No. 98-1152

In the Supreme Court of the United States

OCTOBER TERM, 1998

FOOD AND DRUG ADMINISTRATION, ET AL.,
PETITIONERS

v.

BROWN AND WILLIAMSON TOBACCO CORP., ET AL.

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

REPLY BRIEF FOR THE PETITIONERS

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A. The Food and Drug Administration seeks certiorari in this case because the court below incorrectly resolved an issue of exceptional public importance. That issue is whether FDA has authority to regulate tobacco products under the Federal Food, Drug, and Cosmetic Act (Act), 21 U.S.C. 301 *et seq.*, given FDA's findings that the nicotine in tobacco products is intended by manufacturers to have substantial effects on the structure and function of the human body, including sustaining a user's addiction and acting as a sedative, stimulant, and appetite suppressant.

In recognition of the overriding public importance of that issue, 39 States have joined a brief as amici curiae urging the court to grant FDA's petition. The States agree that review is warranted because the case is of "enormous public importance"; the decision below "misapplies important, well-settled principles of administrative law"; and the decision "fundamentally misconstrues the relationship between the States and the federal government." States' Br. 2, 3-4.

Respondents do not deny the importance of the question presented. Instead, they argue that the question is of such exceptional public importance that only Congress should resolve it. Congress, however, has already given FDA authority under the Act to regulate "drug[s]" and "device[s]." 21 U.S.C. 321(g)(1) (C) and (h)(3). And, after the most important rule-making in its history, FDA has determined that tobacco products are subject to regulation as both. The question whether FDA's determination falls within the authority that Congress has already conferred on it is uniquely one for the courts, not for Congress.

Respondents also argue that the decision of the court of appeals is correct. We address below respondents' attempts to defend the decision below. Before we do, however, we note that the decision whether to grant certiorari does not depend on how the question presented ultimately should be resolved. For purposes of granting certiorari, it is only necessary to conclude that the court below resolved "an important question of federal law that has not been, but should be, settled by this Court." Sup. Ct. R. 10(c). That standard is plainly satisfied here. The question whether FDA has authority to regulate the product that is the leading cause of preventable death in the United States, 61 Fed. Reg. 44,398 (1996), should not be left to a single regional court of appeals. A question of such momentous importance should be finally resolved by this Court.

B. Respondents contend (see, *e.g.*, Br. in Opp. 21-23) that the decision below is correct because, in their view, Congress unambiguously made clear that tobacco products as customarily marketed are not "drug[s]" or "device[s]" within the meaning of the Act. That argument cannot be reconciled with (i) the Act's controlling definitions of "drug" and "device," which define those terms to include products that are "intended to affect the structure or any function of the body," 21 U.S.C. 321(g)(1)(C) and (h)(3); (ii) FDA's detailed findings that the nicotine in tobacco products is intended by

tobacco manufacturers to have significant effects on the structure and function of the body, including satisfying a user's addiction, and acting as a sedative, stimulant, and appetite suppressant; (iii) the absence of any exemption for tobacco products from the controlling definitions of "drug" and "device," in contrast to the Act's express exemption of tobacco products from the definition of "dietary supplement," 21 U.S.C. 321(ff)(1); and (iv) the similarity between tobacco products and other products indisputably subject to FDA regulation under the Act.

1. Because the language of the "drug" and "device" definitions, when applied to FDA's findings, provides such compelling support for FDA's determination that tobacco products are covered by the Act, it is not surprising that respondents in their 28-page opposition never once quote the controlling definitions. Nor is it surprising that respondents never once directly confront FDA's specific findings about the effects of nicotine on the structure and function of the human body intended by tobacco manufacturers. The force of the controlling definitions and FDA's findings does not dissipate, however, simply because respondents refuse to acknowledge them. As we explain in our petition (at 16-18), they constitute the key to a correct decision in this case.

At the very least, the Act's definitions, when applied to FDA's findings, completely undermine respondents' argument that the present case can be resolved in their favor at step one of the analysis set forth in *Chevron U.S.A. Inc.* v. *Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984). Given those definitions and findings, it simply is not possible to conclude that Congress specifically addressed the question and clearly denied FDA authority to regulate tobacco products. And, once it is accepted that the present case must be resolved at step two of *Chevron*, the result is clear. FDA reasonably determined that tobacco products are subject to regulation under the Act.

