *i.e.* to induce sleep in those who needed it but had difficulty in obtaining enough. Without further laboring the point it will suffice to say that the records involved are "devices within the meaning of § 201(h)(2) of the Act. . . ."

United States v. Undetermined Quantities of Article of Device

Med. Devices Rep. (CCH) ¶ 15,055 (W.D. Mich. 1982).

This is an action by the United States . . . seeking the condemnation and forfeiture of thirty-two different tape recordings, marketed by the

claimant, Potentials Unlimited, Inc. under various titles. These tape recordings were initially seized, pursuant to warrant, on January 6, 1981. The tapes sought to be condemned include:

1. "Relief of Back Pain" or "Back Pain"
2. "Removal of Warts"
3. "Bust Enlargement" or "Natural Bust Enlargement"
4. "Migraine Relief" or "Headaches"

.... [28 additional titles suggesting disease or structure/function effects]

Although the claimant disputes whether the labeling of the tapes is false or misleading and whether they lack adequate directions for use, it does not dispute that the tapes were manufactured in an unregistered establishment, that the tapes themselves are not registered as medical devices, or that there was no premarket notification of their manufacture and sale. It follows that if, in fact, the tapes are medical devices, they are in violation of the Act and are subject to forfeiture. Therefore, the resolution of this action turns upon one question; are these tapes medical devices within the meaning of the Act?

In January, 1981 Potentials Unlimited marketed over 100 tape recordings. Most of these are unrelated to health or medical problems, as evidenced by the fact that only 32 of the tapes are under seizure. The catalogue distributed by Potentials identifies many different "self-hypnosis" tapes with such titles as "Memory," "Good Study Habits," "Fear of Flying," "Stop Smoking," "Freedom from Guilt," "Jealousy," "Self-Confidence," "How to be Popular," "Be a Better Bowler," and "How to be a Great Golfer." . . . The tapes are divided, by the catalogue, into several different "series." Most of the seized tapes fall under the "Health Series" although a few are listed under other categories.

The Potentials Unlimited catalogue comprises the most significant and detailed promotional literature used to market the tapes. . . . The introduction refers to the tape recordings, at one point, as "learning"; however, read as a whole, the introduction leaves the impression that the positive suggestions contained on the tapes will act upon the "subconscious mind" to automatically bring about the changes which a person desires. Any teaching and learning aspects of the tapes are deemphasized or negated by the reference to "magic" and the implication that the tapes will work better, "without any interference from your conscious mind." Indeed, the introduction suggests that the tapes will be more beneficial if played during sleep, rather than actually being listened to and assimilated.

The catalogue distributed in 1981 contains a disclaimer on page 3, in small but easily legible print, which states:

No therapeutic claims of any kind are made with regard to these tape programs. We believe cures or improvements are a matter of mind over matter and these tapes are not intended as a substitute for seeing your physician, or for medical treatment. Parental guidance is suggested for children's use.

An earlier version of this disclaimer was introduced into the catalogue sometime in 1980 after the FDA had begun investigating Potentials Unlimited in February of that year. In previous catalogues no such disclaimer was included.

The general introduction applies to all of the self-hypnosis tapes. The separate descriptive paragraphs contained in the catalogue refer by title and content to specific tapes and the specific problem or aspect of a person's life which that tape is designed to improve. The paragraphs are not specific regarding how the tapes work, instead they are anecdotal and conversational attempts to interest the reader in the specific tape. When combined with the general introduction, the individual descriptions generally leave the impression that the tapes will cure or treat the specific health-related problem indicated by the title of the tape.

Generally there is no dispute that the tapes purport to effect [sic] structures or functions of the body or to mitigate the effects of diseases. . . .

The tape recordings themselves are very similar in style, structure, and content. They begin with brief instructions regarding the use and purpose of the particular tape, a standard hypnotic induction, and a series of statements, descriptions of visual images, and suggestions designed to influence the listener's thinking. Many of the images are repeated in more than one tape.

All of the tapes clearly convey a number of related ideas revolving around a central theme, *i.e.* that a person's thoughts can influence their health or physical characteristics. This central theme is developed through an emphasis on the benefits of relaxation, the elimination of negative feelings such as anger, hate and jealousy, the creation of a positive self-image, and the idea that reality is a reflection of one's own perceptions. Thus, according to the tapes, if a person thinks of himself in a particular, desired way, such as thin, free of allergies or pain, or generally healthy, the person will actually take on those desired characteristics. The tapes are clearly designed to communicate both this central tenet, and a method for putting it into practice.

The court does not find that the tapes themselves are, apart from the claims made in the catalogue, designed or intended to be used in the cure or treatment of the physical and mental conditions indicated by their titles. Each tape is designed to teach a method of mental therapy which it is claimed will have beneficial effects on a particular aspect of a person's life. Any therapeutic results flow from the listener's successful implementation of the lessons contained on the tape. The purported "treatment", therefore, consists of the new thought patterns, beliefs, and behaviors which the listener has learned and adopted. The lessons contained on the tapes are communicated linguistically, and can be understood as well by reading transcripts of the tapes as by listening to the tapes. The contents of the tapes could also be transmitted directly between two individuals, using speech, without the use of tape recording devices. Therefore, the court finds that the mechanical components of these tape recordings are not part of any medical treatment and are used only as a means of communicating the verbal ideas and methods found on the tapes.

The tapes use hypnosis and hypnotic suggestion to communicate the ideas which they contain. The American Medical Association has recognized hypnosis as a useful "modality" for medical treatment, when used in conjunction with other treatments, since 1957. There are controlled studies indicating that hypnosis techniques may be useful in the removal of warts, the treatment of asthma, the mitigation of all kinds of pain, the reduction of myopia (near-sightedness), and in enlarging the female bust. In addition, there are anecdotal reports of the successful use of hypnosis to cure or treat virtually every condition encompassed by the 32 self-hypnosis tapes under seizure. Scientific research regarding the use of hypnosis in treating these other conditions has generally been negative. No research has been done, specifically, regarding the use of hypnotic tape recordings. . . .

