This case involves one of the most troubling public health problems facing our Nation today: the thousands of premature deaths that occur each year because of tobacco use. In 1996, the Food and Drug Administration (FDA), after having expressly disavowed any such authority since its inception, asserted jurisdiction to regulate tobacco products.... The FDA concluded that nicotine is a "drug" within the meaning of the Food, Drug, and Cosmetic Act (FDCA or Act),..., and that cigarettes and smokeless tobacco are "combination products" that deliver nicotine to the body.... Pursuant to this authority, it promulgated regulations intended to reduce tobacco consumption among children and adolescents.... The agency believed that, because most tobacco consumers begin their use before reaching the age of 18, curbing tobacco use by minors could substantially reduce the prevalence of addiction in future generations and thus the incidence of tobacco-related death and disease....

Regardless of how serious the problem an administrative agency seeks to address, however, it may not exercise its authority "in a manner that is inconsistent with the administrative structure that Congress enacted into law."... And although agencies are generally entitled to deference in the interpretation of statutes that they administer, a reviewing "court, as well as the agency, must give effect to the unambiguously expressed intent of Congress."...In this case, we believe that Congress has clearly precluded the FDA from asserting jurisdiction to regulate tobacco products. Such authority is inconsistent with the intent that Congress has expressed in the FDCA's overall regulatory scheme and in the tobacco-specific legislation that it has enacted subsequent to the FDCA. In light of this clear intent, the FDA's assertion of jurisdiction is impermissible....

The FDCA grants the FDA...the authority to regulate, among other items, "drugs" and "devices."...The Act defines "drug" to include "articles (other than food) intended to affect the structure or any function of the body."... It defines "device," in part, as "an instrument, apparatus, implement, machine, contrivance, . . . or other similar or related article, including any component, part, or accessory, which is . . . intended to affect the structure or any function of the body."... The Act also grants the FDA the authority to regulate so-called "combination products," which "constitute a combination of a drug, device, or biologic product."...

On August 28, 1996, the FDA issued a final rule entitled "Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents."... The FDA determined that nicotine is a "drug" and that cigarettes and smokeless tobacco are "drug delivery devices," and therefore it had jurisdiction under the FDCA to regulate tobacco products as customarily marketed -- that is, without manufacturer claims of therapeutic benefit.... First, the FDA found that tobacco products "affect the structure or any function of the body" because nicotine "has significant pharmacological effects."... Specifically, nicotine "exerts psychoactive, or mood-altering, effects on the brain" that cause and sustain addiction, have both tranquilizing and stimulating effects, and control weight.... Second, the FDA determined that these effects were "intended" under the FDCA because they
"are so widely known and foreseeable that [they] may be deemed to have been intended by the manufacturers"...; consumers use tobacco products "predominantly or nearly exclusively" to obtain these effects...; and the statements, research, and actions of manufacturers revealed that they "have 'designed' cigarettes to provide pharmaceutically active doses of nicotine to consumers"... Based on these findings, the FDA promulgated regulations concerning tobacco products' promotion, labeling, and accessibility to children and adolescents....

Respondents, a group of tobacco manufacturers, retailers, and advertisers, filed suit in United States District Court for the Middle District of North Carolina challenging the regulations.... They moved for summary judgment on the grounds that the FDA lacked jurisdiction to regulate tobacco products customarily marketed, the regulations exceeded the FDA's authority under 21 U.S.C. § 360j(e), and the advertising restrictions violated the First Amendment....

A threshold issue is the appropriate framework for analyzing the FDA's assertion of authority to regulate tobacco products. Because this case involves an administrative agency's construction of a statute that it administers, our analysis is governed by Chevron U.S.A. Inc.... 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."... In determining whether Congress has specifically addressed the question at issue, a reviewing court should not confine itself to examining a particular statutory provision in isolation. The meaning -- or ambiguity -- of certain words or phrases may only become evident when placed in context....

With these principles in mind, we find that Congress has directly spoken to the issue here and precluded the FDA's jurisdiction to regulate tobacco products.... Viewing the FDCA as a whole, it is evident that one of the Act's core objectives is to ensure that any product regulated by the FDA is "safe" and "effective" for its intended use.... The FDCA requires premarket approval of any new drug, with some limited exceptions, and states that the FDA "shall issue an order refusing to approve the application" of a new drug if it is not safe and effective for its intended purpose.... If the FDA discovers after approval that a drug is unsafe or ineffective, it "shall, after due notice and opportunity for hearing to the applicant, withdraw approval" of the drug.... The Act also requires the FDA to classify all devices into one of three categories.... Regardless of which category the FDA chooses, there must be a "reasonable assurance of the safety and effectiveness of the device."....