2. FDA's judgment does not, however, rest only on the application of the plain language of the Act to FDA's thoroughly documented findings that the nicotine in tobacco products is intended by tobacco manufacturers to sustain addiction and act as a sedative, stimulant, and appetite suppressant. FDA also relied on the similarity of tobacco products to other products that are covered by the Act, including tranquilizers (such as Valium), stimulants (such as NoDoz), weight-loss products (such as Dexatrim), narcotics used to treat addiction (such as methadone), and nicotine replacement products (such as nicotine inhalers).

Respondents attempt (Br. in Opp. 13) to distinguish those products on the ground that they are marketed with therapeutic claims, while tobacco products are marketed only to provide smoking pleasure. That distinction, however, finds no support in the text of the Act or in its public health purposes. The text of the Act makes "intended" effect, not "market claims," the decisive factor. 21 U.S.C. 321(g)(1)(C) and (h)(3). Coverage of tobacco products therefore does not depend on whether a manufacturer expressly represents that tobacco products satisfy an addictive need or act as a sedative, stimulant, or appetite suppressant. While such claims would be sufficient to establish intended effect, they are not the only bases for such a finding. When, as here, manufacturers know that most consumers use tobacco products to satisfy addiction and to obtain other physiological effects, and manufacturers engineer their products to deliver the amount of nicotine necessary to sustain addiction, an intended effect on the structure and function of the body is equally apparent. Tobacco manufacturers may not escape regulation by relying on a euphemistic market claim that cigarettes are intended for smoking pleasure.[1]

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[1] Respondents refer (Br. in Opp. 25) to FDA's finding of intent as resting on the foreseeability of the effects of tobacco products. FDA's finding of intended effects, however, does not rest on foreseeability alone. As noted above, FDA also relied on evidence that tobacco manufacturers

From a public health perspective, no other result could be justified. The risks to the public health and the appropriateness of regulation under the Act exist regardless of whether the intended effect is established through market claims or by other evidence. Under respondents' view, FDA would not have been able to regulate "caine," an imitation cocaine product that was marketed as incense, or "khat," an imported stimulant that was sold without any market claim. 61 Fed. Reg. at 45,167 (explaining that those products were regulated because they were found to have intended effects on the body based on, *inter alia*, widespread consumer use of the products for their physiological effects). Indeed, if respondents were correct in their understanding of the Act, the marketers of nicotine inhalers could escape FDA regulation as long as they eliminated any therapeutic claims and marketed their products as providing "breathing pleasure." FDA correctly rejected such an approach as inconsistent with the text of the Act and its public health purposes.

3. Because the nicotine in tobacco products falls within the core of FDA's regulatory authority, respondents are also mistaken in asserting (Br. in Opp. 26) that FDA's interpretation of the Act would expand its application to products such as thermal pajamas and air conditioners. Those examples raise the question whether it would be reasonable to rely on the plain language of a definition when it leads to an application that is far removed from the ordinary understanding of the term that is being defined. See *Gustafson* v. *Alloyd Co.*, 513 U.S. 561, 574-576 (1995). This case, however, does not raise that question. In ordinary usage, no one would say that thermal pajamas and air conditioners have drug-like effects. By contrast, as internal

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have long known that consumers use tobacco products to sustain addiction and for their other physiological effects, and on evidence that manufacturers have designed their products to produce the dosage of nicotine necessary to sustain addiction, as well as evidence of actual consumer use for drug-like effects.

industry documents in the record make clear, manufacturers of tobacco products have long characterized the nicotine in tobacco products as having such effects, while denying such effects publicly. See Pet. 5.

