NUTRITIONAL HEALTH ALLIANCE, Plaintiff–Appellant,

v.

FOOD AND DRUG ADMINISTRATION and Donna Shalala, in her official capacity as Secretary, U.S. Department of Health and Human Services, Defendants–Appellees.

Docket No. 01–6011.

United States Court of Appeals, Second Circuit.

Argued: Nov. 6, 2001.

Decided: Jan. 21, 2003.

Association of dietary supplement manufacturers brought suit for declaratory and injunctive relief regarding enforcement of dosage-unit packaging rule promulgated by the Food and Drug Administration (FDA). The United States District Court for the Eastern District of New York, Sterling Johnson, Jr., J., denied plaintiff's motion for summary judgment and granted summary judgment to defendants, and appeal was taken. The Court of Appeals, F.I. Parker, Circuit Judge, held that regulation promulgated by the FDA, which required that solid dose dietary supplements and drugs containing thirty milligrams or more of iron per dosage unit had to be packaged in nonreusable containers designed to hold only one dosage unit, was unrelated to any risk of adulteration, so as to be in excess of authority granted to the FDA under the Food, Drug and Cosmetic Act (FDC Act).

Reversed and remanded.

1. Federal Courts ⚿776

District court's conclusion as to whether Food and Drug Administration (FDA) had acted pursuant to Congressionally delegated authority in promulgating rule would be reviewed de novo.

2. Statutes ⚿219(2, 4)

When administrative agency asserts jurisdiction to regulate a particular subject matter of public concern based upon its construction of statute that it administers, reviewing court must conduct *Chevron* analysis to determine: (1) whether Congress has directly spoken to precise question at issue; and if not, then (2) whether agency's construction of statute is permissible one.

3. Food ⚿5

Health ⚿306

Food, Drug and Cosmetic Act (FDC Act) provides Food and Drug Administration (FDA) with broad authority to regulate food, drug and dietary supplement products in order to ensure public health and safety. Federal Food, Drug, and Cosmetic Act, § 1 et seq., 21 U.S.C.A. § 301 et seq.

4. Food ⚿5

Health ⚿302

Food, Drug and Cosmetic Act (FDC Act) should receive a liberal construction where Food and Drug Administration (FDA) has taken remedial steps in response to perceived public health problem. Federal Food, Drug, and Cosmetic Act, § 1 et seq., 21 U.S.C.A. § 301 et seq.

5. Food ⚿5

Health ⚿302

Food, Drug and Cosmetic Act (FDC Act) should not be read too restrictively but in manner consistent with FDC Act's overriding purpose to protect public health. Federal Food, Drug, and Cosmetic Act, § 1 et seq., 21 U.S.C.A. § 301 et seq.

6. Administrative Law and Procedure ⚿386

When agency rulemaking serves purposes of statute, courts should refuse to adopt a narrow construction of enabling legislation, where this would undercut agency's authority to promulgate such rules; rather, court's role should be one of constructive cooperation with agency in furtherance of the public interest.

7. Food ⚿5

Health ⚿302

Court's obligation to read the Food, Drug and Cosmetic Act (FDC Act) in liberal manner and work in constructive cooperation with Food and Drug Administration (FDA) did not obviate its responsibility to ensure that regulatory authority exercised by the FDA was actually rooted in statute. Federal Food, Drug, and Cosmetic Act, § 1 et seq., 21 U.S.C.A. § 301 et seq.

8. Food ⚿5

Health ⚿307

Food, Drug and Cosmetic Act (FDC Act) did not delegate to Food and Drug Administration (FDA) authority to address packaging of food, drug and dietary supplement products except to extent necessary to address risks of adulteration. Federal Food, Drug, and Cosmetic Act, § 1 et seq., 21 U.S.C.A. § 301 et seq.

9. Health ⚿307

Regulation promulgated by Food and Drug Administration (FDA), which required that solid dose dietary supplements and drugs containing thirty milligrams or more of iron per dosage unit had to be packaged in nonreusable containers designed to hold only one dosage unit, was plainly promulgated in response to series of child deaths from iron overdoses, to address risk that these products would be used/misused by unintended recipients, and was unrelated to any risk of adulteration, so as to be in excess of authority granted to Food and Drug Administration (FDA) under the Food, Drug and Cosmetic Act (FDC Act). Federal Food, Drug, and Cosmetic Act, § 1 et seq., 21 U.S.C.A. § 301 et seq.

10. Health ⚿306

Even assuming that there was any ambiguity in provisions of the Food, Drug and Cosmetic Act (FDC Act) pursuant to which the Food and Drug Administration (FDA) purported to act in enacting packaging rule applicable to solid dose dietary supplements and drugs containing thirty milligrams or more of iron per dosage unit, court could not defer to FDA's interpretation of such allegedly ambiguous language, where doing so would allow the FDA to circumvent detailed regulatory scheme, including express constraints set forth by Congress in the Poison Prevention Packaging (PPP) Act. Poison Prevention Packaging Act of 1970, § 2 et seq., 15 U.S.C.A. § 1471 et seq.; Federal Food, Drug, and Cosmetic Act, § 1 et seq., 21 U.S.C.A. § 301 et seq.

11. Statutes ⚿223.4

Later-enacted, more specific, comprehensive statute that targets specific subject matter at issue in case controls the construction of more general statute when there is potential conflict or discrepancy between burdens imposed upon affected entities.

West Codenotes

Held Invalid

21 C.F.R. § 111.50.

21 C.F.R. § 310.518.

John M. Desiderio, Desiderio, PC & Associates, New York, NY, (Robert Ullman and H. Elliot Wales on the brief) for Appellant.

