

BREYER, J., dissenting

SUPREME COURT OF THE UNITED STATES

No. 98–1152

FOOD AND DRUG ADMINISTRATION, ET AL., PETITIONERS v. BROWN & WILLIAMSON TOBACCO CORPORATION ET AL.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FOURTH CIRCUIT

[March 21, 2000]

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” Federal Food, Drug and Cosmetic Act (FDCA), 21 U. S. C. §321(g)(1)(C). 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. See *United States v. Article of Drug ... Bacto-Unidisk*, 394 U. S. 784, 798 (1969) (FDCA “is to be given a liberal construction consistent with [its] overriding purpose to protect the public health” (emphasis added)).

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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).

Despite the FDCA’s literal language and general purpose (both of which support the FDA’s finding that cigarettes come within its statutory authority), the majority nonetheless reads the statute as *excluding* tobacco products for two basic reasons:

- (1) the FDCA does not “fit” the case of tobacco because the statute requires the FDA to prohibit dangerous drugs or devices (like cigarettes) outright, and the agency concedes that simply banning the sale of cigarettes is not a proper remedy, *ante*, at 19–20; and
- (2) Congress has enacted other statutes, which, when viewed in light of the FDA’s long history of denying tobacco-related jurisdiction and considered together with Congress’ failure explicitly to grant the agency tobacco-specific authority, demonstrate that Congress did not intend for the FDA to exercise jurisdiction over tobacco, *ante*, at 33–34.

In my view, neither of these propositions is valid. Rather, the FDCA does not significantly limit the FDA’s remedial alternatives. See *infra*, at 14–21. And the later statutes do not tell the FDA it cannot exercise jurisdiction, but simply leave FDA jurisdictional law where Congress found it. See *infra*, at 21–26; cf. Food and Drug Administration Modernization Act of 1997, 111 Stat. 2380 (codified at note following 21 U. S. C. §321 (1994 ed., Supp. III)) (statute “shall” *not* “be construed to affect the question of whether” the FDA “has any authority to regulate any tobacco product”).

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The bulk of the opinion that follows will explain the basis for these latter conclusions. In short, I believe that the most important indicia of statutory meaning— language and purpose— along with the FDCA’s legislative history (described briefly in Part I) are sufficient to establish that the FDA has authority to regulate tobacco. The statute-specific arguments against jurisdiction that the tobacco companies and the majority rely upon (discussed in Part II) are based on erroneous assumptions and, thus, do not defeat the jurisdiction-supporting thrust of the FDCA’s language and purpose. The inferences that the majority draws from later legislative history are not persuasive, since (as I point out in Part III) one can just as easily infer from the later laws that Congress did not intend to affect the FDA’s tobacco-related authority at all. And the fact that the FDA changed its mind about the scope of its own jurisdiction is legally insignificant because (as Part IV establishes) the agency’s reasons for changing course are fully justified. Finally, as I explain in Part V, the degree of accountability that likely will attach to the FDA’s action in this case should alleviate any concern that Congress, rather than an administrative agency, ought to make this important regulatory decision.

I

Before 1938, the federal Pure Food and Drug Act contained only two jurisdictional definitions of “drug”:

“[1] medicines and preparations recognized in the United States Pharmacopoeia or National Formulary . . . and [2] any substance or mixture of substances intended to be used for the cure, mitigation, or prevention of disease.” Act of June 30, 1906, ch. 3915, §6, 34 Stat. 769.

In 1938, Congress added a third definition, relevant here:

“(3) articles (other than food) intended to affect the

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structure or any function of the body” Act of June 25, 1938, ch. 675, §201(g), 52 Stat. 1041 (codified at 21 U. S. C. §321(g)(1)(C)).

It also added a similar definition in respect to a “device.” See §201(h), 52 Stat. 1041 (codified at 21 U. S. C. §321(h)). As I have mentioned, the literal language of the third definition and the FDCA’s general purpose both strongly support a projurisdiction reading of the statute. See *supra*, at 1–2.

The statute’s history offers further support. The FDA drafted the new language, and it testified before Congress that the third definition would expand the FDCA’s jurisdictional scope significantly. See Hearings on S. 1944 before a Subcommittee of the Senate Committee on Commerce, 73d Cong., 2d Sess., 15–16 (1933), reprinted in 1 FDA, Legislative History of the Federal Food, Drug, and Cosmetic Act and Its Amendments 107–108 (1979) (hereinafter Leg. Hist.). Indeed, “[t]he purpose” of the new definition was to “make possible the regulation of a great many products that have been found on the market that cannot be alleged to be treatments for diseased conditions.” *Id.*, at 108. While the drafters focused specifically upon the need to give the FDA jurisdiction over “slenderizing” products such as “antifat remedies,” *ibid.*, they were aware that, in doing so, they had created what was “admittedly an inclusive, a wide definition.” *Id.*, at 107. And that broad language was included *deliberately*, so that jurisdiction could be had over “*all* substances and preparations, other than food, and *all* devices intended to affect the structure or any function of the body” *Ibid.* (emphasis added); see also Hearings on S. 2800 before the Senate Committee on Commerce, 73d Cong., 2d Sess. 516 (1934), reprinted in 2 Leg. Hist. 519 (statement of then-FDA Chief Walter Campbell acknowledging that “[t]his definition of ‘drugs’ is all-inclusive”).

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After studying the FDCA's history, experts have written that the statute "is a purposefully broad delegation of discretionary powers by Congress," J. O'Reilly, 1 Food and Drug Administration §6.01, p. 6–1 (2d ed. 1995) (hereinafter O'Reilly), and that, in a sense, the FDCA "must be regarded as a *constitution*" that "establish[es] general principles" and "permit[s] implementation within broad parameters" so that the FDA can "implement these objectives through the most effective and efficient controls that can be devised." Hutt, *Philosophy of Regulation Under the Federal Food, Drug and Cosmetic Act*, 28 Food Drug Cosm. L. J. 177, 178–179 (1973) (emphasis added). This Court, too, has said that the

"historical expansion of the definition of drug, and the creation of a parallel concept of devices, clearly show . . . 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." *Bacto-Unidisk*, 394 U. S., at 798.