C. 1. Respondents' remaining efforts to avoid the force of the controlling definitions and FDA's findings are also unpersuasive. For example, respondents attempt (Br. in Opp. 9-12) to draw support for their position from FDA's refusals in 1977 and in 1980 to regulate tobacco products as "drug[s]" or "device[s]." But an agency is always free to change its interpretation of a statute or its position on an issue, *Rust* v. *Sullivan*, 500 U.S. 173, 186-187 (1991); *Chevron*, 467 U.S. at 863-864, as long as it provides a reasonable explanation for the change. FDA satisfied that obligation by explaining the circumstances that led to its change in position.

First, while no major health organization had determined that nicotine was an addictive drug before 1980, by 1994 every leading scientific panel or organization had concluded that nicotine "is addictive or dependence-producing." 61 Fed. Reg. at 45,228. Second, since 1980 scientific evidence has shown that as many as 92% of all smokers and 75% of smokeless tobacco users are addicted; and slightly less than three-quarters of all cigarette smokers and more than one-half of all smokeless tobacco consumers use those products as a sedative. *Id.* at 45,233-45,234. In contrast, before 1980 evidence regarding the proportion of users who were addicted was extremely limited, and the evidence was insufficient to conclude that tobacco products were consumed primarily for their pharmacological effects. *Id.* at 45,234-45,235. Third, recently released internal industry documents show that tobacco manufacturers have long known that consumers use tobacco products primarily to sustain addiction and for their other pharmacological effects, and that manufacturers have engineered their products to deliver active doses of nicotine. *Id.* at 45,235-45,236. Almost

none of that evidence was publicly available in 1980. *Id.* at 45,237. FDA's change in position was therefore "based on an overwhelming body of new evidence that ha[d] become available since FDA last considered this issue." *Ibid.*[2]

Respondents contend (Br. in Opp. 13) that FDA's 1977 and 1980 decisions were not based on the absence of the evidence discussed above, but on a categorical view that tobacco products are not covered by the Act absent specific health claims. Respondents have misread those decisions.

In its 1977 decision rejecting a petition filed by Action on Smoking & Health (ASH) to regulate cigarettes based on ASH's assertions concerning how consumers use them, FDA stated that "FDA can assert jurisdiction over cigarettes containing nicotine (or nicotine separately) when a jurisdictional basis for doing so exists, *e.g.*, health claims made by the vendors." Letter from Donald Kennedy, FDA Commissioner, to John F. Banzhaf, III, ASH Executive Director 1 (Dec. 5, 1977). In its brief defending the decision, the government explained that FDA had concluded that cigarettes could not be regulated as drugs "in the absence of health claims by the manufacturers or vendors *or other evidence of the manufacturers' or vendors' intent to affect the bodily structure or function*." Appellees C.A. Br. at 14, *Action on Smoking & Health* v. *Harris*, No. 79-1397 (emphasis added). And, in affirming FDA's decision, the D.C. Circuit stated that "we do not read [FDA's decision] to mean either that the Commissioner will never consider evidence of consumer intent on this question or that he simply ignored

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[2] Because the evidence discussed above was not available in 1938, when the Act was passed, or in 1964, when the Surgeon General issued his report, respondents err in asserting that application of FDA's legal standard for determining coverage under the Act would have led FDA to conclude in 1938 and 1964 that tobacco products were covered. Respondents' reliance (Br. in Opp. 24-25) on the Surgeon General's 1964 Report is particularly puzzling given the report's (erroneous) conclusion that smoking is not addictive.

the evidence presented to him in this petition." *Action on Smoking & Health* v. *Harris*, 655 F.2d 236, 239 (1980). Instead, the petition failed because ASH had failed to "meet the high standard established in cases where the statutory 'intent' is derived from consumer use alone." *Ibid.*

Similarly, in rejecting ASH's second petition in 1980, FDA stated:

> ASH asserts that objective evidence other than manufacturers' claims can be material to a determination of intended use under the statutory definition. * * * We agree. * * * [E]vidence of consumer use can be one element of objective evidence to be weighed in determining if the intended purpose of a product subjects it to regulation under the Act. ASH has not established that consumers use attached cigarette filters * * * to the extent necessary to allow FDA to impute the requisite intended uses to manufacturers or vendors.