Charles S. Kleinberg, Assistant U.S. Attorney, U.S. Attorney's Office, Brooklyn, NY, (Alan Vinegrad, U.S. Attorney and Deborah B. Zwany, Assistant U.S. Attorney on the brief) for Appellees.

Before: KEARSE, MINER, F.I. PARKER Circuit Judges.

F.I. PARKER, Circuit Judge.

Plaintiff-appellant, Nutritional Health Alliance ("NHA"), appeals from a judgment entered on November 15, 2000 by the United States District Court for the Eastern District of New York (Sterling Johnson, Jr., *Judge*) denying NHA's motion for summary judgment and granting the cross-motion of defendants-appellees, the Food and Drug Administration ("FDA") and Secretary of Health and Human Services ("Secretary"), for summary judgment dismissing NHA's complaint.

The issue raised by this appeal is whether the FDA has been delegated authority by Congress to regulate the packaging of solid dosage dietary supplements and drugs for the purpose of poison prevention. In an attempt to protect children from accidental iron poisoning, the FDA promulgated regulations requiring drug and dietary supplement manufacturers to distribute their products containing thirty milligrams or more of iron per dosage unit in unit-dose packages [hereinafter "unit-dose packaging rule"]. In response, NHA, an association including manufacturers and distributors of iron-containing dietary supplements, filed a complaint seeking both a declaration that the regulations were "invalid and without legal force and effect" and a permanent injunction barring the defendants from enforcing the regulations. The basis for NHA's claims is that the FDA lacked statutory authority to promulgate and enforce poison prevention packaging regulations.

The FDA argues that it acted pursuant to the broad authority delegated to it by the Food, Drug and Cosmetic Act ("FDC Act"), 21 U.S.C. §§ 301, et seq., to regulate dietary supplements and drugs for safety. Specifically, the FDA points to the "injurious to health" provisions of the FDC Act as the primary source of statutory authority for its unit-dose packaging rule,[1] and to the "current good manufacturing practices" provisions of the FDC Act as an alternative basis for the rule.[2]

NHA argues principally that in 1972, Congress transferred jurisdiction over the Poison Prevention Packaging Act ("PPP Act") and subject matter within the scope of the PPP Act from the FDA to the Consumer Product Safety Commission ("CPSC") by enacting the Consumer Product Safety Act ("CPS Act"). *See* 15 U.S.C. §§ 1471 et seq. (PPP Act); 15 U.S.C. §§ 2051 et seq. (CPS Act). According to NHA, authority to regulate "poison prevention packaging," was *exclusively* vested in the CPSC and, therefore, the FDA overstepped its statutory authority by issuing the unit-dose packaging rule. On appeal, the FDA does not dispute that its rule is a poison prevention packaging rule, but rather contends that the CPSC and the FDA share concurrent, overlapping authority to promulgate and enforce poison prevention packaging regulations. NHA responds that even if we decide that the CPS Act left open the possibility that

1. *See* 21 U.S.C. §§ 342(a)(4) (food/dietary supplements), 351(a)(2)(A) (drugs).

2. *See* 21 U.S.C. §§ 342(g) (dietary supplements), 351(a)(2)(B) (drugs).

the CPSC and the FDA have concurrent jurisdiction over poison prevention packaging, the FDA's proffered construction of the FDC Act is impermissible.

The District Court agreed with the FDA's position and held that the defendants prevail under either prong of a *Chevron* analysis. *See Chevron U.S.A., Inc. v. Natural Resources Def. Council, Inc.,* 467 U.S. 837, 842–43, 104 S.Ct. 2778, 81 L.Ed.2d 694 (1984). The District Court dismissed NHA's argument regarding the CPS Act's transfer of regulatory authority from the FDA to the CPSC by concluding that NHA "has not provided sufficient evidence for the Court to conclude that in passing the [PPP Act] or transferring its administration to the CPSC[,] Congress intended to eliminate entirely the authority of the FDA to regulate the packaging of drugs and dietary supplements when it finds it to be injurious to the health of consumers." Memorandum and Order, 97 CV 5042(SJ) at 6 (E.D.N.Y. Nov. 1, 2000). The District Court also reasoned that NHA failed to "successfully show[ ] that the [PPP Act] and the FDC Act are irreconcilable such that an inquiry into whether there was an implied repeal would be justified at this time." *Id.*

We conclude that the provisions of the FDC Act relied upon by the FDA unambiguously fail to provide the FDA with authority to regulate packaging for poison prevention purposes. The provisions that the FDA relies upon are plainly limited to delegation of authority to the FDA to regulate conditions under which a drug or dietary supplement product may be *adulterated* precisely to prevent the manufacture and distribution of adulterated products. The risk of accidental poisoning that the FDA sought to address through its unit-dose packaging regulation is unrelated to adulteration under any reasonable interpretation of that term. Accordingly, we reverse and remand.

I. BACKGROUND

The facts in this case are undisputed. We briefly summarize the relevant facts and note that an extensive administrative record has been developed by the FDA. *See, e.g.,* Final Rule, *Iron–Containing Supplements and Drugs: Label Warning Statements and Unit–Dose Packaging Requirements,* 62 Fed.Reg. 2218 (Jan. 15, 1997); Proposed Rule, 59 Fed.Reg. 51,030 (Oct. 6, 1994).

This case involves a challenge to an FDA rule requiring that solid dose dietary supplements and drugs containing thirty milligrams or more of iron per dosage unit be packaged in "unit-dose packaging." 62 Fed.Reg. 2218. "Unit-dose packaging" means "a method of packaging a product into a nonreusable container designed to hold a single dosage unit intended for administration directly from that container, irrespective of whether the recommended dose is one or more than one of these units." 21 C.F.R. §§ 111.50 (dietary supplements), 310.518(a) (drugs).