That Congress would grant the FDA such broad jurisdictional authority should surprise no one. In 1938, the President and much of Congress believed that federal administrative agencies needed broad authority and would exercise that authority wisely— a view embodied in much Second New Deal legislation. Cf. *Gray v. Powell*, 314 U. S. 402, 411–412 (1941) (Congress "could have legislated specifically" but decided "to delegate that function to those whose experience in a particular field gave promise of a better informed, more equitable" determination). Thus, at around the same time that it added the relevant language to the FDCA, Congress enacted laws granting other administrative agencies even broader powers to regulate much of the Nation's transportation and communication. See, e.g., Civil Aeronautics Act of 1938, ch. 601, §401(d)(1), 52 Stat.

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987 (Civil Aeronautics Board to regulate airlines within confines of highly general “public convenience and necessity” standard); Motor Carrier Act of 1935, ch. 498, §204(a)(1), 49 Stat. 546 (Interstate Commerce Commission to establish “reasonable requirements” for trucking); Communications Act of 1934, ch. 652, §201(a), 48 Stat. 1070 (Federal Communications Commission (FCC) to regulate radio, later television, within confines of even broader “public interest” standard). Why would the 1938 New Deal Congress suddenly have hesitated to delegate to so well established an agency as the FDA all of the discretionary authority that a straightforward reading of the relevant statutory language implies?

Nor is it surprising that such a statutory delegation of power could lead after many years to an assertion of jurisdiction that the 1938 legislators might not have expected. Such a possibility is inherent in the very nature of a broad delegation. In 1938, it may well have seemed unlikely that the FDA would ever bring cigarette manufacturers within the FDCA’s statutory language by proving that cigarettes produce chemical changes in the body and that the makers “intended” their product chemically to affect the body’s “structure” or “function.” Or, back then, it may have seemed unlikely that, even assuming such proof, the FDA actually would exercise its discretion to regulate so popular a product. See R. Kluger, *Ashes to Ashes* 105 (1997) (in the 1930’s “Americans were in love with smoking . . .”).

But it should not have seemed unlikely that, assuming the FDA decided to regulate and proved the particular jurisdictional prerequisites, the courts would rule such a jurisdictional assertion fully authorized. Cf. *United States v. Southwestern Cable Co.*, 392 U. S. 157, 172 (1968) (reading Federal Communications Act as authorizing FCC jurisdiction to regulate cable systems while noting that “Congress could not in 1934 have foreseen the development of”

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advanced communications systems). After all, this Court has read more narrowly phrased statutes to grant what might have seemed even more unlikely assertions of agency jurisdiction. See, e.g., *Permian Basin Area Rate Cases*, 390 U. S. 747, 774–777 (1968) (statutory authority to regulate interstate “transportation” of natural gas includes authority to regulate “prices” charged by field producers); *Phillips Petroleum Co. v. Wisconsin*, 347 U. S. 672, 677–684 (1954) (independent gas producer subject to regulation despite Natural Gas Act’s express exemption of gathering and production facilities).

I shall not pursue these general matters further, for neither the companies nor the majority denies that the FDCA’s literal language, its general purpose, and its particular legislative history favor the FDA’s present jurisdictional view. Rather, they have made several specific arguments in support of one basic contention: even if the statutory delegation is broad, it is not broad *enough* to include tobacco. I now turn to each of those arguments.

II

A

The tobacco companies contend that the FDCA’s words cannot possibly be read to mean what they literally say. The statute defines “device,” for example, as “an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article . . . intended to affect the structure or any function of the body” 21 U. S. C. §321(h). Taken literally, this 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. See Brief for Respondent United States Tobacco Co. 8–9.

The companies may well be right that the statute should

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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. See *Bacto-Unidisk*, 394 U. S., at 798 (third definition is “clearly, broader than any strict medical definition”); 1 Leg. Hist. 108 (definition covers products “that cannot be alleged to be treatments for diseased conditions”). 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.

Although I now oversimplify, the FDA has determined that once nicotine enters the body, the blood carries it almost immediately to the brain. See 61 Fed. Reg. 44698–44699 (1966). Nicotine then binds to receptors on the surface of brain cells, setting off a series of chemical reac-

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tions that alter one's mood and produce feelings of sedation and stimulation. See *id.*, at 44699, 44739. Nicotine also increases the number of nicotinic receptors on the brain's surface, and alters its normal electrical activity. See *id.*, at 44739. And nicotine stimulates the transmission of a natural chemical that "rewards" the body with pleasurable sensations (dopamine), causing nicotine addiction. See *id.*, at 44700, 44721–44722. The upshot is that nicotine stabilizes mood, suppresses appetite, tranquilizes, and satisfies a physical craving that nicotine itself has helped to create— all through chemical action within the body after being metabolized.

This physiology— and not simply smoker psychology— helps to explain why as many as 75% of adult smokers believe that smoking "reduce[s] nervous irritation," 60 Fed. Reg. 41579 (1995); why 73% of young people (10- to 22-year-olds) who begin smoking say they do so for "relaxation," 61 Fed. Reg. 44814 (1996); and why less than 3% of the 70% of smokers who want to quit each year succeed, *id.*, at 44704. That chemistry also helps to explain the Surgeon General's findings that smokers believe "smoking [makes them] feel better" and smoke more "in situations involving negative mood." *Id.*, at 44814. And, for present purposes, that chemistry demonstrates that nicotine affects the "structure" and "function" of the body in a manner that is quite similar to the effects of other regulated substances. See *id.*, at 44667 (FDA regulates Valium, NoDoz, weight-loss products). Indeed, addiction, sedation, stimulation, and weight loss are *precisely* the kinds of product effects that the FDA typically reviews and controls. And, since the nicotine in cigarettes plainly is not a "food," its chemical effects suffice to establish that it is as a "drug" (and the cigarette that delivers it a drug-delivery "device") for the purpose of the FDCA.

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B

The tobacco companies' principal definitional argument focuses upon the statutory word "intended." See 21 U. S. C. §321(g)(1)(C). The companies say that "intended" in this context is a term of art. See Brief for Respondent Brown & Williamson Tobacco Corp. 2. 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. *Ibid.* 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. See *id.*, at 19–20.