The fundamental finding regarding hypnosis, as it impacts upon this case, is that hypnosis is an ill defined and little understood concept which it is at least possible to view as a special form of communication or as a teaching device. This finding is significant since the court has found that the tapes under seizure communicate several clearly identifiable ideas. Since hypnosis can be considered a form of communication, the fact that the tapes use hypnosis techniques, does not prevent their classification as communication or teaching devices. The court rejects Dr. Reyher's testimony that communication must be logical, rational, or objectively purposeful. His definition of communication, besides being outside his field of expertise (as he readily admitted) would exclude poetry, art, music, and drama from the area of communication. Whatever the merits of such a restricted definition for some purposes, it does not comport with the ordinary concept of communication and is irrelevant for First Amendment purposes.

There is no evidence that the self-hypnosis tapes manufactured by Potentials Unlimited can actually achieve the results which are claimed in the Potential catalogue. The tapes could be harmful if they caused someone to delay seeking adequate medical care for a disease condition. Additionally, the uncontrolled use of hypnosis could be dangerous because persons could develop anxiety reactions to some of the suggestions contained on the tapes.

This case illustrates the difficulty which inevitably arises in balancing the ideal of philosophical and economic freedom against the practical need to protect unwary and vulnerable individuals from the claims of rapacious and unethical businessmen. . . . Underlying this case, of course, is the fundamental question of whether consumers should be allowed the choice of buying Potentials Unlimited self-hypnosis tapes without the prior intervention and approval of the Federal government in the form of the Food and Drug Administration.

Representing the other side of the balancing dilemma is society's concern for the gullible or the desperate individual who is induced to forego necessary medical treatment by the fraudulent, or simply mistaken, claims of the purveyors of medical drugs and devices. Although the construction and fantastic claims made for many quack devices over the years often seem quite amusing, use of these devices can have serious health consequences. Whether sold to a consumer or a health professional, a device which does not perform as promised may pose a risk to health as well as an

economic detriment to the purchaser. Reliance on unwarranted claims made for a device, recommending use in serious disease conditions, may induce the purchaser to forego seeking timely and appropriate medical treatment.

Fortunately, the court need not confront the problem presented in this case from the fundamental level of balancing the costs and benefits of the two competing perspectives suggested above. Congress has already engaged in such a balancing process and has determined that "medical devices" should be regulated by the FDA for the protection and benefit of the consuming public seeking medical treatment. In doing so, Congress has adopted a broad definition of medical device which is to be liberally construed in order to effectuate the purpose of the Act. *United States v. Bacto-Unidisk*, 394 U.S. 784 (1969).

There is no doubt that a tape recording is an implement, apparatus, or contrivance [as required by the FD&C Act definition]. However, a distinction must be made in this case between the tapes themselves, and the ideas that are contained on the tapes. Congress did not intend to regulate an article or device, the sole function of which is to serve as a means of communicating health related ideas or information. Had Congress had such an intent it would have expressly included books, the quintessential communication device, in the definition of "medical device." It did not do so.

The idea that a person can control and improve their [sic] health in general, or specific physical conditions, through the intervention of their thoughts, *i.e.* with their minds, is simply that, an idea, which anyone, including the claimant in this case, is free to believe, to disseminate, and, unless specifically prohibited, to act upon as they wish by virtue of the First Amendment. As found by the court, the tape recordings under seizure in this case are designed and intended to communicate and to teach certain ideas, beliefs, and mental processes which are claimed to have health benefits when adopted and practiced by the listener. Congress did not purport to regulate quack medical ideas or beliefs when it drafted the definition of medical device contained in the Act. By no stretch of language can an idea or a mental process be considered an instrument, apparatus, implement, machine, contrivance, implant, or *in vitro* reagent, or a similar or related article.

The "liberal interpretation" to be accorded the Act must yield somewhat when it comes into conflict with First Amendment freedoms. . . . Since ideas, beliefs and mental processes do not come within the statutory definition they are outside the jurisdiction of the FDA. Mechanical devices which do no more than communicate or expound such ideas, beliefs and mental processes are likewise outside the jurisdiction of the FDA. To include such devices within the definition would have grave First Amendment implications and would, by implication, bring health related books, magazines, and publications within the agency jurisdiction. That is a result Congress clearly did not contemplate or intend.

The fact that the tapes in issue do no more than communicate certain ideas using hypnosis as a tool in that communication does not end the inquiry into whether these tapes, as marketed by Potentials Unlimited, are subject to regulation as medical devices. Articles and devices which have no

intended therapeutic qualities may be regulated if they are sold by the vendor accompanied by therapeutic claims. Thus, the seller's objective manifestation of a therapeutic intent brings otherwise medically benign articles within the purview of the Act. . . .

The therapeutic claims contained in promotional literature can convert the most innocent of articles into drugs or devices within the meaning of the Act. . . . The conduct of Potentials Unlimited in marketing these tapes as therapeutic medical devices is subject to regulation by Congress, even if the tapes themselves communicate ideas.

As stated in the court's findings of fact, the catalogue distributed by Potentials Unlimited tells the reader through its general introduction, that the self-hypnosis tapes will work "like magic," by "saturating the subconscious mind with positive suggestions." This language creates the expectation of an automatic and mechanical process by which suggestions will be implanted in the brain, much like a drug, and miraculous cures will result from the therapeutic effects of these suggestions. The whole introduction is designed to imply a therapeutic result from listening to the tapes, rather than a simple act of communication. Hypnosis is regarded, in the catalogue, as a treatment rather than a form of communication. Coupled with the titles of the seized tapes, an intended therapeutic use for the tapes is objectively manifested. This objective manifestation makes the tapes, as they are presently marketed, medical devices, to the extent they are used in treating disease or to affect body function. . . .

The petition for condemnation against the . . . tapes . . . is granted. . . .

Draft Policy Guidance for Regulation of Computer Products

52 Fed. Reg. 36104 (September 25, 1987).

FDA is making available for public comment draft policy guidance for the regulation of computer products. The draft policy guidance clarifies how FDA would apply existing statutory requirements to the regulation of computer products (*i.e.*, both hardware and software) when such products meet the definition of a medical device in the Medical Device Amendments of 1976. . . .

Under the draft policy, FDA would not regard computer products used only for traditional "library" functions such as storage, retrieval, and dissemination of information—functions traditionally carried out through textbooks and journals—to be medical devices subject to regulation by the agency. Similarly, the policy notes that FDA's device regulations and authorities also would not apply to computer products used for general accounting or communications functions or solely for instructional purposes, rather than to diagnose or treat patients.