The challenged regulation was issued in response to a widespread problem of "acute iron poisonings, including deaths, in children less than 6 years of age attributable to accidental overdoses of iron-containing products." 62 Fed.Reg. at 2218; *see also* 59 Fed.Reg. at 51,032–36. Data obtained by the FDA showed that from 1986 through 1992, there were nearly 63,000 reports to poison control centers of iron overdoses involving adult products, with over 47,000 of these reports involving children under six years of age. *Id.* at 51,032. For pediatric iron-containing products, there were over 76,000 reports during the same time period, including over 69,000 reports involving children under six years of age. *Id.*

According to evidence presented by the American Association of Poison Control Centers ("AAPCC"), iron products are a leading cause of poisoning deaths in children under six years of age. *See id.* Iron poisoning is a particular threat to young children because of their lower body weight, which raises the likelihood of serious injury or death in some cases. *Id.* at 51,031. In addition, many iron-containing tablets resemble candy and are therefore particularly appealing to young children. *See* 62 Fed.Reg. at 2231.

In October 1994, following several citizen petitions requesting that the FDA address the iron poisoning problem, the FDA issued a proposed rule requiring a new warning label and unit-dose packaging for products containing thirty milligrams or more of iron per dosage unit. 59 Fed.Reg. at 51,057–58. The proposed rule was revised on February 16, 1995, and the comment period reopened after the passage of the Dietary Supplement Health and Education Act ("DSHEA") of 1994, Pub.L. No. 103–417, 108 Stat. 4325. *See* 60 Fed.Reg. 8989 (1995).

On January 15, 1997, the FDA issued its final rule. 62 Fed.Reg. 2218. The rule requires unit-dose packaging for drug products and dietary supplements offered in solid oral dose form that use iron and iron salts as iron sources and contain thirty milligrams or more of iron per dosage unit. 21 C.F.R. §§ 111.50 (dietary supplements), 310.518 (drugs). The scientific analysis and public health considerations underlying the rule are set forth in the *Federal Register* publications and show that the action was taken in response to the large number of acute iron poisonings in children under the age of six. 62 Fed. Reg. 2218, 2229. The FDA determined that requiring individually-dosed packaging would limit the number of capsules or tablets a child could consume if the child accidentally gained access to the product.

Notably, in its Proposed Rule, the FDA expressly acknowledged the statutory authority of the CPSC under the CPS Act and the PPP Act as well as the existence of the CPSC's special packaging regulations pertaining to products containing iron. 59 Fed.Reg. at 51,047, 51,049. In its Final Rule, the FDA explained that it intended "to reduce the risk of accidental iron poisonings of young children" by supplementing and strengthening "the existing requirements of the [CPSC] for child-resistant packaging for household substances." 62 Fed.Reg. at 2218; *see also* 59 Fed.Reg. at 51,038. The FDA amended the wording of its proposed regulations before issuing them in final form to conform to the CPSC's request [3] that the FDA clarify that manufacturers of iron-containing products must comply with both the CPSC child-resistant packaging regulations and the FDA unit-dose packaging regulations. *See* 62 Fed.Reg. at 2228; 21 C.F.R. §§ 111.50, 310.518 (stating that iron-containing products subject to the unit-dose packaging regulations are also subject to the child-resistant special packaging regulations).

The Final Rule became effective on July 15, 1997, and NHA filed its complaint seeking declaratory and injunctive relief on August 29, 1997. After a hearing at which both parties agreed that no material factual issues were in dispute, the parties filed motions for summary judgment in

3. The FDA argues that by submitting comments on the FDA's proposed rule, the CPSC endorsed the FDA's exercise of jurisdiction and implicitly interpreted the CPS Act, and further that such an interpretation is entitled to deference. We disagree. The comments were submitted by CPSC staff, who expressly noted that the comments had not been reviewed or approved by the CPSC Commissioners.

April 1998. In an order entered November 6, 2000, the district court granted summary judgment to the FDA. NHA filed a timely notice of appeal.

II. DISCUSSION

A. *Analytical Framework*

[1, 2] The issue presented by this appeal is whether the FDA acted pursuant to congressionally delegated authority in promulgating its unit-dose packaging rule. We review the district court's analysis of this issue de novo. When an administrative agency asserts jurisdiction to regulate a particular subject matter of public concern based on its construction of a statute that it administers,[4] our analysis is governed by *Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 104 S.Ct. 2778, 81 L.Ed.2d 694 (1984); *see, e.g., Food and Drug Administration v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 132, 120 S.Ct. 1291, 146 L.Ed.2d 121 (2000). As the Supreme Court reiterated in *Brown & Williamson:*

> Under *Chevron*, a reviewing court must first ask whether Congress has directly spoken to the precise question at issue. If Congress has done so, the inquiry is at an end; the court must give effect to the unambiguously expressed intent of Congress. 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. Such deference is justified because the responsibilities for assessing the wisdom of such policy choices and resolving the struggle between competing views of the public interest are not judicial ones, and because of the agency's greater familiarity with the ever-changing facts and circumstances surrounding the subjects regulated.

Id. (internal quotation marks and citations omitted).