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." 41 Fed. Reg. 6896 (1976) (codified at 21 CFR §801.4 (1999)); see also 41 Fed. Reg. 6896 (1976) ("objective intent" shown if "article is, with the knowledge [of its makers], offered and used" for a particular purpose). 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. See, e.g., 60 Fed. Reg. 41527–41531 (1995) (describing agency's regulation of topical hormones, sunscreens, fluoride, tanning lamps, thyroid in food supplements, novelty condoms— all marketed without express claims); see also O'Reilly, Food and Drug Administration §13.04, at 13–15 ("Sometimes the very nature of the material makes it a drug . . .").

Courts ordinarily reverse an agency interpretation of this kind only if Congress has clearly answered the interpretive question or if the agency's interpretation is unreasonable. *Chevron U. S. A. Inc. v. Natural Resources Defense*

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Council, Inc., 467 U. S. 837, 842–843 (1984). The companies, in an effort to argue the former, point to language in the legislative history tying the word “intended” to a technical concept called “intended use.” But nothing in Congress’ discussion either of “intended” or “intended use” suggests that an express claim (which *often* shows intent) is *always* necessary. Indeed, the primary statement to which the companies direct our attention says only that a manufacturer can determine what kind of regulation applies— “food” or “drug”— because, “through his representations in connection with its sale, [the manufacturer] can determine” whether an article is to be used as a “food,” as a “drug,” or as “both.” S. Rep. No. 361, 74th Cong., 1st Sess., 4 (1935), reprinted in 3 Leg. Hist. 696.

Nor is the FDA’s “objective intent” interpretation unreasonable. It falls well within the established scope of the ordinary meaning of the word “intended.” See *Agnew v. United States*, 165 U. S. 36, 53 (1897) (intent encompasses the known consequences of an act). 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 companies also cannot deny that the evidence of their intent is sufficient to satisfy the statutory word “intended” as the FDA long has interpreted it. In the first place, there was once a time when they actually *did* make express advertising claims regarding tobacco’s mood-stabilizing and weight-reducing properties— and historical representations can portend present expectations. In the late 1920’s, for example, the American Tobacco Company urged weight-conscious smokers to “Reach for a Lucky in-

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stead of a sweet.’” Kluger, *Ashes to Ashes*, at 77–78. The advertisements of R.J. Reynolds (RJR) emphasized mood stability by depicting a pilot remarking that “‘It Takes Steady Nerves To Fly the Mail At Night That’s why I smoke Camels. And I smoke plenty!’” *Id.*, at 86. RJR also advertised the stimulating quality of cigarettes, stating in one instance that “‘You get a Lift with a Camel,’” and, in another, that Camels are “‘A Harmless Restoration of the Flow of Natural Body Energy.’” *Id.*, at 87. And claims of medical proof of mildness (and of other beneficial effects) once were commonplace. See, e.g., *id.*, at 93 (Brown & Williamson advertised Kool-brand mentholated cigarettes as “a tonic to hot, tired throats”); *id.*, at 101, 131 (Phillip Morris contended that “[r]ecognized laboratory tests have conclusively proven the advantage of Phillip Morris”); *id.*, at 88 (RJR proclaimed “‘For Digestion’s sake, smoke Camels! . . . Camels make mealtime more pleasant— digestion is stimulated— alkalinity increased’”). Although in recent decades cigarette manufacturers have stopped making express health claims in their advertising, consumers have come to understand what the companies no longer need to express— that through chemical action cigarettes stabilize mood, sedate, stimulate, and help suppress appetite.

Second, even though the companies refused to acknowledge publicly (until only very recently) that the nicotine in cigarettes has chemically induced, and habit-forming, effects, see, e.g., Regulation of Tobacco Products (Part 1): Hearings before the House Subcommittee on Health and the Environment, 103d Cong., 2d Sess., 628 (1994) (hereinafter 1994 Hearings) (heads of seven major tobacco companies testified under oath that they believed “nicotine is *not* addictive” (emphasis added)), the FDA recently has gained access to solid, documentary evidence proving that cigarette manufacturers have long *known* tobacco produces these effects within the body through the metabo-

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lizing of chemicals, and that they have long *wanted* their products to produce those effects in this way.

For example, in 1972, a tobacco-industry scientist explained that “[s]moke is beyond question the most optimized vehicle of nicotine,” and “the cigarette is the most optimized dispenser of smoke.” 61 Fed. Reg. 44856 (1996). That same scientist urged company executives to

“[t]hink of the cigarette pack as a storage container for a day’s supply of nicotine. . . . Think of the cigarette as a dispenser for a dose unit of nicotine [and] [t]hink of a puff of smoke as a vehicle of nicotine.” *Ibid.* (Philip Morris).

That same year, other tobacco industry researchers told their superiors that

“in different situations and at different dose levels, nicotine appears to act as a stimulant, depressant, tranquilizer, psychic energizer, appetite reducer, anti-fatigue agent, or energizer. . . . Therefore, [tobacco] products may, in a sense, compete with a variety of other products with certain types of drug action.” *Id.*, at 44669 (RJR).

A draft report prepared by authorities at Philip Morris said that nicotine

“is a physiologically active, nitrogen containing substance [similar to] quinine, cocaine, atropine and morphine. [And] [w]hile each of these [other] substances can be used to affect human physiology, nicotine has a particularly broad range of influence.” *Id.*, at 44668–44669.

And a 1980 manufacturer’s study stated that

“the pharmacological response of smokers to nicotine is believed to be responsible for an individual’s smoking behaviour, providing the motivation for and the

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degree of satisfaction required by the smoker.’” *Id.*, at 44936 (Brown & Williamson).

With such evidence, the FDA has more than sufficiently established that the companies “intend” their products to “affect” the body within the meaning of the FDCA.

C

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. *Ante*, at 20. 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. *Ibid.*

This argument is curious because it leads with similarly “inescapable” force to precisely the opposite conclusion, namely, that the FDA *does* have jurisdiction but that it must ban cigarettes. More importantly, the argument fails to take into account the fact that a statute interpreted as requiring the FDA to pick a more dangerous over a less dangerous remedy would be a perverse statute, *causing*, rather than preventing, unnecessary harm whenever a total ban is likely the more dangerous response. And one can at least imagine such circumstances.