When a computer product is a "component, part, or accessory" of a product recognized as a medical device in its own right, the computer component is regulated according to the requirements for the parent device (unless the component of the device is separately classified).

Computer products which are medical devices, and not components, parts, or accessories of other articles which are themselves medical devices, are regulated with the least degree of control necessary to provide reasonable assurance of safety and effectiveness. For example, many software products known as "expert" or "knowledge based" systems that are not used with existing medical devices and that are intended to involve competent human intervention before any impact on human health occurs (e.g., where clinical judgment and experience can be used to check and interpret a system's output) are exempt from registration, listing, premarket notification, and premarket approval requirements. FDA is also not aware of any computer product that is not a component, part, or accessory of another device that would require [a] . . . premarket approval (PMA) application before marketing.

The agency is cognizant of the need to safeguard First Amendment protections and recognizes that, in some cases, it may be difficult to make a clear distinction between software products that perform traditional "book" or "library" functions, and software products that fall within the definition of a medical device under the draft policy, based on their intended use in the diagnosis or management of health-related conditions. FDA believes flexible guidance is necessary for effective implementation of the medical devices law and specifically invites comments on the appropriateness of the approach taken in the draft policy.

NOTES

1. *Further Developments*. A November 13, 1989, revised draft of the POLICY FOR THE REGULATION OF COMPUTER PRODUCTS reiterated the basic statements of the 1987 draft. FDA has never finalized the policy. The agency has more recently announced that it is considering establishing a risk-based classification of stand-alone computer software products that fit the definition of a medical device, but it has not taken any further action. 65 Fed. Reg. 73822 (Nov. 30, 2000). See generally Bruce M. Fried & Jason M. Zuckerman, *FDA Regulation of Medical Software*, 33 J. HEALTH L. 129 (2000); E. Stewart Crumpler & Harvey Rudolph, *FDA Software Policy and Regulation of Medical Device Software*, 52 FOOD & DRUG L.J. 511 (1997); Dee Simons, *Medical Device Software Regulation; An Industry Perspective*, 52 FOOD & DRUG L.J. 189 (1997).

2. *Specific Case*. In FDA Regulatory Letter BOS-88-10 (June 23, 1988), FDA Boston District Director E. J. McDonnell took the position that a computerized blood bank and laboratory management system that takes data directly from automated blood analyzers and uses it as the basis for labeling blood and blood components is a medical device and subject to the premarket notification requirements of section 510(k). This position was reaffirmed in 1994 in a letter from CBER Director Kathryn C. Zoon to Blood Establishment Computer Software Manufacturers (Mar. 31, 1994).

E. IMPLICIT LIMITS ON FDA'S JURISDICTION: TOBACCO

In 1995, FDA announced that it was going to assert jurisdiction over cigarettes and smokeless tobacco and regulate their manufacture, labeling, and advertising. For legal authority, the agency invoked the FD&C Act.

Contending that tobacco products were responsible for as many as 400,000 American deaths annually, the agency mounted what it considered a compelling case for government intervention. The agency's goal was to protect adolescents who had not yet begun to smoke. Its plan was designed to obstruct their access to tobacco and discourage manufacturer promotional efforts to attract new smokers. FDA's notice of proposed rulemaking immediately precipitated litigation that probed the boundaries of the agency's legal authority. The eventual failure of FDA's initiative exposed new limits of the Act's definitions as measures of its regulatory jurisdiction.

Decades before the 1995 announcement, FDA had asserted its authority over at least some tobacco products. Shortly after World War II, the agency successfully challenged the marketing of two brands of cigarettes that it claimed were illegal drugs. In *United States v. 46 Cartons . . . Fairfax Cigarettes*, 113 F. Supp. 336 (D.N.J. 1953), FDA seized a shipment of cigarettes whose labeling "represents that the article is effective in preventing respiratory disease, common cold, influenza, pneumonia" and more than a dozen other illnesses. The government charged that these express claims made Fairfax Cigarettes a "drug" under the Act, and thus that the product required FDA approval. The district court agreed and ordered the seized goods relabeled or destroyed. The manufacturer, of course, abandoned the challenged claims, effectively depriving FDA of jurisdiction. A similar result followed FDA's seizure of another brand of cigarettes making weight-loss claims. See *United States v. 354 Bulk Cartons Trim Reducing-Aid Cigarettes*, 178 F. Supp. 847 (D.N.J. 1959).

FDA thereafter appears to have lost interest in contesting the health claims made for different brands of cigarettes. Within a decade, however, Congress began to explore measures to combat the health effects of tobacco. In 1964 the Surgeon General released a ground-breaking report which documented the heavy price smokers paid for the pleasure of smoking. See *SMOKING AND HEALTH: REPORT OF THE ADVISORY COMMITTEE OF THE SURGEON GENERAL OF THE PUBLIC HEALTH SERVICE* (1964). The report inspired several proposals to regulate the manufacture, labeling, and sale of cigarettes and, later, of smokeless tobacco. During congressional hearings on these bills, FDA officials were asked what, if any, role their agency could play. Their uniform response was that FDA had no authority over cigarettes unless they bore claims that they could prevent or relieve disease.

Ultimately, suggestions that FDA be given authority to regulate cigarettes were rejected in favor of statutes passed in 1965 and 1969 curbing the labeling and, later, the advertising for cigarettes and requiring their labels to bear mild warnings about their health effects. The 1960s came to an end with no material change in the marketing of cigarettes despite mounting evidence of their adverse effects.

Advocates of tobacco control, however, never lost hope that FDA might be persuaded to acknowledge, and then exercise, jurisdiction over tobacco. In 1977, Action on Smoking and Health (ASH), a citizen action group, filed a petition urging the agency to assert jurisdiction over cigarettes under the FD&C Act and impose restrictions on their advertising and distribution. The petition cited evidence that smokers smoked to gain the physiological

effects of nicotine, and it contended that these effects were thus "intended." Once again, FDA declined to exercise jurisdiction:

The petitioners have presented no evidence that manufacturers or vendors of cigarettes represent that the cigarettes are "intended to affect the structure or any function of the body of man . . ." 21 U.S.C. § 321(g)(1)(C). Statements by the petitioners and citations in the petition that cigarettes are used by smokers to affect the structure or any functions of their bodies are not evidence of such intent by the manufacturers or vendors of cigarettes, as required under the provisions of 21 U.S.C. § 321(g)(1)(C) . . .