The District Court applied *Chevron* and held that the defendants prevail under either prong because (1) the plain meaning of the relevant provisions of the FDC Act support the FDA's authority to issue its unit-dose packaging rule and Congressional intent to delegate such authority is clear; and (2) even assuming *arguendo* "that there was ambiguity in the meaning of the FDC Act," "the FDA has acted based on a reasonable and permissible construction of th[at] statute." *See Chevron*, 467 U.S. at 842–43, 104 S.Ct. 2778. For the reasons discussed below, we disagree and hold that the FDC Act provisions relied upon by the FDA unambiguously fail to provide it with authority to prescribe its unit-dose packaging rule.

B. *The FDC Act*

a. *General construction*

[3–6] The FDC Act provides the FDA with broad authority to regulate food, drug and dietary supplement[5] products to en-

4. As noted above, the FDA maintains that it promulgated its unit-dose packaging rule pursuant to the "injurious to health" and/or "current good manufacturing practices" provisions of the FDC Act, a statute that the FDA administers.

5. Dietary supplements are considered "foods" for the purposes of the adulterated food provisions of the FDC Act. *See* 21 U.S.C. § 321(ff)(final paragraph). The original FDC act of 1934 did not include dietary supplements, but various subsequent amendments added explicit FDA jurisdiction over dietary supplements, which was similar, but not identical, to its jurisdiction over foods. *See, e.g.*, Dietary Supplement Health and Education Act of 1994, Pub.L. No. 103–417, 108 Stat. 4325. Ultimately, a 2000 amendment added to the chapter's definitions section: "a dietary supplement shall be deemed to be a food within the meaning of this chapter." 21 U.S.C. § 321(ff). For the purposes of this

sure public health and safety. Act of June 25, 1938, 52 Stat. 1040. It is well-settled that the FDC Act should receive a liberal construction when, as here, the FDA has taken remedial action in response to a perceived public health problem. *See, e.g., United States v. Dotterweich*, 320 U.S. 277, 280, 64 S.Ct. 134, 88 L.Ed. 48 (1943) ("The purposes of this legislation thus touch phases of the lives and health of people which, in the circumstances of modern industrialism, are largely beyond self-protection. Regard for these purposes should infuse construction of the legislation if it is to be treated as a working instrument of government and not merely as a collection of English words."). "[W]hen we are dealing with the public health, the language of the Food, Drug and Cosmetic Act should not be read too restrictively, but rather as 'consistent with the Act's overriding purpose to protect the public health.'" *United States v. Nova Scotia Food Prods. Corp.*, 568 F.2d 240, 246 (2d Cir.1977) (quoting *United States v. Bacto–Unidisk*, 394 U.S. 784, 798, 89 S.Ct. 1410, 22 L.Ed.2d 726 (1969)). As we further stated in *Nova Scotia*, "[w]hen agency rulemaking serves the purposes of the statute, courts should refuse to adopt a narrow construction of the enabling legislation which would undercut the agency's authority to promulgate such rules.... [Rather,] [t]he court's role should be one of constructive cooperation with the agency in furtherance of the public interest." 568 F.2d at 246.

[7] Of course, reading the FDC Act in a liberal manner and working in "constructive cooperation" with the FDA does not obviate our responsibility to ensure that the regulatory authority exercised by the FDA is actually rooted in the statute. It is the statutory text that delegates power to an administrative agency. *See Brown & Williamson*, 529 U.S. at 132–33, 120 S.Ct. 1291; *Oncale v. Sundowner Offshore Servs., Inc.*, 523 U.S. 75, 79, 118 S.Ct. 998, 140 L.Ed.2d 201 (1998) ("[I]t is ultimately the provisions of our laws rather than the principal concerns of our legislators by which we are governed."). When we interpret a statute and attempt to divine the intended scope of a delegation, statutory purpose, to the extent that such purpose is evident, sets boundaries and requires consistency between purpose and textual interpretation. Statutory purpose, however, is not in itself a source of delegated power. Thus, we cannot simply conclude that because the FDA is charged with regulation of food and drugs in order to protect public health, and its unit-dose packaging regulations were promulgated in response to a public health problem, therefore the FDA acted pursuant to delegated authority. Rather, we must look to the statutory text of the FDC Act.

b. Specific Construction

In promulgating its unit-dose packaging regulations, the FDA relied upon two sets of provisions in the FDC Act which define what qualifies as an "adulterated product."[6] First, the FDA relied upon provisions that deem a product adulterated if it "has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to

opinion we need not delve further, because at no point did the FDA receive a delegation of authority sufficient to impose a requirement of unit dose packaging for the dietary supplements in this case.

6. A significant portion of the FDC Act is concerned with definitions of different adulterated products, as well as mechanisms for removing them from the stream of commerce and punishments for their manufacturers. *See, e.g.,* 21 U.S.C. §§ 331, 332 and 333.

health." 21 U.S.C. § 351(a)(2)(A) (relating to drugs).[7] Second, the FDA relied upon those provisions that allow the FDA to deem a product adulterated if it has been "packed" under "conditions" that do not conform to "current good manufacturing practice[s]" ("CGMP provisions"), together with provisions allowing the FDA to prescribe permissible manufacturing practices. *See* 21 U.S.C. §§ 342(g) (dietary supplements), 351(a)(2)(B) (drugs).[8]

1. Chevron Step One

[8, 9] Under the first step of the *Chevron* analysis, we must determine whether Congress has spoken unambiguously on the scope of the FDA's delegated authority. *See Chevron*, 467 U.S. at 842–43, 104 S.Ct. 2778. Our analysis begins with the statutory text of the FDC Act. Each statutory provision relied upon by the FDA delegates authority to the FDA to regulate conditions under which a drug or dietary supplement product is deemed *adulterated*. *See* 21 U.S.C. §§ 342(a)(4), 351(a)(2)(A), 351(a)(2)(B), 342(g). The term adulterate means "to corrupt, debase, or make impure by the addition of a foreign or baser substance: prepare (as for sale) with one or more ingredients included that are not part of the alleged substance." Webster's Third New International Dictionary of the English Language(14th ed.1963); *see United States v. Wiesenfeld Warehouse Co.*, 376 U.S. 86, 89, 84 S.Ct. 559, 11 L.Ed.2d 536 (1964) ("The separate offense of adulteration . . . is concerned solely with deterioration or contamination of the commodity itself."). Thus, a grant of authority to regulate "adulterated" products plainly categorizes the types of health and safety risks that Congress was concerned with and that the FDA was delegated authority to address. *See id.* We find the plain meaning of the term imposes an important textual limit on the scope of Congress's delegation to the FDA under the "injurious to health" and the CGMP provisions.