Suppose, for example, that a commonly used, mildly addictive sleeping pill (or, say, a kind of popular contact lens), plainly within the FDA’s jurisdiction, turned out to pose serious health risks for certain consumers. Suppose further that many of those addicted consumers would ignore an immediate total ban, turning to a potentially more dangerous black-market substitute, while a less draconian remedy (say, adequate notice) would wean them gradually away to a safer product. Would the FDCA still *force* the FDA to impose the more dangerous remedy? For the following reasons, I think not.

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First, the statute’s language does not restrict the FDA’s remedial powers in this way. The FDCA permits the FDA to regulate a “combination product”— *i.e.*, a “device” (such as a cigarette) that contains a “drug” (such as nicotine)—under its “device” provisions. 21 U. S. C. §353(g)(1). And the FDCA’s “device” provisions explicitly grant the FDA wide remedial discretion. For example, where the FDA cannot “otherwise” obtain “reasonable assurance” of a device’s “safety and effectiveness,” the agency may restrict by regulation a product’s “sale, distribution, or use” upon “*such . . . conditions as the Secretary may prescribe.*” §360j(e)(1) (emphasis added). And the statutory section that most clearly addresses the FDA’s power to ban (entitled “Banned devices”) says that, where a device presents “an unreasonable and substantial risk of illness or injury,” the Secretary “*may*”— not *must*— “initiate a proceeding . . . to make such device a banned device.” §360f(a) (emphasis added).

The Court points to other statutory subsections which it believes require the FDA to ban a drug or device entirely, even where an outright ban risks more harm than other regulatory responses. See *ante*, at 12–13. But the cited provisions do no such thing. It is true, as the majority contends, that “the FDCA requires the FDA to place all devices” in “one of three classifications” and that Class III devices require “premarket approval.” *Ante*, at 12, 13. But it is not the case that the FDA *must* place cigarettes in Class III because tobacco itself “present[s] a potential unreasonable risk of illness or injury.” 21 U. S. C. §360c(a)(1)(C). In fact, Class III applies *only* where *regulation* cannot otherwise “provide reasonable assurance of . . . safety.” §§360c(a)(1)(A), 360c(a)(1)(B) (placing a device in Class I or Class II when regulation can provide that assurance). Thus, the statute plainly allows the FDA to consider the relative, overall “safety” of a device in light of its regulatory alternatives, and where the FDA has chosen

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the least dangerous path, *i.e.*, the safest path, then it can— and does— provide a “reasonable assurance” of “safety” within the meaning of the statute. A good football helmet provides a reasonable assurance of safety for the player even if the sport itself is still dangerous. And the safest regulatory choice by definition offers a “reasonable” assurance of safety in a world where the other alternatives are yet more dangerous.

In any event, it is not entirely clear from the statute’s text that a Class III categorization would require the FDA affirmatively to *withdraw* from the market dangerous devices, such as cigarettes, which are already widely distributed. See, *e.g.*, §360f(a) (when a device presents an “unreasonable and substantial risk of illness or injury,” the Secretary “may” make it “a banned device”); §360h(a) (when a device “presents an unreasonable risk of substantial harm to the public health,” the Secretary “may” require “notification”); §360h(b) (when a defective device creates an “unreasonable risk” of harm, the Secretary “may” order “repair, replacement, or refund”); cf. O’Reilly, Food and Drug Administration §18.08, at 18-38 (point of Class III “premarket approval” is to allow “careful scientific review” of each “truly new” device “*before* it is exposed” to users (emphasis added)).

Noting that the FDCA requires banning a “misbranded” drug, the majority also points to 21 U. S. C. §352(j), which deems a drug or device “misbranded” if “it is dangerous to health when used” as “prescribed, recommended, or suggested in the labeling.” See *ante*, at 12. In addition, the majority mentions §352(f)(1), which calls a drug or device “misbranded” unless “its labeling bears . . . adequate directions for use” as “are necessary for the protection of users.” *Ibid.* But this “misbranding” language is not determinative, for it permits the FDA to conclude that a drug or device is *not* “dangerous to health” and that it *does* have “adequate” directions *when regulated so as to render*

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it as harmless as possible. And surely the agency can determine that a substance is comparatively “safe” (*not* “dangerous”) whenever it would be *less* dangerous to make the product available (subject to regulatory requirements) than suddenly to withdraw it from the market. Any other interpretation risks substantial harm of the sort that my sleeping pill example illustrates. See *supra*, at 14. And nothing in the statute prevents the agency from adopting a view of “safety” that would avoid such harm. Indeed, the FDA already seems to have taken this position when permitting distribution of toxic drugs, such as poisons used for chemotherapy, that are dangerous for the user but are not deemed “dangerous to health” in the relevant sense. See 61 Fed. Reg. 44413 (1996).

The tobacco companies point to another statutory provision which says that if a device “would cause serious, adverse health consequences or death, the Secretary *shall* issue” a cease distribution order. 21 U. S. C. §360h(e)(1) (emphasis added). But that word “shall” in this context cannot mean that the Secretary must resort to the recall remedy *whenever* a device would have serious, adverse health effects. Rather, that language must mean that the Secretary “shall issue” a cease distribution order in compliance with the section’s procedural requirements *if* the Secretary chooses *in her discretion* to use that particular subsection’s recall remedy. Otherwise, the subsection would trump and make meaningless the same section’s provision of other lesser remedies such as simple “notice” (which the Secretary similarly can impose if, but only if, she finds that the device “presents an unreasonable risk of substantial harm to the public”). §360h(a)(1). And reading the statute to compel the FDA to “recall” every dangerous device likewise would conflict with that same subsection’s statement that the recall remedy “shall be *in addition to* [the other] remedies provided” in the statute. §360h(e)(3) (emphasis added).

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The statute's language, then, permits the agency to choose remedies consistent with its basic purpose—the overall protection of public health.