Letter memorandum from Donald Kennedy, Commissioner, FDA, to ASH (Dec. 5, 1977), *quoted in Action on Smoking and Health v. Harris*, 655 F.2d 236, 239 (D.C. Cir. 1980).

The D.C. Circuit upheld FDA's refusal to regulate cigarettes in the following words:

. . . [B]y failing to introduce any evidence of vendors' intent—whether based upon subjective vendor claims or objective evidence such as labeling, promotional material, and advertising—ASH placed itself in the position of having to meet the high standard established in cases where the statutory "intent" is derived from consumer use alone. Clearly, it is well established "that the 'intended use' of a product, within the meaning of the Act, is determined from its label, accompanying labeling, promotional claims, advertising, and any other relevant source." Whether evidence of consumer intent is a "relevant source" for these purposes depends upon whether such evidence is strong enough to justify an inference as to the vendors' intent. This requires a substantial showing . . .

In cases such as the one at hand, consumers must use the product predominantly—and in fact nearly exclusively—with the appropriate intent before the requisite statutory intent can be inferred . . . ASH did not establish, and arguably cannot establish, the near-exclusivity of consumer use of cigarettes with the intent "to affect the structure or any function of the body of man . . ."

Action on Smoking and Health v. Harris, 655 F.2d 236, 239–40 (D.C. Cir. 1980).

In separate petitions, ASH also requested FDA to assert jurisdiction over both attached and detached cigarette filters as medical devices, based on a recommendation by an FDA advisory committee that they be classified as class III under the Medical Device Amendments of 1976. Following a court order to rule on the petitions, *Action on Smoking and Health v. Food and Drug Administration*, FDLI 1978–1980 Jud. Rec. 862 (D.D.C. 1980), FDA denied both in a letter from Deputy Commissioner M. Novitch to J.F. Banzhaf, III, FDA Dkt Nos. 77P–0185 & 78P–0338/CP (Nov. 25, 1980).

Both FDA and the D.C. Circuit in *ASH* left open the possibility that the agency might be able to assert jurisdiction over cigarettes if there were evidence that the manufacturers themselves intended their products to "affect the structure or function of the body." Events soon reopened this

line of analysis. In the early 1990s, several states sued the major manufacturers of cigarettes to recover the costs of state-funded medical care provided to smokers suffering from tobacco-related illness. In the course of discovery in these cases, some of the defendants disgorged documents that strongly suggested, and in the view of many proved beyond question, that the companies knew their customers smoked to gain the effects of nicotine and designed their products to satisfy this desire. These disclosures provided FDA the opportunity to revisit the issue left open by the *ASH* case: Could sellers of tobacco products be said to intend the bodily effects of nicotine?

FDA faced this question shortly after the appointment of a new Commissioner, David Kessler. A series of petitions renewed demands that the agency assert jurisdiction over cigarettes as “drugs” or “devices” and take steps to curb or prohibit their sale. Kessler launched FDA’s own extensive investigation into the cigarette business—how they were made and marketed, and what the manufacturers knew or intended about their effects. At the same time, agency lawyers were directed to design a plan for regulating cigarettes that would substantially dampen their appeal to younger people, without threatening an outright ban that could cause Congress to intervene.

Shortly afterwards, FDA published a notice of proposed rulemaking in which it asserted jurisdiction over cigarettes as a “device” for delivering the “drug” nicotine. 60 Fed. Reg. 41314 (Aug. 11, 1995). The agency proposed measures to make cigarettes difficult for young people to obtain and less appealing to consumers generally, including mandatory carding of youthful customers, relocation of cigarette displays, and outright bans on the industry’s favorite promotions, including sponsorship of concerts, art exhibits, and sporting events. To support this proposal, FDA contended that the evidence from company files made clear that the cigarette manufacturers did “intend” their products to affect the bodily functions of their customers. In addition, the agency asserted that the FD&C Act allowed a range of remedial options short of an outright ban.

The cigarette manufacturers, along with representatives of advertising interests who saw FDA’s proposed curbs on promotion as an assault on the First Amendment, did not wait for the rulemaking to conclude; they brought suit immediately, contending that FDA’s lack of jurisdiction was so obvious that they need not exhaust the opportunity for comment that the agency had provided. The exhaustion question was never resolved, because the United States District Court for the Middle District of North Carolina, where the manufacturers had chosen to file their suit, did not take up the parties’ cross motions for summary judgment until after publication of FDA’s final rule in 61 Fed. Reg. 44396 (Aug. 28, 1996). In its preamble to the final rule, the agency made some adjustments to its defense of its jurisdiction and more significant revisions to its regulatory scheme, but its fundamental claims remained the same. The agency contended that the evidence now revealed that cigarettes were intended by their manufacturers to affect the body by delivering nicotine and that FDA could restrict their promotion and sale as “devices” without having to confront the Act’s categorical ban of any “drug” that cannot be shown to be safe.

The District Court scheduled a full day of argument on the cross motions for summary judgment. Within a few weeks of the argument, Judge Osteen rendered a decision that was widely interpreted as a victory for FDA. It focused on the central issue of the agency's jurisdiction to regulate.

The precise question presented to the court is whether Congress has evidenced its clear intent to withhold from FDA jurisdiction to regulate tobacco products as customarily marketed. The inquiry as to whether Congress has directly spoken to the issue should begin with an examination of the text of the FDCA. A product is subject to the FDCA if it meets the statute's definition of a "food," "drug," "device," or "cosmetic." Rather than itemize each product subject to regulation under the FDCA, Congress defined these categories broadly so that each encompasses a wide range of products.

... [T]he court finds that tobacco products fit within the FDCA's definitions of "drug" and "device." Therefore, Plaintiffs must prove to the court that Congress has expressed its clear intent to withhold from FDA jurisdiction to regulate tobacco products in some place other than the text of the FDCA....

... This court is convinced that neither the text nor the legislative history of the FDCA evidences clear congressional intent to withhold from FDA authority to regulate tobacco products....

FDA offers that tobacco products fall within the FDCA's definitions of "drugs" and "devices" because they are "intended to affect the structure or any function of the body." FDA explains that the nicotine in tobacco products affects the structure or function of the body by causing and sustaining addiction and by acting as a stimulant, sedative, and weight regulator. FDA further argues that manufacturers intend nicotine to produce such effects....