In its rulemaking proceeding, the FDA quite exhaustively documented that "tobacco products are unsafe," "dangerous," and "cause great pain and suffering from illness."... It found that the consumption of tobacco products "presents extraordinary health risks," and that "tobacco use is the single leading cause of preventable death in the United States."... It stated that "more than 400,000 people die each year from tobacco-related illnesses, such as cancer, respiratory illnesses, and heart disease, often suffering long and painful deaths," and that "tobacco alone kills more people each year in the United States than acquired immunodeficiency syndrome (AIDS), car accidents, alcohol, homicides, illegal drugs, suicides, and fires, combined."... Indeed, the FDA characterized smoking as "a pediatric disease,"... because "one out of every three young people who become regular smokers . . . will die prematurely as a result."....

These findings logically imply that, if tobacco products were "devices" under the FDCA, the FDA would be required to remove them from the market. Consider, first, the FDCA's provisions concerning the misbranding of drugs or devices. The Act prohibits "the introduction or delivery for introduction into
interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded."... In light of the FDA's findings, two distinct FDCA provisions would render cigarettes and smokeless tobacco misbranded devices. First, § 352(j) deems a drug or device misbranded "if it is dangerous to health when used in the dosage or manner, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof."... The FDA's findings make clear that tobacco products are "dangerous to health" when used in the manner prescribed. Second, a drug or device is misbranded under the Act "unless its labeling bears . . . adequate directions for use . . . in such manner and form, as are necessary for the protection of users," except where such directions are "not necessary for the protection of the public health."... Given the FDA's conclusions concerning the health consequences of tobacco use, there are no directions that could adequately protect consumers... Thus, were tobacco products within the FDA's jurisdiction, the Act would deem them misbranded devices that could not be introduced into interstate commerce. Contrary to the dissent's contention, the Act admits no remedial discretion once it is evident that the device is misbranded.

Second, the FDCA requires the FDA to place all devices that it regulates into one of three classifications.... Given the FDA's findings regarding the health consequences of tobacco use, the agency would have to place cigarettes and smokeless tobacco in Class III because, even after the application of the Act's available controls, they would "present a potential unreasonable risk of illness or injury."... As Class III devices, tobacco products would be subject to the FDCA's premarket approval process.... Under these provisions, the FDA would be prohibited from approving an application for premarket approval without "a showing of reasonable assurance that such device is safe under the conditions of use...." ...

The FDA's misbranding and device classification provisions therefore make evident that were the FDA to regulate cigarettes and smokeless tobacco, the Act would require the agency to ban them. In fact, based on these provisions, the FDA itself has previously taken the position that if tobacco products were within its jurisdiction, "they would have to be removed from the market because it would be impossible to prove they were safe for their intended use."...

Congress, however, has foreclosed the removal of tobacco products from the market. A provision of the United States Code currently in force states that "the marketing of tobacco constitutes one of the greatest basic industries of the United States with ramifying activities which directly affect interstate and foreign commerce at every point, and stable conditions therein are necessary to the general welfare."... More importantly, Congress has directly addressed the problem of tobacco and health through legislation on six occasions since 1965. See Federal Cigarette Labeling and Advertising Act (FCLAA), [listing 5 other statutes].... Nonetheless, Congress stopped well short of ordering a ban. Instead, it has generally regulated the labeling and advertisement of tobacco products....

The FDA apparently recognized this dilemma and concluded, somewhat ironically, that tobacco products are actually "safe" within the meaning of the FDCA. In promulgating its regulations, the agency conceded that "tobacco products are unsafe, as that term is conventionally understood."... Nonetheless, the FDA reasoned that, in determining whether a device is safe under the Act, it must consider "not only the risks presented by a product but also any of the countervailing effects of use of that product, including the consequences of not permitting the product to be marketed."... Applying this standard, the FDA found that, because of the high level of addiction among tobacco users, a ban would likely be "dangerous."...

[T]he FDA's judgment that leaving tobacco products on the market "is more effective in achieving public health goals than a ban," ibid., is no substitute for the specific safety determinations required by the
FDCA's various operative provisions. Several provisions in the Act require the FDA to determine that the product itself is safe as used by consumers. That is, the product's probable therapeutic benefits must outweigh its risk of harm. In contrast, the FDA's conception of safety would allow the agency, with respect to each provision of the FDCA that requires the agency to determine a product's "safety" or "dangerousness," to compare the aggregate health effects of alternative administrative actions. This is a qualitatively different inquiry. Thus, although the FDA has concluded that a ban would be "dangerous," it has not concluded that tobacco products are "safe" as that term is used throughout the Act.

A straightforward reading of [the FDCA] dictates that the FDA must weigh the probable therapeutic benefits of the device to the consumer against the probable risk of injury. Applied to tobacco products, the inquiry is whether their purported benefits -- satisfying addiction, stimulation and sedation, and weight control -- outweigh the risks to health from their use. To accommodate the FDA's conception of safety, however, one must read "any probable benefit to health" to include the benefit to public health stemming from adult consumers' continued use of tobacco products, even though the reduction of tobacco use is the raison d'etre of the regulations. In other words, the FDA is forced to contend that the very evil it seeks to combat is a "benefit to health." This is implausible.