7. Dietary supplements are covered under the rubric of ''foods'' by a nearly identical provision, 21 U.S.C. § 342(a)(4), upon which the FDA also relied for authority.

8. In 1962, Congress amended the FDC Act to strengthen and broaden the existing regulatory structure by, *inter alia*, providing the FDA with additional authority to prevent the distribution of adulterated products by regulating manufacturing practices beyond the confines of the manufacturing plant. *See* Drug Amendments of 1962, Pub.L. No. 87–781, § 101, 76 Stat. 780, 780–81. The 1962 Amendments added the CGMP provision for drugs, which deems a product ''adulterated,'' if

> it is a drug and the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with *current good manufacturing practice* to assure that such drug meets the requirements of this chapter as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess;

21 U.S.C. § 351(a)(2)(B) (emphasis added). The Dietary Supplement Health and Education Act of 1994, Pub.L. No. 103–417, § 3(a), 108 Stat. 4325, 4327 further amended the FDC Act and added the dietary supplement CGMP, which deems a product ''adulterated,'' if

> it is a dietary supplement and it has been prepared, packed, or held under conditions that do not meet current good manufacturing practice regulations, including regulations requiring, when necessary, expiration date labeling, issued by the Secretary under subparagraph (2).

21 U.S.C. § 342(g)(1). Subparagraph (2) of § 342(g) provides that ''[t]he Secretary may by regulation prescribe good manufacturing practices for dietary supplements. Such regulations shall be modeled after current good manufacturing practice regulations for food and may not impose standards for which there is no current and generally available analytical methodology.'' 21 U.S.C. § 342(g)(2).

The adulteration provisions of the FDC Act, including the "injurious to health" and CGMP provisions, delegate authority to the FDA to delineate by regulation conditions under which a product may be deemed adulterated as a matter of law.[9] As a result, the FDA is empowered to regulate manufacturing processes and conditions that give rise to a *risk* of adulteration. *See, e.g., United States v. An Article of Drug,* 484 F.2d 748, 751 (7th Cir. 1973)(per curiam)("[C]urrent good manufacturing practice [standards are] designed to insure the production of unadulterated drugs."); *United States v. Various Articles of Device . . . Proplast II,* 800 F.Supp. 499, 502 (S.D.Tex.1992); *United States v. 789 Cases, More or Less, of Latex Surgeons' Gloves,* 799 F.Supp. 1275, 1286 (D.P.R.1992) (*rev'd on other grounds,* 13 F.3d 12 (1st Cir.1993)); *United States v. Bel–Mar Labs., Inc.,* 284 F.Supp. 875, 881 (E.D.N.Y.1968).

Sections 342(a)(4) (food/dietary supplements) and 351(a)(2)(A) (drugs) are each directed toward the control of insanitary conditions causing contamination or rendering the food, dietary supplement or drug potentially harmful. The text of the provisions deems a product to be adulterated "if it has been . . . packed . . . under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health." *Id.* The requirement of single unit dose packaging simply bears no relationship to the unambiguous authority to protect against "insanitary conditions" that may cause contamination or render the product injurious.

The FDA's reliance on its authority to protect against adulterated products is misplaced because the public health risks that it seeks to address with the unit-dose packaging rule are so dissimilar to adulteration risks. Absent packaging, the iron-containing products of concern in this case are not banned by the FDA as unsafe, even though the products naturally pose some safety risks to consumers, because the products are considered safe for their intended use. *See, e.g., Brown & Williamson,* 529 U.S. at 142, 120 S.Ct. 1291 ("A fundamental precept of the FDCA is that any product regulated by the FDA—but not banned—must be safe for its intended use."); *id.* ("Various provisions of the Act make clear that ['safe for its intended use'] refers to the safety of using the product to obtain its intended effects, not the public health ramifications of alternative administrative actions by the FDA."); *id.* at 133–34, 120 S.Ct. 1291 (same).

The FDA argues that where health risks associated with an *unintended* yet predictable use (or misuse) of an unadulterated product, such as the accidental ingestion of iron-containing products by children, may be alleviated through special packaging, failure to use such packaging renders the product adulterated. This argument fails, however, because the adulteration provisions plainly concern the dangers of "deterioration or contamination of the [product] itself," not unintended use (or misuse) of the product. *Wiesenfeld Warehouse Co.,* 376 U.S. at 89, 84 S.Ct. 559. Regardless of whether the product is used or misused in

9. It is well-settled that the government need not prove that a particular product was adulterated in fact in order for that product to be "deemed adulterated." *See, e.g., United States v. Various Articles of Device . . . Proplast II,* 800 F.Supp. 499, 502 (S.D.Tex.1992) ("In order to prove a claim of adulteration of a device based upon noncompliance with GMP (Good Manufacturing Practices) regulations, the Government need not establish that the device is *actually deficient* as a result of the GMP violation."); *United States v. 789 Cases, More or Less, of Latex Surgeons' Gloves,* 799 F.Supp. 1275, 1286 (D.P.R.1992) (citing cases).

an unintended manner, the iron-containing product is not subject to contamination, deterioration, or any other change that causes it to be unsafe. We reject the FDA's construction because the risk that a product will be used or misused in an unintended manner is simply unrelated to "adulteration" under any reasonable interpretation of that term.