Plaintiffs claim that a product's "intended use" can be established only by manufacturer representations about the product.³⁰ FDA counters that it appropriately relied on evidence of foreseeability, consumer use, and internal manufacturer memoranda to establish intended use. The text, legislative history, and past judicial and agency interpretation of the structure-or-function definitions of "drug" and "device" reveal that intended use may be established by evidence other than manufacturer representations.

... Although the regulations defining "intended use" [21 C.F.R. 201.128, 801.4] clearly anticipate the establishment of intended use through evidence of promotional claims, the plain language does not prohibit the establishment of intended use by

³⁰ FDA does not contend that tobacco manufacturers make any representations in connection with the sale of tobacco products. Therefore, if intended use can be established

only by manufacturer representations, tobacco products would not be subject to regulation pursuant to the FDCA.

other evidence. To illustrate, the regulations specifically provide that intent may be shown by circumstances surrounding the sale of the article and that one such circumstance could be the offering and use of a product for a purpose for which it is neither advertised nor labeled with the manufacturer's knowledge. The regulations defining "intended use" do not prohibit reliance on evidence other than manufacturer representations to establish intended use.

....

Plaintiffs infer that Congress intended for the structure-or-function definition of device to "apply only to products that are marketed to provide some medical or other health benefit to users." They support their argument in part by noting that Congress entitled its 1976 amendments to the FDCA's device provisions the "Medical Device Amendments" ("MDA"). The definition of device, however, expressly includes those products "intended to affect the structure or any function of the body of man or other animals" and gives no indication that it is to apply only to those devices with a medical purpose. 21 U.S.C. § 321(h)....

Coyne Beahm, Inc. v. U.S. Food and Drug Administration, 966 F. Supp. 1374 (M.D.N.C. 1997).

On one important issue, however, Judge Osteen's opinion disappointed FDA. He ruled that the FD&C Act did not authorize the agency—by invoking its power to "restrict" the "sale" of a device—to impose any limits on its advertising. This issue, discussed *infra* p. 1051, was briefed on appeal but was not reached by the Fourth Circuit, which, by a 2–1 vote, overturned Judge Osteen's ruling upholding FDA's assertion of jurisdiction. *Brown & Williamson Tobacco Corporation v. Food and Drug Administration*, 153 F.3d 155 (4th Cir. 1999). Predictably, the Supreme Court granted the government's Petition for Certiorari.

The opposing opinions of Justice O'Connor and Justice Breyer focused on several questions that together framed the issue of FDA's jurisdiction. Could an article's "intended" use be shown by evidence of the manufacturers' private plans? Did the evidence assembled by FDA establish that cigarettes are intended to produce drug-like effects? Did the Act's requirements permit the continued sale of a drug or device that the agency had said was unsafe? And, critically, had Congress left FDA free to invoke its authority under the FD&C Act?

Food and Drug Administration v. Brown & Williamson Tobacco Corp.

529 U.S. 120 (2000).

■ JUSTICE O'CONNOR delivered the opinion of the Court.

....

The FDA's assertion of jurisdiction to regulate tobacco products is founded on its conclusions that nicotine is a "drug" and that cigarettes and

smokeless tobacco are "drug delivery devices." Again, the FDA found that tobacco products are "intended" to deliver the pharmacological effects of satisfying addiction, stimulation and tranquilization, and weight control because those effects are foreseeable to any reasonable manufacturer, consumers use tobacco products to obtain those effects, and tobacco manufacturers have designed their products to produce those effects. As an initial matter, respondents take issue with the FDA's reading of "intended," arguing that it is a term of art that refers exclusively to claims made by the manufacturer or vendor about the product. That is, a product is not a drug or device under the FDCA unless the manufacturer or vendor makes some express claim concerning the product's therapeutic benefits. We need not resolve this question, however, because assuming, *arguendo*, that a product can be "intended to affect the structure or any function of the body" absent claims of therapeutic or medical benefit, the FDA's claim to jurisdiction contravenes the clear intent of Congress.

A threshold issue is the appropriate framework for analyzing the FDA's assertion of authority to regulate tobacco products. Because this case involves an administrative agency's construction of a statute that it administers, our analysis is governed by *Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984). Under *Chevron*, a reviewing court must first ask "whether Congress has directly spoken to the precise question at issue." *Id.*, at 842. If Congress has done so, the inquiry is at an end; the court "must give effect to the unambiguously expressed intent of Congress." *Id.*, at 843. But if Congress has not specifically addressed the question, a reviewing court must respect the agency's construction of the statute so long as it is permissible. . . .

In determining whether Congress has specifically addressed the question at issue, a reviewing court should not confine itself to examining a particular statutory provision in isolation. The meaning—or ambiguity—of certain words or phrases may only become evident when placed in context. A court must therefore interpret the statute "as a symmetrical and coherent regulatory scheme," *Gustafson v. Alloyd Co.*, 513 U.S. 561, 569 (1995), and "fit, if possible, all parts into an harmonious whole," *FTC v. Mandel Brothers, Inc.*, 359 U.S. 385, 389 (1959). Similarly, the meaning of one statute may be affected by other Acts, particularly where Congress has spoken subsequently and more specifically to the topic at hand. In addition, we must be guided to a degree by common sense as to the manner in which Congress is likely to delegate a policy decision of such economic and political magnitude to an administrative agency.

With these principles in mind, we find that Congress has directly spoken to the issue here and precluded the FDA's jurisdiction to regulate tobacco products.

Viewing the FDCA as a whole, it is evident that one of the Act's core objectives is to ensure that any product regulated by the FDA is "safe" and "effective" for its intended use. This essential purpose pervades the FDCA. . . . Thus, the Act generally requires the FDA to prevent the marketing of any drug or device where the "potential for inflicting death or physical injury is not offset by the possibility of therapeutic benefit." *United States v. Rutherford*, 442 U.S. 544, 556 (1979).

In its rulemaking proceeding, the FDA quite exhaustively documented that “tobacco products are unsafe,” “dangerous,” and “cause great pain and suffering from illness.” It found that the consumption of tobacco products presents “extraordinary health risks,” and that “tobacco use is the single leading cause of preventable death in the United States.” . . .

These findings logically imply that, if tobacco products were “devices” under the FDCA, the FDA would be required to remove them from the market. . . .