The second reason the FDCA does not require the FDA to select the more dangerous remedy, see *supra*, at 14, is that, despite the majority's assertions to the contrary, the statute does not distinguish among the kinds of health effects that the agency may take into account when assessing safety. The Court insists that the statute only permits the agency to take into account the health risks and benefits of the “*product itself*” as used by individual consumers, *ante*, at 17, and, thus, that the FDA is prohibited from considering that a ban on smoking would lead many smokers to suffer severe withdrawal symptoms or to buy possibly stronger, more dangerous, black market cigarettes—considerations that the majority calls “the aggregate health effects of alternative administrative actions.” *Ibid.* But the FDCA expressly *permits* the FDA to take account of comparative safety in precisely this manner. See, e.g., 21 U. S. C. §360h(e)(2)(B)(i)(II) (no device recall if “risk of recal[l]” presents “a greater health risk than” no recall); §360h(a) (notification “unless” notification “would present a greater danger” than “no such notification”).

Moreover, one cannot distinguish in this context between a “specific” health risk incurred by an individual and an “aggregate” risk to a group. *All* relevant risk is, at bottom, risk to an individual; *all* relevant risk attaches to “the product itself”; and *all* relevant risk is “aggregate” in the sense that the agency aggregates health effects in order to determine risk to the individual consumer. If unregulated smoking will kill 4 individuals out of a typical group of 1,000 people, if regulated smoking will kill 1 out of 1,000, and if a smoking ban (because of the black market) will kill 2 out of 1,000; then these three possibilities means that in each group four, one, and two individuals, on average, will die respectively. And the risk to each

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individual consumer is 4/1000, 1/1000, and 2/1000 respectively. A “specific” risk to an individual consumer and “aggregate” risks are two sides of the same coin; each calls attention to the same set of facts. While there may be a theoretical distinction between the risk of the product itself and the risk related to the presence or absence of an intervening voluntary act (*e.g.*, the search for a replacement on the black market), the majority does not rely upon any such distinction, and the FDA’s history of regulating “replacement” drugs such as methadone shows that it has long taken likely actual alternative consumer behavior into account.

I concede that, as a matter of logic, one could consider the FDA’s “safety” evaluation to be different from its choice of remedies. But to read the statute to forbid the agency from taking account of the realities of consumer behavior either in assessing safety or in choosing a remedy could increase the risks of harm—doubling the risk of death to each “individual user” in my example above. Why would Congress insist that the FDA ignore such realities, even if the consequent harm would occur only unusually, say, where the FDA evaluates a product (a sleeping pill; a cigarette; a contact lens) that is already on the market, potentially habit forming, or popular? I can find no satisfactory answer to this question. And that, I imagine, is why the statute itself says nothing about any of the distinctions that the Court has tried to draw. See 21 U. S. C. §360c(a)(2) (instructing FDA to determine the safety and effectiveness of a “device” in part by weighing “*any* probable benefit to health . . . against *any* probable risk of injury or illness . . .”) (emphasis added).

Third, experience counsels against an overly rigid interpretation of the FDCA that is divorced from the statute’s overall health-protecting purposes. A different set of words, added to the FDCA in 1958 by the Delaney Amendment, provides that “no [food] additive shall be deemed to

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be safe if it is found [after appropriate tests] to induce cancer in man or animal.” §348(c)(3). The FDA once interpreted this language as requiring it to ban any food additive, no matter how small the amount, that appeared in any food product if that additive was ever found to induce cancer in any animal, no matter how large a dose needed to induce the appearance of a single carcinogenic cell. See H. R. Rep. No. 95–658, p. 7 (1977) (discussing agency’s view). The FDA believed that the statute’s ban mandate was absolute and prevented it from establishing a level of “safe use” or even to judge whether “the benefits of continued use outweigh the risks involved.” *Id.*, at 5. This interpretation— which in principle could have required the ban of everything from herbal teas to mushrooms— actually led the FDA to ban saccharine, see 42 Fed. Reg. 19996 (1977), though this extremely controversial regulatory response never took effect because Congress enacted, and has continually renewed, a law postponing the ban. See Saccharin Study and Labeling Act, Pub. L. 95–203, §3, 91 Stat. 1452; e.g., Pub. L. 102–142, Tit. VI, 105 Stat. 910.

The Court’s interpretation of the statutory language before us risks Delaney-type consequences with even less linguistic reason. Even worse, the view the Court advances undermines the FDCA’s overall health-protecting purpose by placing the FDA in the strange dilemma of either banning completely a potentially dangerous drug or device or doing nothing at all. Saying that I have misunderstood its conclusion, the majority maintains that the FDA “may clearly regulate many ‘dangerous’ products without banning them.” *Ante*, at 19. But it then adds that the FDA *must* ban— rather than otherwise regulate— a drug or device that “cannot be used safely for any therapeutic purpose.” *Ibid.* If I misunderstand, it is only because this linchpin of the majority’s conclusion remains unexplained. *Why* must a widely-used but unsafe device

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be withdrawn from the market when that particular remedy threatens the health of many and is thus more dangerous than another regulatory response? It is, indeed, a perverse interpretation that reads the FDCA to require the ban of a device that has no “safe” therapeutic purpose where a ban is the most dangerous remedial alternative.

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. A statute so interpreted easily “fit[s]” this, and other, drug- and device-related health problems.

III

In the majority’s view, laws enacted since 1965 require us to deny jurisdiction, whatever the FDCA might mean in their absence. But why? Do those laws contain language barring FDA jurisdiction? The majority must concede that they do not. Do they contain provisions that are inconsistent with the FDA’s exercise of jurisdiction? With one exception, see *infra*, at 24, the majority points to no such provision. Do they somehow repeal the principles of law (discussed in Part II, *supra*) that otherwise would lead to the conclusion that the FDA has jurisdiction in this area? The companies themselves deny making any such claim. See Tr. of Oral Arg. 27 (denying reliance on doctrine of “partial repeal”). Perhaps the later laws “shape” and “focus” what the 1938 Congress meant a generation earlier. *Ante*, at 20. But this Court has warned against using the views of a later Congress to construe a statute enacted many years before. See *Pension Benefit Guaranty Corporation v. LTV Corp.*, 496 U. S. 633, 650 (1990) (later history is “a hazardous basis for inferring the intent of an earlier’ Congress” (quoting *United States v. Price*, 361 U. S.