In a sense, the FDA argues that inadequately protective packaging is itself an adulterant. This argument is nonsensical, however, because packaging does not cause a deleterious change in the product. With or without packaging, the iron-containing product is not subject to contamination, deterioration, or any other change that causes it to be unsafe. The FDA does not argue, nor is there evidence in the record to support the argument, that the FDA sought to prescribe unit-dose packaging based on a finding that other types of packaging might cause a deleterious change in the iron-containing product. *See, e.g., United States v. Dino,* 919 F.2d 72, 75 (8th Cir.1990) (adulteration of cough syrup where syrup may have been contaminated by material used to make storage jugs).[10]

We therefore hold that the plain language of both the injurious to health and the CGMP provisions of the FDC Act unambiguously fail to delegate to the FDA authority to require manufacturers of iron-containing products to use unit-dose packaging in the absence of any showing by the FDA that iron-containing product may be adulterated without such packaging. *See Chevron,* 467 U.S. at 842–43, 104 S.Ct. 2778.

2. Chevron Step Two

[10] Even if there were some ambiguity in the statutory text of the FDC Act, we

10. Our conclusion that the FDA has plainly not been delegated authority under the CGMP provisions of the FDC Act to regulate packaging except to address adulteration risks will not invalidate or call into question the validity of the FDA's existing CGMP regulations. Our review of the CGMP regulations that touch on packaging shows that the regulations directly address adulteration risks. Various drug CGMP regulations set forth process-oriented requirements, *e.g.,* inspections, pertaining to packaging and labeling controls. *See* 21 C.F.R. §§ 211.122, 211.130, 211.134. In particular, the FDA refers us to its tamper-evident packaging CGMP regulation. *See* 21 C.F.R. § 211.132 (requiring tamper-evident packaging for over-the-counter drugs). Although the FDA attempts to draw a parallel between its tamper-evident packaging regulation and its unit-dose packaging regulation to suggest that both are "designed to prevent injuries to consumers that are caused by the intentional *misuse* of the drug," Appellees' Br. at 29 (emphasis in original), we find the argument misleading. As expressly stated in the tamper-evident packaging regulation, the purpose of requiring such packaging is to "reduce the likelihood of successful tampering and to increase the likelihood that consumers will discover if a product has been tampered with." *See* 21 C.F.R. § 211.132(b). The risk of drug product tampering is clearly a risk of adulteration and not intentional misuse of the drug product.

The FDA's food CGMP regulations, upon which dietary supplement CGMP regulations must be modeled, 21 U.S.C. § 342(g)(2), also directly address adulteration risks. *See, e.g.,* 21 C.F.R. § 110.80(b)(13) (packaging of food must be performed in such a way that the food is protected from contamination); *id.* § 110.80(b)(14) (requiring procedures that prevent the growth of microorganisms, including "[p]rotecting finished food from moisture pickup, by use of a moisture barrier or by other means"). Compliance with the food packaging CGMP, § 110.80(b)(13), may be accomplished through various methods, including: (I) the use of quality-control procedures, (ii) "cleaning and sanitizing of all food-contact surfaces and food containers," (iii) "[u]sing materials for food containers and food-packaging materials that are safe and suitable, as defined in § 130.3(d)," (iv) "[p]roviding physical protection from contamination, particularly airborne contamination," and (v) "[u]sing sanitary handling procedures." *Id.* § 110.80(b)(13)(i)-(v).

would find the FDA's proposed construction impermissible. Under the second prong of *Chevron*, we would find it necessary to analyze not only the FDC Act, which the FDA administers, but also the PPP Act and the CPS Act, both of which are administered by the CPSC and not the FDA. With respect to the appropriate framework for analyzing the impact of the PPP Act and CPS Act on the construction of ambiguous terms in the FDC Act, the Supreme Court provided the following instructive guidance in *Brown & Williamson:*

> At the time a statute is enacted, it may have a range of plausible meanings. Over time, however, subsequent acts can shape or focus those meanings. The classic judicial task of reconciling many laws enacted over time, and getting them to make sense in combination, necessarily assumes that the implications of a statute may be altered by the implications of a later statute. This is particularly so where the scope of the earlier statute is broad but the subsequent statutes more specifically address the topic at hand. As we recognized recently in *United States v. Estate of Romani*, "a specific policy embodied in a later federal statute should control our construction of the [earlier] statute, even though it ha[s] not been expressly amended." 523 U.S. [517,] 530–531, 118 S.Ct. 1478, 140 L.Ed.2d 710 [(1998)].

Brown & Williamson, 529 U.S. at 143, 120 S.Ct. 1291 (quotation marks and citation omitted, alterations to *Romani* in original);[11] *see also id.* at 133, 120 S.Ct. 1291 ("[T]he meaning of one statute may be affected by other Acts, particularly where Congress has spoken subsequently and more specifically to the topic at hand.").