Second, the FDCA requires the FDA to place all devices that it regulates into one of three classifications. See § 360c(b)(1). . . . Given the FDA’s findings regarding the health consequences of tobacco use, the agency would have to place cigarettes and smokeless tobacco in Class III because, even after the application of the Act’s available controls, they would “present a potential unreasonable risk of illness or injury.” 21 U.S.C. § 360c(a)(1)(C). As Class III devices, tobacco products would be subject to the FDCA’s premarket approval process. See 21 U.S.C. § 360c(a)(1)(C); 21 U.S.C. § 360e. Under these provisions, the FDA would be prohibited from approving an application for premarket approval without “a showing of reasonable assurance that such device is safe under the conditions of use prescribed, recommended, or suggested on the labeling thereof.” 21 U.S.C. § 360e(d)(2)(A). In view of the FDA’s conclusions regarding the health effects of tobacco use, the agency would have no basis for finding any such reasonable assurance of safety. Thus, once the FDA fulfilled its statutory obligation to classify tobacco products, it could not allow them to be marketed.

In determining whether Congress has spoken directly to the FDA’s authority to regulate tobacco, we must also consider in greater detail the tobacco-specific legislation that Congress has enacted over the past 35 years. . . .

Congress has enacted six separate pieces of legislation since 1965 addressing the problem of tobacco use and human health. . . .

In adopting each statute, Congress has acted against the backdrop of the FDA’s consistent and repeated statements that it lacked authority under the FDCA to regulate tobacco absent claims of therapeutic benefit by the manufacturer. In fact, on several occasions over this period, and after the health consequences of tobacco use and nicotine’s pharmacological effects had become well known, Congress considered and rejected bills that would have granted the FDA such jurisdiction. Under these circumstances, it is evident that Congress’ tobacco-specific statutes have effectively ratified the FDA’s long-held position that it lacks jurisdiction under the FDCA to regulate tobacco products. Congress has created a distinct regulatory scheme to address the problem of tobacco and health, and that scheme, as presently constructed, precludes any role for the FDA. . . .

. . . Reading the FDCA as a whole, as well as in conjunction with Congress’ subsequent tobacco-specific legislation, it is plain that Congress has not given the FDA the authority that it seeks to exercise here. For these reasons, the judgment of the Court of Appeals for the Fourth Circuit is affirmed.

It is so ordered.

■ JUSTICE BREYER, with whom JUSTICE STEVENS, JUSTICE SOUTER, and JUSTICE GINSBURG join, dissenting.

....

The Food and Drug Administration (FDA) has the authority to regulate “articles (other than food) intended to affect the structure or any function of the body....” Unlike the majority, I believe that tobacco products fit within this statutory language.

In its own interpretation, the majority nowhere denies the following two salient points. First, tobacco products (including cigarettes) fall within the scope of this statutory definition, read literally. Cigarettes achieve their mood-stabilizing effects through the interaction of the chemical nicotine and the cells of the central nervous system. Both cigarette manufacturers and smokers alike know of, and desire, that chemically induced result. Hence, cigarettes are “intended to affect” the body’s “structure” and “function,” in the literal sense of these words.

Second, the statute’s basic purpose—the protection of public health—supports the inclusion of cigarettes within its scope. . . . Unregulated tobacco use causes “[m]ore than 400,000 people [to] die each year from tobacco-related illnesses, such as cancer, respiratory illnesses, and heart disease.” 61 Fed. Reg. 44398 (1996). Indeed, tobacco products kill more people in this country every year “than . . . AIDS . . . , car accidents, alcohol, homicides, illegal drugs, suicides, and fires, *combined*.” *Ibid.* (emphasis added). . . .

. . . Taken literally, [the structure/function] definition might include everything from room air conditioners to thermal pajamas. The companies argue that, to avoid such a result, the meaning of “drug” or “device” should be confined to *medical* or *therapeutic* products, narrowly defined.

The companies may well be right that the statute should not be read to cover room air conditioners and winter underwear. But I do not agree that we must accept their proposed limitation. For one thing, such a cramped reading contravenes the established purpose of the statutory language. For another, the companies’ restriction would render the other two “drug” definitions superfluous. *See* 21 U.S.C. §§ 321(g)(1)(A), (g)(1)(B) (covering articles in the leading pharmacology compendia and those “intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease”).

Most importantly, the statute’s language itself supplies a different, more suitable, limitation: that a “drug” must be a *chemical* agent. The FDCA’s “device” definition states that an article which affects the structure or function of the body is a “device” only if it “does *not* achieve its primary intended purposes through chemical action within . . . the body,” and “is *not* dependent upon being metabolized for the achievement of its primary intended purposes.” § 321(h) (emphasis added). One can readily infer from this language that at least an article that *does* achieve its primary purpose through chemical action within the body and that *is* dependent upon being metabolized is a “drug,” provided that it otherwise falls within the scope of the “drug” definition. And one need not hypothesize about air conditioners or thermal pajamas to recognize that the chemical nicotine, an important tobacco ingredient, meets this test. . . .

The tobacco companies' principal definitional argument focuses upon the statutory word "intended." The companies say that "intended" in this context is a term of art. They assert that the statutory word "intended" means that the product's maker has made an *express claim* about the effect that its product will have on the body. Indeed, according to the companies, the FDA's inability to prove that cigarette manufacturers make such claims is precisely why that agency historically has said it lacked the statutory power to regulate tobacco.

The FDCA, however, does not use the word "claimed"; it uses the word "intended." And the FDA long ago issued regulations that say the relevant "intent" can be shown not only by a manufacturer's "expressions," *but also* "by the circumstances surrounding the distribution of the article." 21 CFR § 801.4. Thus, even in the absence of express claims, the FDA has regulated products that affect the body if the manufacturer wants, and knows, that consumers so use the product. . . .

Nor is the FDA's "objective intent" interpretation unreasonable. It falls well within the established scope of the ordinary meaning of the word "intended." And the companies acknowledge that the FDA can regulate a drug-like substance in the ordinary circumstance, *i.e.*, where the manufacturer makes an express claim, so it is not unreasonable to conclude that the agency retains such power where a product's effects on the body are so well known (say, like those of aspirin or calamine lotion), that there is no *need* for express representations because the product speaks for itself. . . .