In determining whether Congress has spoken directly to the FDA's authority to regulate tobacco, we must also consider in greater detail the tobacco-specific legislation that Congress has enacted over the past 35 years. Congress has enacted six separate pieces of legislation since 1965 addressing the problem of tobacco use and human health. In adopting each statute, Congress has acted against the backdrop of the FDA's consistent and repeated statements that it lacked authority under the FDCA to regulate tobacco absent claims of therapeutic benefit by the manufacturer. In fact, on several occasions over this period, and after the health consequences of tobacco use and nicotine's pharmacological effects had become well known, Congress considered and rejected bills that would have granted the FDA such jurisdiction. Under these circumstances, it is evident that Congress' tobacco-specific statutes have effectively ratified the FDA's long-held position that it lacks jurisdiction under the FDCA to regulate tobacco products. Congress has created a distinct regulatory scheme to address the problem of tobacco and health, and that scheme, as presently constructed, precludes any role for the FDA.

The dissent alternatively argues that, even if Congress' subsequent tobacco-specific legislation did, in fact, ratify the FDA's position, that position was merely a contingent disavowal of jurisdiction. Specifically, the dissent contends that "the FDA's traditional view was largely premised on a perceived inability to prove the necessary statutory 'intent' requirement." A fair reading of the FDA's representations prior to 1995, however, demonstrates that the agency's position was essentially unconditional.

Finally, our inquiry into whether Congress has directly spoken to the precise question at issue is shaped, at least in some measure, by the nature of the question presented. Deference under Chevron to an agency's construction of a statute that it administers is premised on the theory that a statute's ambiguity constitutes an implicit delegation from Congress to the agency to fill in the statutory gaps. In extraordinary cases, however, there may be reason to hesitate before concluding that Congress has intended such an implicit delegation.

This is hardly an ordinary case. Contrary to its representations to Congress since 1914, the FDA has now asserted jurisdiction to regulate an industry constituting a significant portion of the American economy. In fact, the FDA contends that, were it to determine that tobacco products provide no "reasonable assurance of safety," it would have the authority to ban cigarettes and smokeless tobacco entirely.
Owing to its unique place in American history and society, tobacco has its own unique political history. Congress, for better or for worse, has created a distinct regulatory scheme for tobacco products, squarely rejected proposals to give the FDA jurisdiction over tobacco, and repeatedly acted to preclude any agency from exercising significant policymaking authority in the area. Given this history and the breadth of the authority that the FDA has asserted, we are obliged to defer not to the agency's expansive construction of the statute, but to Congress' consistent judgment to deny the FDA this power.

We are confident that Congress could not have intended to delegate a decision of such economic and political significance to an agency in so cryptic a fashion. To find that the FDA has the authority to regulate tobacco products, one must not only adopt an extremely strained understanding of "safety" as it is used throughout the Act -- a concept central to the FDCA's regulatory scheme -- but also ignore the plain implication of Congress' subsequent tobacco-specific legislation. It is therefore clear, based on the FDCA's overall regulatory scheme and the subsequent tobacco legislation, that Congress has directly spoken to the question at issue and precluded the FDA from regulating tobacco products.

**Dissent**

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

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

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

Second, the statute's basic purpose -- the protection of public health -- supports the inclusion of cigarettes within its scope.

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.
After studying the FDCA's history, experts have written that the statute "is a purposefully broad delegation of discretionary powers by Congress"... and that, in a sense, the FDCA "must be regarded as a constitution" that "establishes general principles" and "permits implementation within broad parameters."... 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.... 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.... 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?...

"[T]he FDA has determined that once nicotine enters the body, the blood carries it almost immediately to the brain.... Nicotine then binds to receptors on the surface of brain cells, setting off a series of chemical reactions that alter one's mood and produce feelings of sedation and stimulation.... Nicotine also increases the number of nicotinic receptors on the brain's surface, and alters its normal electrical activity.... And nicotine stimulates the transmission of a natural chemical that "rewards" the body with pleasurable sensations (dopamine), causing nicotine addiction.... 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."...

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

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.

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.... 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.... 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."

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.... 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."... But it is not the case that the FDA must place cigarettes in Class III because tobacco itself "presents a potential unreasonable risk of illness or injury."... In fact, Class III applies only where regulation cannot otherwise "provide reasonable assurance of . . . safety."... 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 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....

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. . . . 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.... 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?...

Third, experience counsels against an overly rigid interpretation of the FDCA that is divorced from the statute's overall health-protecting purposes....

[T]he 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 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 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....

[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.

Consider, for example, Congress' failure to provide the FDA with express authority to regulate tobacco -- a circumstance that the majority finds significant.... 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.... 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....

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.... 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....

[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.]