[11] In *Romani*, for example, the Supreme Court explained that the government could not side-step the Tax Lien Act of 1966, 26 U.S.C. § 6321 *et seq.*, by relying on the federal priority statute, 31 U.S.C. § 3713(a). 523 U.S. at 534, 118 S.Ct. 1478. In its analysis, the Court emphasized that a later-enacted, more specific, comprehensive statute that targets the specific subject matter at issue in the case controls the construction of a more general statute when there is a potential conflict or discrepancy between the burdens imposed upon affected entities. *See id.* at 530–32, 534, 118 S.Ct. 1478. The Court held that the federal government was precluded from executing the equivalent of a "secret lien," by relying on the federal priority statute, "as a substitute for the expressly authorized tax lien that Congress has said 'shall not be valid' in a case of this kind." *Id.* at 534, 118 S.Ct. 1478. Simply put, the government could not circumvent the limitations imposed upon it by the Tax Lien Act in a case involving a federal tax claim by relying on the broadly applicable federal priority statute.

The principles enunciated in *Romani* and *Brown & Williamson* would clearly apply in this case, if it were necessary to shift our analysis into the second prong of *Chevron.* Congress enacted the PPP Act in 1970, subsequent to the enactment of the FDC Act in 1938 and the drug CGMP amendment in 1962. In doing so, Congress specifically targeted the problem of accidental poisoning of children caused by the ingestion of (or exposure to) a wide range of ordinary household products, including drugs and medicines,[12] with a com-

11. In *Brown & Williamson,* the Supreme Court emphasized the importance of six statutes, enacted by Congress subsequent to the enactment of the FDC Act, that specifically addressed tobacco products. 529 U.S. at 137–38, 120 S.Ct. 1291.

12. In an opening statement before the Subcommittee for Consumers of the United States

prehensive yet circumscribed regulatory solution. Specifically, the PPP Act conferred to the FDA authority to establish and enforce regulatory standards for the "special packaging" [13] of any "household substance" [14] found to be a hazard to children (*i.e.*, poison prevention packaging). It is particularly important that the PPP Act expressly set forth comprehensive "instructions," including specific regulatory constraints, as to how this authority should be exercised: First, special packaging standards can only be established where "packaging is required to protect children from serious personal injury or serious illness resulting from handling, using or ingesting [a] substance." 15 U.S.C. § 1472(a)(1). Second, special packaging must be "technically feasible, practicable, and appropriate." *Id.* § 1472(a)(2). Third, standards must be established pursuant to the following considerations listed in the PPP Act:

(1) the reasonableness of such standard;

(2) available scientific, medical, and engineering data concerning special packaging and concerning childhood accidental ingestions, illness, and injury caused by household substances;

(3) the manufacturing practices of industries affected by this Act; and

(4) the nature and use of the household substance.

Senate Committee on Commerce for a hearing on S. 2162, the bill eventually enacted as the PPP Act, Senator Frank E. Moss, Chairman of the Subcommittee, described the problem as follows:

> The problem is clear. At this very moment some small child is innocently exploring the limited environment of his home. In the process he is poking into the medicine cabinet, reaching into his mother's purse, crawling under the kitchen or bathroom sink, or rummaging in the garden shed and possibly swallowing a potential poison. Poisoning by household substances is the most common medical emergency facing young children. The loss that it imposes—in pain, suffering, and death—is incalculable.

Hearings on S. 2162 Before the Consumer Subcomm. of the Senate Comm. On Commerce, 91st Cong. 1 (1969)(Statement of Senator Frank E. Moss). As Senator Moss further explained in his opening statement:

> Two tactics, treatment and education against the hazards of household substances, have predominated in the fight against accidental poisonings. The first tactic is exemplified by the operations of [FDA] Poison Control Centers where information is collected to speed and improve the treatment of poisoning victims. The second tactic is exemplified by the familiar warning, ''Keep out of the reach of children.'' .... S. 2162 [and thus, the PPP Act] would begin strong action on a third tactic—that of prevention. [It] would authorize the Secretary of Health, Education, and Welfare to require packaging that would prevent children from getting into hazardous substances. The possibility of poisoning is reduced at the primary level by keeping children and hazardous substances separated.

Id. at 1–2; *see also* H.R.Rep. No. 91–1642, *reprinted in* 1970 U.S.C.C.A.N. 5326 (PPP Act addresses risk of accidental exposure).

13. ''Special packaging'' is defined as ''packaging that is designed or constructed to be significantly difficult for children under five years of age to open or obtain a toxic or harmful amount of the substance contained therein within a reasonable time and not difficult for normal adults to use properly, but does not mean packaging which all such children cannot open or obtain a toxic or harmful amount within a reasonable time.'' 15 U.S.C. § 1471(4). There is no doubt that the FDA's unit-dose packaging rule constitutes a ''special packaging'' standard within the meaning of the PPP Act. As noted above, the Government does not dispute that the FDA's rule constitutes a poison prevention packaging regulation but rather argues that it has concurrent jurisdiction with the CPSC to promulgate such a regulation.

14. ''Household substances'' were defined to include, *inter alia*, ''a food, drug, or cosmetic,'' within the meaning of the FDC Act. *Id.* § 1471(2)(B).

Id. § 1472(b). Finally, the PPP Act expressly prohibited the FDA from prescribing "specific packaging designs, product content, package quantity, or with [one] exception ... labeling." *Id.* § 1472(d). Congress believed such decisions should be left to industry. *Id.; see* H.R.Rep. No. 91–1642, *reprinted in* 1970 U.S.C.C.A.N. at 5332–33, 5336.

In 1972, the FDA was stripped of its PPP Act authority when Congress enacted the CPS Act, created the CPSC for the purpose of consolidating regulatory efforts pertaining to consumer product safety, and transferred the FDA's authority to administer and enforce the PPP Act to the CPSC.[15] *See* Consumer Product Safety Act, Pub.L. No. 92–573, (1972); *Wahba v. H & N Prescription Ctr. Inc.*, 539 F.Supp. 352, 354 (E.D.N.Y.1982) (discussing history of CPS Act).