The majority nonetheless reaches the "inescapable conclusion" that the language and structure of the FDCA as a whole "simply do not fit" the kind of public health problem that tobacco creates. That is because, in the majority's view, the FDCA requires the FDA to ban outright "dangerous" drugs or devices (such as cigarettes); yet, the FDA concedes that an immediate and total cigarette-sale ban is inappropriate. . . .

In my view, where linguistically permissible, we should interpret the FDCA in light of Congress' overall desire to protect health. That purpose requires a flexible interpretation that both permits the FDA to take into account the realities of human behavior and allows it, in appropriate cases, to choose from its arsenal of statutory remedies. . . .

NOTES

1. *Action in Congress.* In July 2004, the Senate passed legislation that would have given FDA specific statutory authority to regulate cigarettes and chewing tobacco. The legislation would not have put these products in the medical device category, but would have added a new chapter to the FD&C Act dedicated to these products. The legislation died in the House of Representatives. In March 2005, the bill was reintroduced in the House (H.R. 1376) and the Senate (S. 666), but it was not been reported out of committee.

2. *FDA Approval of Smoking Cessation Products.* In 1984, FDA approved a new drug application (NDA) for Nicorette chewing gum, which was indicated "as a temporary aid to the cigarette smoker seeking to give up his or her smoking habit while participating in a behavior modification program under medical or dental supervision." Nicorette, originally approved as a prescription drug but now sold over-the-counter, contains either 2 mg or 4 mg nicotine in each piece of chewing gum. FDA considered, but ultimately rejected, establishing an over-the-counter

monograph for smoking deterrent drug products. 58 Fed. Reg. 31236 (June 1, 1993). Consequently, any drug product that is labeled, represented, or promoted as a smoking deterrent is a new drug subject to the NDA process. 21 C.F.R. 310.544.

FDA has since approved NDAs for nicotine transdermal patches and nicotine inhalers to aid in smoking cessation. The former are now available over-the-counter, whereas the latter remain available only by prescription. In 2002, FDA found that “nicotine lollipops” and “lip balm,” promoted to assist smoking cessation were intended for use as drugs. The FDA based its decision on the manufacturers’ claims that these products are a “convenient, tasty way” to replace cigarettes and helped to decrease the “hand to mouth” fixation associated with smoking. FDA Talk Paper No. T02-17, *FDA Warns Sellers of Nicotine Lollipops & Lip Balm that their Products are Illegal* (Apr. 10, 2002).

3. *FDA’s Regulation of Other Tobacco and Nicotine Products.* In December 2001, after the Supreme Court decided *Brown & Williamson*, a consortium of major public health organizations submitted four citizen petitions requesting that the agency regulate various tobacco and nicotine products marketed as safer than traditional cigarettes or smokeless tobacco.

Reduced-Risk Cigarettes. One type of product addressed by the petitions was reduced-risk cigarettes. Eclipse is a cigarette that primarily heats, rather than burns, the tobacco. It claims a reduced risk of cancer, respiratory inflammation, bronchitis, and emphysema as compared with other cigarettes. OMNI and Advance, which use other technologies, claim reduced carcinogenicity. (OMNI cigarettes are no longer commercially available.) The health organizations’ petition urged FDA to regulate these cigarettes as drugs or medical devices, asserting that the explicit claims of risk reduction distinguished these products from the conventional cigarettes addressed in *Brown & Williamson*. FDA has not yet ruled on these petitions. FDA Docket No. 01P-0570 (Eclipse); Docket No. 01P-0571 (OMNI and Advance). Some of the comments filed by industry opposing the petitions acknowledged that a cigarette making affirmative therapeutic claims, as opposed to risk-reduction claims, would fall under FDA’s jurisdiction. In other words, they acknowledged the continuing validity of the *Fairfax Cigarettes* decision, *supra* p. 78.

Nicotine Water. The manufacturer of this product attempted to market it as a dietary supplement exempt from the FD&C Act’s requirements for drugs. FDA granted the health organizations’ petition requesting that it regulate Nicotine Water as a drug. FDA Docket No. 01P-0573. The agency concluded that the manufacturer promoted Nicotine Water to treat or mitigate nicotine addiction. It based this conclusion on statements on the manufacturer’s website describing Nicotine Water as a smoking cessation product that “contains the nicotine equivalent of 2 cigarettes” in one bottle of water and is “more effective than the Patch or Gum using Less Nicotine.” Upon FDA’s conclusion, the manufacturer of Nicotine Water then labeled its product a “homeopathic nicotinum formula.”

Tobacco Lozenges. Ariva, a mint-flavored lozenge, contains tobacco powder compressed into tablet form. The organizations petitioned FDA to classify tobacco lozenges like Ariva as “drugs” or, alternatively, as “foods” containing a food additive. FDA disagreed, concluding in part that Ariva was a “customarily marketed” tobacco product as defined by *FDA v. Brown & Williamson Tobacco Corp.* See Docket Nos. 01P-0572 and 02P-0075.

F. HUMAN BIOLOGICAL PRODUCTS

The Public Health Service Act gives FDA jurisdiction to regulate “biological products.” Under the PHS Act, most biological products are

subject to a regulatory regime similarly rigorous to that for drugs, including premarket review by FDA for safety and effectiveness. Section 262(i) of the PHS Act defines “biological product” as follows:

In this section, the term “biological product” means a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition of human beings.

This definition, with its list of examples and reference to “analogous” products, is of a different character from the FD&C Act’s product definitions. It presents its own interpretive problems.

David M. Dudzinski, *Reflections on Historical, Scientific, and Legal Issues Relevant to Designing Approval Pathways for Generic Versions of Recombinant Protein-Based Therapeutics and Monoclonal Antibodies*

60 FOOD & DRUG LAW JOURNAL 143 (2005).

... Concurrent with rising demand for treatments for the major nineteenth century diseases, private entities began to manufacture vaccine and antitoxin. Especially after the introduction of diphtheria antitoxin in 1894 from Germany, many small outfits run by pharmacies and physicians, as well as two large pharmaceutical ventures, H.K. Mulford Co. and Parke Davis, moved to produce antitoxins and supplant the government suppliers. While Mulford and Parke Davis had devoted significant resources to quality control and standardization of their antitoxin products, other smaller concerns manufacturing antitoxins did not. Instances of unscrupulous behavior by some smaller firms had previously resulted in a fake smallpox vaccine being sold in the early 1800s. Instances of contamination of commercial products also became a frequently recognized problem: large outbreaks of tetanus allegedly occurred via contamination of diphtheria antitoxin in the late 1890s and contamination of smallpox vaccine in 1901.