Letter from Jere E. Goyan, FDA Commissioner, to John F. Banzhaf, III, ASH Executive Director 8-9 (Nov. 25, 1980). In light of the above, we do not understand how respondents can assert (Br. in Opp. 13) that "[n]one of FDA's statements disavowing jurisdiction relied on * * * lack of evidence."

2. Respondents contend (Br. in Opp. 17) that Congress could not have intended to give FDA authority to ban tobacco products. FDA, however, has not taken any steps to ban tobacco products. The regulatory actions at issue here are FDA's prohibition on the sale of tobacco products to minors and certain access and advertising restrictions that are aimed at preventing circumvention of that prohibition. The question whether FDA has authority to ban the sale of tobacco products to adults is therefore not presented.

Respondents argue (Br. in Opp. 23-24) that, if tobacco products are covered by the Act, FDA would necessarily have to ban their sale altogether. From that premise, respondents contend that Congress could not have intended for FDA to have *any* authority over tobacco products. The

premise of respondents' argument is simply incorrect. As we note in our petition, FDA determined that, even though tobacco products cause serious adverse health consequences, their sudden withdrawal "would be dangerous," both because the health care system "would be overwhelmed by * * * treatment demands," and because of the likely development of black market tobacco products "even more dangerous than those currently marketed." 61 Fed. Reg. at 44,413. Based on those findings, FDA concluded that a ban on the sale of tobacco products to adults is neither appropriate nor required under the Act. See Pet. 3, 8-9.

Since FDA is entitled to *Chevron* deference on its interpretation of the Act, FDA's conclusion that the Act does not require it to ban the sale of tobacco products to adults must be upheld unless Congress "directly" and "unambiguously" provided otherwise. 467 U.S. at 842, 843. Far from demonstrating such a clear and unambiguous congressional intent, respondents have not identified any language in the Act that removes FDA's discretion to enforce the Act so as to avoid the harmful health consequences of a total ban. Indeed, they do not even cite the provisions of the Act and regulations on which FDA reasonably relied in weighing the health risks of permitting continued sales of tobacco products to adults against the health risks of prohibiting such sales. See Pet. 23 (citing 21 U.S.C. 360c(a)(2)(C) and 21 C.F.R. 860.7(d)(1)).

3. Respondents' reliance (Br. in Opp. 8-9, 25-26) on certain tobacco-specific statutes as evidence that FDA has no authority to regulate tobacco products is similarly misplaced. Respondents' misreading of the Federal Cigarette Labeling and Advertising Act (FCLAA), Pub. L. No. 89-92, 79 Stat. 282, which requires certain warning labels on cigarettes, see 15 U.S.C. 1333, illustrates the mistake in respondents' approach. FCLAA precludes FDA from requiring warning labels different from those prescribed by that statute. See 15 U.S.C. 1334(a) ("No statement relating to smoking and health, other than the statement required by

[Section 1333], shall be required on any cigarette package."). But the text of FCLAA does not limit FDA's authority to regulate tobacco products in any other way. In particular, it does not remotely suggest that FDA lacks authority to prohibit the sale of cigarettes to minors or to promulgate advertising restrictions designed to prevent circumvention of that prohibition. For that matter, FCLAA does not limit any authority of FDA to ban tobacco products altogether, just as it does not limit the authority of a State to do so. As the Court explained in *Cipollone* v. *Liggett Group, Inc.*, 505 U.S. 504, 518 (1992), FCLAA "merely prohibit[s] state and federal rulemaking bodies from mandating particular cautionary statements on cigarette labels." FCLAA therefore provides no support for respondents' challenge to the regulatory program at issue here. Respondents' reliance on the other tobacco-specific statutes suffers from the same basic flaw. See Pet. 27.

4. Finally, respondents contend (Br. in Opp. 27-28) that FDA's regulation of tobacco products would impermissibly intrude on state authority to regulate tobacco products. Thirty-nine States, however, strongly disagree. As the States explain in their amicus brief (at 4), "FDA regulation of tobacco products is fully authorized by the FDCA and performs a critical function in the comprehensive effort that is needed to address this important public health issue."

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For the reasons discussed above as well as those set forth in our petition, it is respectfully submitted that the petition for a writ of certiorari should be granted.

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APRIL 1999