Following *Romani* and *Brown & Williamson*, we would not defer to the FDA regarding its interpretation of ambiguous language in the FDC Act where doing so would allow the FDA to circumvent the detailed regulatory scheme, including express constraints, set forth by Congress in the PPP Act. *See Romani*, 523 U.S. at 530–32, 534, 118 S.Ct. 1478; *Brown & Williamson*, 529 U.S. at 125–26, 159, 120 S.Ct. 1291.

While the PPP Act does not directly constrain the FDA because the FDA Act no longer administers that Act, the fact that Congress transferred PPP Act authority from the FDA to the CPSC only weakens the FDA's argument that it retains delegated authority to regulate poison prevention packaging. Thus, even assuming arguendo that the FDC Act provisions relied upon by the FDA were ambiguous, we would find the FDA's interpretation of those provisions impermissible because (1) the PPP Act specifically and unambiguously targets the accidental poisoning problem and prescribes a specific regulatory approach to addressing the problem through packaging standards, (2) the CPS Act unambiguously transferred authority to administer and enforce the PPP Act from the FDA to the CPSC, and (3) the FDA's assertion of concurrent jurisdiction rings a discordant tone with the regulatory structure created by Congress. *See id.* at 132–33, 120 S.Ct. 1291.

Finally, we note that the FDA's dubious construction of the "injurious to health" and CGMP provisions would further cement our conclusions under the second prong of *Chevron* that its proffered interpretation is not reasonable. The FDA relies on select terms from the statutory text piecemeal and fails to give meaning to other important terms. For example, with respect to the injurious to health provisions,[16] the FDA fails to recognize (or even

15. Specifically, Congress provided as follows:

> The functions of the Secretary of Health, Education, and Welfare under ... the [PPP Act] are transferred to the [CPSC]. The functions of the Secretary of Health, Education, and Welfare under the [FDC Act], to the extent such functions relate to the administration and enforcement of the [PPP Act], are transferred to the [CPSC].

15 U.S.C. § 2079(a). Congress further provided that:

> For purposes of this section, (1) the term "function" includes power and duty, and (2) the transfer of a function, under any provision of law, of an agency or the head of a department shall also be a transfer of all functions under such law which are exercised by any office or officer of such agency, or department.

Id. § 2079(f).

16. Similarly, with respect to the CGMP provisions, the FDA fails to define "current good manufacturing practice" or explain how the process-oriented provisions reach packaging design. We find unconvincing and unhelpful the FDA's mere assertions that (1) "manufacturers must 'pack' their products in accor-

attempt to grapple with) the fact that the phrase "prepared, packed, or held under insanitary conditions" has consistently been interpreted to refer to the *place* where a product is prepared, packed, or held. *See Supreme Beef Processors, Inc. v. U.S. Dep't of Agric.*, 275 F.3d 432, 442 n. 38 (5th Cir.2001) (citing cases). Furthermore, the FDA completely ignores the term "renders," which "indicates that a deleterious change in the product must occur while it is being 'prepared, packed or held' owing to insanitary conditions." *Id.* at 440 (interpreting identical language in the Federal Meat Inspection Act). We, however, must "give effect, if possible, to every clause and word of a statute." *Id.* at 440 (quoting *Duncan v. Walker*, 533 U.S. 167, 174, 121 S.Ct. 2120, 150 L.Ed.2d 251 (2001)); *see also Williams v. Taylor*, 529 U.S. 362, 404, 120 S.Ct. 1495, 146 L.Ed.2d 389 (2000) (describing this rule as a "cardinal principle of statutory construction"). As discussed above with respect to adulteration, there is simply no basis for concluding that packaging causes "a deleterious change" to iron-containing products.

III. CONCLUSION

For the reasons set forth in this opinion, the judgment of the district court below is REVERSED and the matter is REMANDED to the district court to fashion an appropriate remedy consistent with this opinion.

John J. CRANLEY, III, Julius Grad and Walter J. Birdsall, on behalf of themselves and all other similarly situated policyholders of National Life of Vermont, Plaintiffs–Appellants,

Betty C. Birdsall, on behalf of herself and all other similarly situated policyholders of National Life of Vermont, Plaintiff,

v.

NATIONAL LIFE INSURANCE COMPANY OF VERMONT, National Life Holding Company, NLV Financial Corporation, Patrick E. Welch, Chairman of the Board of Directors and Chief Executive Officer of National Life Insurance Company of Vermont, Thomas MacLeay, President and Chief Operating Officer, and member of the Board of Directors of National Life Insurance Company of Vermont, James A. Mallon, Executive Vice President and Chief Marketing Officer of National Life Insurance Company of Vermont, William A. Smith, Executive Vice President and Chief Financial Officer of National Life Insurance Company of Vermont, Rodney A. Buck, Senior Vice President and Chief Investment Officer of National Life Insurance Company of Vermont, Gregory H. Doremus, Senior Vice President of National Life Insurance Company of Vermont, Charles C. Kittredge, Senior Vice President of National Life Insurance Company of Vermont, Robert E. Boardman, David R. Coates, Benjamin F. Edwards, III, Earle H. Harbison, Jr., Roger B. Porter, E. Miles Prentice, III, Thomas P. Salmon, A. Gary Shilling, Thomas R.

dance with 'current' good manufacturing practices to ensure the products' 'safety' " and (2) the unit-dose packaging rule was promulgated as a CGMP to ensure safety. Appellees' Brief at 28.