Though numerous investigations revealed that the tetanus outbreak in 1901 was most likely not associated with the smallpox vaccine, the “report[s] did not silence public outcry.” The major manufacturers of biologics, pitted against each other by the assignment of blame for the tetanus outbreaks, found themselves under increasing scrutiny of the state governments and public. In response, the majors buried their disputes and redoubled their efforts to attack the smaller biologics manufacturers who were more likely to have “unsanitary and outmoded” facilities. Ultimately, it was deaths of thirteen children from tetanus-contaminated vaccine that “convinced Congress and the public that producing antitoxin or vaccine was not a simple matter like weighing out a dose of a drug on a scale” and provided an impetus for legislation.

Congress responded to the recent outbreaks as well as to the companies’ lobbying by enacting the Biologics Act of 1902, the first enduring

scheme of national regulation for any pharmaceutical product. The Biologics Act was groundbreaking in part because it set new precedents both in terms of shifting from retrospective post-market to prospective pre-market government review, and modifying the common law notion of punishing conduct only of intentional or reckless actors, in favor of moving toward pro-active safety measures for all entities.

The Biologics Act exerted jurisdiction over “viruses, therapeutic serums, toxins, antitoxins, or analogous products” as “biologics” that were intended for the “prevention, and cure of diseases of man.” Each of the categories of regulated biologics represent immunologic agents, and Congress seemed to select these particular substances out of particular concern for immunologic, allergenic, and (at least what was then perceived to be) possibly contagious side effects. Viruses and toxins function to stimulate development of active immunity and antibody production when introduced into humans. Vaccines had been made for decades by exposing patients to a relatively non-pathogenic strain of bacteria or killed or inactivated pathogens. Antitoxins and therapeutic serums confer passive immunity simply by providing preformed antibodies, often developed by another animal like horse or goat in response to the toxin. All of these products—even in their final form after “manufacturing”—remained relatively crude mixtures; in fact, most of the products regulated in 1902 had a purity less than 1%. The Congressional concern for immunologic side effects was heightened especially in light of the biologics’ animal origin and their parenteral, or injectable route of administration; compared to oral administration, where the digestive system provided some barriers protecting the body, injection gave the biologics direct access to the inner body....

... In 1963 *United States v. Steinschreiber* held blood plasma and other components derived from processing of blood were subject to biologics regulations as analogues to serum. 219 F. Supp. 373, 382–83 (S.D.N.Y. 1963), *aff’d*, 326 F.2d 759 (2d Cir. 1964) (*per curiam*). In contrast, in 1968 *Blank v. United States* held blood and red blood cells were drugs but exempt from biologics regulation. 400 F.2d at 305 (5th Cir. 1968). Individual adjudications are a poor means to develop any comprehensive regulatory scheme because of the lack of a guiding principle and the resultant fragmented, confusing system. Recognizing that every “[f]ederal court ... has held that blood is a drug” but diverged on the issue of blood as a biologic, Congress unified the law by amending the PHSA § 351 to include the classes of “blood, blood components or derivatives”. Heart Disease, Cancer, Stroke, and Kidney Disease Amendments [to the Public Health Service Act] of 1970, 84 Stat. 1297, 1308 (Oct. 30, 1970)....

The very notion of a biologic has changed many times over the last century, and has deviated far from the root concern of grouping and regulating non-human organism (virus, bacteria, or large animal) immunogenic molecules. By statute, biological products are now “defined” as including viruses, therapeutic sera, toxins and antitoxins, vaccines, blood, blood components or derivatives, allergenic products, any analogous products, and arsphenamines used treating disease. Though several of these terms (*e.g.* therapeutic sera, antitoxin) lack crisp scientific meaning, no actual definition of “biologic” is offered in the statute or its regulations.

However, no definition is probably preferable to the alternative of scientifically invalid definition, such as for virus, which is "interpreted to be a product containing the minute living cause of an infectious disease and includes but is not limited to filterable viruses, bacteria, rickettsia, fungi, and protozoa." 21 C.F.R. § 600.3(h)(1). It is also far from clear that the earliest premise of biologics regulation was even internally consistent, as many of the first substances considered to be biologics were not really immunogenic per se, but designed to confer passive immunity. The more modern additions to the family of designated biologics are also questionable. Arsphenamines, while toxic, do no more to affect the immune process or cause immunogenic toxicities than do other well-known antibiotics and anti-microbials. Moreover the "analogous" language greatly amplifies the specter of biologics: for example, a product is analogous to 1) a virus if it is merely prepared from any "potentially infectious agent", 2) a therapeutic serum if it contains "some organic constituent" from blood (amino acids and hormones, like insulin and human growth hormone, excepted), or 3) a toxin or antitoxin if it addresses human disease "through a specific immune process." 21 C.F.R. § 600.3(h)(5)(i)-(iii). When one considers that virtually every chemical, including small molecules, can be an allergen to a certain fraction of the population, and that "products analogous to blood" has been theorized to encompass everything from the most well-characterized and well-purified serum protein all the way to whole organs, bewilderment about the definition of a biologic is understandable.

....

NOTES

1. *Dual Classification.* Because the definition of "biological products" refers exclusively to articles "applicable to the prevention, treatment, or cure of a disease or condition of human beings," all biologics are simultaneously also drugs or devices. This dual classification raises many issues regarding the appropriate application of the requirements of PHS Act and the FD&C Act to biologics, as well as the division of responsibility over these products among FDA's biologics, drug, and device centers. These issues are addressed in Chapter VI.

2. *Human Cellular and Tissue-Based Products.* Human tissue products have been used by doctors for decades. Skin, tendons, bones, heart valves, and corneas that are damaged or diseased are replaced by tissues removed the body of a donor. Semen, ova, and embryos are transferred to aid reproduction. Recent years have seen an explosion of research into human cellular products for therapeutic purposes, including somatic cell therapy products and gene therapy products. FDA deems some human cellular and tissue-based products to be biologics, as well as medical devices or drugs. The agency's regulation of these products is discussed in Chapter VI, *infra*.