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304, 313 (1960))). And, while the majority suggests that the subsequent history “control[s] our construction” of the FDCA, see *ante*, at 20 (citation and internal quotation marks omitted), this Court expressly has held that such subsequent views are not “controlling.” *Haynes v. United States*, 390 U. S. 85, 87–88, n. 4 (1968); accord, *Southwestern Cable Co.*, 392 U. S., at 170 (such views have “‘very little, if any, significance’”); see also *Sullivan v. Finkelstein*, 496 U. S. 617, 632 (1990) (SCALIA, J., concurring) (“Arguments based on subsequent legislative history . . . should not be taken seriously, not even in a footnote.”).

Regardless, the later statutes do not support the majority’s conclusion. That is because, whatever individual Members of Congress after 1964 may have assumed about the FDA’s jurisdiction, the laws they enacted did not embody any such “no jurisdiction” assumption. And one cannot automatically *infer* an antijurisdiction intent, as the majority does, for the later statutes are both (and similarly) consistent with quite a different congressional desire, namely, the intent to proceed without interfering with whatever authority the FDA otherwise may have possessed. See, e.g., Cigarette Labeling and Advertising—1965: Hearings on H. R. 2248 et al. before the House Committee on Interstate and Foreign Commerce, 89th Cong., 1st Sess., 19 (1965) (hereinafter 1965 Hearings) (statement of Rep. Fino that the proposed legislation would *not* “erode” agency authority). As I demonstrate below, the subsequent legislative history is critically ambivalent, for it can be read *either* as (a) “ratif[ying]” a no-jurisdiction assumption, see *ante*, at 34, *or* as (b) leaving the jurisdictional question just where Congress found it. And the fact that both inferences are “equally tenable,” *Pension Benefit Guaranty Corp.*, *supra*, at 650 (citation and internal quotation marks omitted); *Johnson v. Transportation Agency, Santa Clara Cty.*, 480 U. S. 616, 672 (1987) (SCALIA, J., dissenting), prevents the majority from drawing from the

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later statutes the firm, antijurisdiction implication that it needs.

Consider, for example, Congress' failure to provide the FDA with express authority to regulate tobacco— a circumstance that the majority finds significant. See *ante*, at 21, 24–25, 32–33. But cf. *Southwestern Cable Co.*, *supra*, at 170 (failed requests do not prove agency “did not already possess” authority). In fact, Congress *both* failed to grant express authority to the FDA when the FDA denied it had jurisdiction over tobacco *and* failed to take that authority expressly away when the agency later asserted jurisdiction. See, e.g., S. 1262, 104th Cong., 1st Sess., §906 (1995) (failed bill seeking to amend FDCA to say that “[n]othing in this Act or any other Act shall provide the [FDA] with any authority to regulate in any manner tobacco or tobacco products”); see also H. R. 516, 105th Cong., 1st Sess., §2 (1997) (similar); H. R. Res. 980, reprinted in 142 Cong. Rec. 5018 (1996) (Georgia legislators unsuccessfully requested that Congress “rescind any action giving the FDA authority” over tobacco); H. R. 2283, 104th Cong., 1st Sess. (1995) (failed bill “[t]o prohibit the [FDA] regulation of the sale or use of tobacco”); H. R. 2414, 104th Cong., 1st Sess., §2(a) (1995) (similar). Consequently, the defeat of various different proposed jurisdictional changes proves nothing. This history shows only that Congress could not muster the votes necessary either to grant or to deny the FDA the relevant authority. It neither favors nor disfavors the majority's position.

The majority also mentions the speed with which Congress acted to take jurisdiction away from other agencies once they tried to assert it. See *ante*, at 22, 26–29. But such a congressional response again proves nothing. On the one hand, the speedy reply might suggest that Congress somehow resented agency assertions of jurisdiction in an area it desired to reserve for itself— a consideration that supports the majority. On the other hand, Congress'

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quick reaction with respect to *other* agencies' regulatory efforts contrasts dramatically with its failure to enact any responsive law (at any speed) after the FDA asserted jurisdiction over tobacco more than three years ago. And that contrast supports the opposite conclusion.

In addition, at least one post-1938 statute reveals quite a different congressional intent than the majority infers. See Note following 21 U. S. C. §321 (1994 ed., Supp. III) (FDA Modernization Act of 1997) (law "shall [*not*] be construed to affect the question of whether the [FDA] has any authority to regulate any tobacco product," and "[s]uch authority, if any, shall be exercised under the [FDCA] as in effect on the day before the date of [this] enactment"). Consequently, it appears that the only interpretation that can reconcile *all* of the subsequent statutes is the inference that Congress did not intend, either explicitly or implicitly, for its later laws to answer the question of the scope of the FDA's jurisdictional authority. See 143 Cong. Rec. S8860 (Sept. 5, 1997) (the Modernization Act will "not interfere or substantially negatively affect any of the FDA tobacco authority").

The majority's historical perspective also appears to be shaped by language in the Federal Cigarette Labeling and Advertising Act (FCLAA), 79 Stat. 282, 15 U. S. C. §1331 *et seq.* See *ante*, at 25–26. The FCLAA requires manufacturers to place on cigarette packages, etc., health warnings such as the following:

"SURGEON GENERAL'S WARNING: Smoking Causes Lung Cancer, Heart Disease, Emphysema, And May Complicate Pregnancy." 15 U. S. C. §1333(a).

The FCLAA has an express pre-emption provision which says that "[n]o statement relating to smoking and health, other than the statement required by [this Act], shall be required on any cigarette package." §1334(a). This pre-emption clause plainly prohibits the FDA from requiring

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on “any cigarette package” any other “statement relating to smoking and health,” but no one contends that the FDA has failed to abide by this prohibition. See, e.g., 61 Fed. Reg. 44399 (1996) (describing the other regulatory prescriptions). Rather, the question is whether the FCLAA’s pre-emption provision does *more*. Does it forbid the FDA to regulate at all?

This Court has already answered that question expressly and in the negative. See *Cipollone v. Liggett Group, Inc.*, 505 U. S. 504 (1992). *Cipollone* held that the FCLAA’s pre-emption provision does not bar state or federal regulation outside the provision’s literal scope. *Id.*, at 518. And it described the pre-emption provision as “merely prohibit[ing] state and federal rulemaking bodies from mandating particular cautionary statements on cigarette labels” *Ibid.*

This negative answer is fully consistent with Congress’ intentions in regard to the pre-emption language. When Congress enacted the FCLAA, it focused upon the regulatory efforts of the Federal Trade Commission (FTC), not the FDA. See 1965 Hearings 1–2. And the Public Health Cigarette Smoking Act of 1969, Pub. L. 91–222, §7(c), 84 Stat. 89, expressly amended the FCLAA to provide that “[n]othing in this Act shall be construed to affirm or deny the [FTC’s] holding that it has the authority to issue trade regulation rules” for tobacco. See also H. R. Conf. Rep. No. 91–897, p. 7 (1970) (statement of House Managers) (we have “no intention to resolve the question as to whether” the FTC could regulate tobacco in a different way); see also 116 Cong. Rec. 7921 (1970) (statement of Rep. Satterfield) (same). Why would one read the FCLAA’s pre-emption clause— a provision that Congress intended to limit even in respect to the agency directly at issue— so broadly that it would bar a different agency from engaging in any other cigarette regulation at all? The answer is that the Court need not, and should not, do so.

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And, inasmuch as the Court already has declined to view the FCLAA as pre-empting the entire field of tobacco regulation, I cannot accept that that same law bars the FDA's regulatory efforts here.

When the FCLAA's narrow pre-emption provision is set aside, the majority's conclusion that Congress clearly intended for its tobacco-related statutes to be the exclusive "response" to "the problem of tobacco and health," *ante*, at 35, is based on legislative silence. Notwithstanding the views voiced by various legislators, Congress itself has addressed expressly the issue of the FDA's tobacco-related authority only once— and, as I have said, its statement was that the statute was *not* to "be construed to affect the question of whether the [FDA] has any authority to regulate any tobacco product." Note following 21 U. S. C. §321 (1994 ed., Supp. III). The proper inference to be drawn from *all* of the post-1965 statutes, then, is one that interprets Congress' general legislative silence consistently with this statement.

IV

I now turn to the final historical fact that the majority views as a factor in its interpretation of the subsequent legislative history: the FDA's former denials of its tobacco-related authority.

Until the early 1990's, the FDA expressly maintained that the 1938 statute did not give it the power that it now seeks to assert. It then changed its mind. The majority agrees with me that the FDA's change of positions does not make a significant legal difference. See *ante*, at 34; see also *Chevron*, 467 U. S., at 863 ("An initial agency interpretation is not instantly carved in stone"); accord, *Smiley v. Citibank (South Dakota), N. A.*, 517 U. S. 735, 742 (1996) ("[C]hange is not invalidating"). Nevertheless, it labels those denials "important context" for drawing an inference about Congress' intent. *Ante*, at 34. In my view,

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the FDA's change of policy, like the subsequent statutes themselves, does nothing to advance the majority's position.

When it denied jurisdiction to regulate cigarettes, the FDA consistently stated *why* that was so. In 1963, for example, FDA administrators wrote that cigarettes did not satisfy the relevant FDCA definitions— in particular, the “intent” requirement— because cigarette makers did not sell their product with accompanying “therapeutic claims.” Letter to Directors of Bureaus, Divisions and Directors of Districts from FDA Bureau of Enforcement (May 24, 1963), in Public Health Cigarette Amendments of 1971: Hearings on S. 1454 before the Consumer Subcommittee of the Senate Committee on Commerce, 92d Cong., 2d Sess., 240 (1972) (hereinafter FDA Enforcement Letter). And subsequent FDA Commissioners made roughly the same assertion. One pointed to the fact that the manufacturers only “recommended” cigarettes “for smoking pleasure.” Two others reiterated the evidentiary need for “health claims.” Yet another stressed the importance of proving “intent,” adding that “[w]e have not had sufficient evidence” of “intent with regard to nicotine.” See, respectively, *id.*, at 239 (Comm’r Edwards); Letter of Dec. 5, 1977, App. 47 (Comm’r Kennedy); 1965 Hearings 193 (Comm’r Rankin); 1994 Hearings 28 (Comm’r Kessler). Tobacco company counsel also testified that the FDA lacked jurisdiction because jurisdiction “depends on . . . intended use,” which in turn “depends, *in general*, on the claims and representations made by the manufacturer.” Health Consequences of Smoking: Nicotine Addiction, Hearing before the Subcommittee on Health and the Environment of the House Committee on Energy and Commerce, 100th Cong., 2d Sess., 288 (1988) (testimony of Richard Cooper) (emphasis added).

Other agency statements occasionally referred to additional problems. Commissioner Kessler, for example, said

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that the “enormous social consequences” flowing from a decision to regulate tobacco counseled in favor of obtaining specific Congressional “guidance.” 1994 Hearings 69; see also *ante*, at 31 (quoting statement of Health and Human Services Secretary Brandt to the effect that Congress wanted to make the relevant jurisdictional decision). But a fair reading of the FDA’s denials suggests that the overwhelming problem was one of proving the requisite manufacturer intent. See *Action on Smoking and Health v. Harris*, 655 F. 2d 236, 238–239 (CA DC 1980) (FDA “comments” reveal its “understanding” that “the crux of FDA jurisdiction over drugs lay in manufacturers’ representations as revelatory of their intent”).

What changed? For one thing, the FDA obtained evidence sufficient to prove the necessary “intent” despite the absence of specific “claims.” See *supra*, at 12–14. This evidence, which first became available in the early 1990’s, permitted the agency to demonstrate that the tobacco companies *knew* nicotine achieved appetite-suppressing, mood-stabilizing, and habituating effects through chemical (not psychological) means, even at a time when the companies were publicly denying such knowledge.

Moreover, scientific evidence of adverse health effects mounted, until, in the late 1980’s, a consensus on the seriousness of the matter became firm. That is not to say that concern about smoking’s adverse health effects is a new phenomenon. See, e.g., Higginson, *A New Counterblast*, in *Out-door Papers* 179, 194 (1863) (characterizing tobacco as “‘a narcotic poison of the most active class’”). It is to say, however, that convincing epidemiological evidence began to appear mid-20th century; that the First Surgeon General’s Report documenting the adverse health effects appeared in 1964; and that the Surgeon General’s Report establishing nicotine’s addictive effects appeared in 1988. At each stage, the health conclusions were the subject of controversy, diminishing somewhat over time,

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until recently— and only recently— has it become clear that there is a wide consensus about the health problem. See 61 Fed. Reg. 44701–44706 (1996).

Finally, administration policy changed. Earlier administrations may have hesitated to assert jurisdiction for the reasons prior Commissioners expressed. See *supra*, at 27–28. Commissioners of the current administration simply took a different regulatory attitude.

Nothing in the law prevents the FDA from changing its policy for such reasons. By the mid-1990’s, the evidence needed to prove objective intent— even without an express claim— had been found. The emerging scientific consensus about tobacco’s adverse, chemically induced, health effects may have convinced the agency that it should spend its resources on this important regulatory effort. As for the change of administrations, I agree with then-JUSTICE REHNQUIST’s statement in a different case, where he wrote:

“The agency’s changed view . . . seems to be related to the election of a new President of a different political party. It is readily apparent that the responsible members of one administration may consider public resistance and uncertainties to be more important than do their counterparts in a previous administration. A change in administration brought about by the people casting their votes is a perfectly reasonable basis for an executive agency’s reappraisal of the costs and benefits of its programs and regulations. As long as the agency remains within the bounds established by Congress, it is entitled to assess administrative records and evaluate priorities in light of the philosophy of the administration.” *Motor Vehicle Mfrs. Assn. of United States, Inc. v. State Farm Mut. Automobile Ins. Co.*, 463 U. S. 29, 59 (1983) (concurring in part and dissenting in part).

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V

One might nonetheless claim that, even if my interpretation of the FDCA and later statutes gets the words right, it lacks a sense of their “music.” See *Helvering v. Gregory*, 69 F. 2d 809, 810–811 (CA2 1934) (L. Hand, J.) (“[T]he meaning of a [statute] may be more than that of the separate words, as a melody is more than the notes . . .”). Such a claim might rest on either of two grounds.

First, one might claim that, despite the FDA’s legal right to change its mind, its original statements played a critical part in the enactment of the later statutes and now should play a critical part in their interpretation. But the FDA’s traditional view was largely premised on a perceived inability to prove the necessary statutory “intent” requirement. See, e.g., FDA Enforcement Letter 240 (“The statutory basis for the exclusion of tobacco products from FDA’s jurisdiction is the fact that tobacco marketed for chewing or smoking without accompanying therapeutic claims, does not meet the definitions . . . for food, drug, device or cosmetic”). The statement, “we cannot assert jurisdiction over substance X unless it is treated as a food” would not bar jurisdiction if the agency later establishes that substance X is, and is intended to be, eaten. The FDA’s denials of tobacco-related authority sufficiently resemble this kind of statement that they should not make the critical interpretive difference.

Second, one might claim that courts, when interpreting statutes, should assume in close cases that a decision with “enormous social consequences,” 1994 Hearings 69, should be made by democratically elected Members of Congress rather than by unelected agency administrators. Cf. *Kent v. Dulles*, 357 U. S. 116, 129 (1958) (assuming Congress did not want to delegate the power to make rules interfering with exercise of basic human liberties). If there is such a background canon of interpretation, how-

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ever, I do not believe it controls the outcome here.

Insofar as the decision to regulate tobacco reflects the policy of an administration, it is a decision for which that administration, and those politically elected officials who support it, must (and will) take responsibility. And the very importance of the decision taken here, as well as its attendant publicity, means that the public is likely to be aware of it and to hold those officials politically accountable. Presidents, just like Members of Congress, are elected by the public. Indeed, the President and Vice President are the *only* public officials whom the entire Nation elects. I do not believe that an administrative agency decision of this magnitude— one that is important, conspicuous, and controversial— can escape the kind of public scrutiny that is essential in any democracy. And such a review will take place whether it is the Congress or the Executive Branch that makes the relevant decision.

* * *

According to the FDA, only 2.5% of smokers successfully stop smoking each year, even though 70% say they want to quit and 34% actually make an attempt to do so. See 61 Fed. Reg. 44704 (1996) (citing Centers for Disease Control and Prevention, Cigarette Smoking Among Adults— United States, 1993; 43 Morbidity and Mortality Weekly Report 929 (Dec. 23, 1994)). The fact that only a handful of those who try to quit smoking actually succeed illustrates a certain reality— the reality that the nicotine in cigarettes creates a powerful physiological addiction flowing from chemically induced changes in the brain. The FDA has found that the makers of cigarettes “intend” these physical effects. Hence, nicotine is a “drug”; the cigarette that delivers nicotine to the body is a “device”; and the FDCA’s language, read in light of its basic

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purpose, permits the FDA to assert the disease-preventing jurisdiction that the agency now claims.

The majority finds that cigarettes are so dangerous that the FDCA would require them to be banned (a result the majority believes Congress would not have desired); thus, it concludes that the FDA has no tobacco-related authority. I disagree that the statute would require a cigarette ban. But even if I am wrong about the ban, the statute would restrict only the agency's choice of remedies, not its jurisdiction.

The majority also believes that subsequently enacted statutes deprive the FDA of jurisdiction. But the later laws say next to nothing about the FDA's tobacco-related authority. Previous FDA disclaimers of jurisdiction may have helped to form the legislative atmosphere out of which Congress' own tobacco-specific statutes emerged. But a legislative atmosphere is not a law, unless it is embodied in a statutory word or phrase. And the relevant words and phrases here reveal nothing more than an intent not to change the jurisdictional status quo.

The upshot is that the Court today holds that a regulatory statute aimed at unsafe drugs and devices does not authorize regulation of a drug (nicotine) and a device (a cigarette) that the Court itself finds unsafe. Far more than most, this particular drug and device risks the life-threatening harms that administrative regulation seeks to rectify. The majority's conclusion is counter-intuitive. And, for the reasons set forth, I believe that the law does not require it.

Consequently, I dissent.