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Tobacco-Litigation [1]

Tobacco - Litigation

No. 97-1604 (consolidated with Nos. 97-1581, 1605, 1606, & 1614)

IN THE UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

BROWN AND WILLIAMSON TOBACCO CORP., *et al.*,

Plaintiffs/Appellants/Cross-Appellees,

v.

FOOD AND DRUG ADMINISTRATION, *et al.*,

Defendants/Appellees/Cross-Appellants.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF NORTH CAROLINA

APPELLEES' PETITION FOR REHEARING AND SUGGESTION FOR REHEARING *EN BANC*

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INTRODUCTION AND RULE 40(b) STATEMENT OF PURPOSE

This case presents a question of exceptional legal and public significance: whether the Food and Drug Administration ("FDA") has the statutory authority to regulate the sale and advertising of tobacco products. FDA determined that it has jurisdiction to regulate tobacco products under the Federal Food, Drug, and Cosmetic Act ("the Act") and, based on that determination, issued regulations that restrict the sale and advertising of tobacco products to minors. The district court upheld FDA's assertion of jurisdiction. However, a divided panel of this Court has now held that, while tobacco products come within the literal language of the Act, they nevertheless are beyond the reach of FDA's authority. That holding rests on basic legal errors regarding the meaning of the Act and the role of the courts in reviewing an agency's construction of its organic statute. If those errors are not corrected, one of the most significant public health initiatives of the past 50 years will be thwarted, and the health — and ultimately the lives — of millions of people will be jeopardized. In light of the grave legal and public health consequences of the majority's decision, panel rehearing or consideration by the Court *en banc* is warranted.

Congress has given FDA broad authority to regulate "drugs" and "devices," defined by the Act to include articles "intended to affect the structure or any function of the body." After conducting the most extensive rulemaking proceeding in its history and evaluating substantial new scientific and other information that has recently come to light, FDA concluded that cigarettes and smokeless tobacco are "drugs" and "devices" under the Act because manufacturers carefully design and engineer these products to deliver to the body a highly addictive substance — nicotine — with the intent of producing quintessential pharmacological effects. The overwhelming evidence established that tobacco products cause effects that are within the very core of FDA's statutory public health mission and are hazardous to health.

The agency decided that the best way to address the unique public health problems caused by tobacco use is to limit the access of children under age 18 to cigarettes and smokeless tobacco, and to restrict the advertising that makes such products attractive to young people. FDA concluded that these restrictions, in conjunction with state and local efforts, can be expected to reduce underage tobacco use substantially. The public health consequences of such a reduction would be dramatic. More than 400,000 people die each year from tobacco-related illnesses — more than from AIDS, alcohol, car accidents, homicides, suicides, illegal drugs, and fires combined. Over 80% of adult smokers start this addictive habit as children, and nearly 3,000 young people begin smoking each day. A significant reduction in tobacco use by minors would therefore extend the lives of countless people who otherwise would face serious illnesses and death as a result of tobacco use.

This is also perhaps the most important administrative law case to come before this Court in decades. In its ruling, the panel majority failed to apply or follow the framework of *Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984), at a number of steps in its analysis. And, as the dissent points out, the majority also erred in looking for evidence that Congress delegated to FDA jurisdiction over the specific subject of tobacco products. The Act's wording and history make clear that Congress defined "drug" and "device" broadly and assigned this expert agency the authority to determine whether the scope of those definitions includes both new products and old ones for which new information arises.

Rehearing by the panel or *en banc* is thus warranted under Cir. R. 40(b) and Fed. R. App. P. 35(a) because, in counsel's judgment, the majority's failure to follow the course prescribed by the Supreme Court in *Chevron* and its misconception regarding the way Congress intended FDA to administer the Act constitute fundamental and material flaws in the decision's legal reasoning and holding. The importance of the legal and public health issues at stake is also beyond dispute.

STATEMENT

1. The Act grants FDA authority to regulate "drug[s]" and "device[s]." Rather than identifying the myriad items that may fall within either category, Congress defined these terms broadly. Thus, both drugs and devices include articles "intended to affect the structure or any function of the body." 21 U.S.C. §§ 321(g)(1)(C), (h)(3). As the Supreme Court concluded in *United States v. An Article of Drug * * * Bacto-Unidisk*, 394 U.S. 784, 798 (1969), "Congress fully intended that **the Act's coverage be as broad as its literal language indicates**," especially given "the Act's overriding purpose to protect the public health" (emphasis added). It is therefore FDA's task to decide whether a particular item falls within the scope of its "drug" or "device" authority.

In response to petitions from public health organizations asking FDA to regulate tobacco products, the agency conducted an extensive investigation, issued a proposed rule and jurisdictional analysis, and invited public comment. 60 Fed. Reg. 41314 (1995). In August 1996, FDA issued the detailed jurisdictional determination and regulations here at issue. 61 Fed. Reg. 44396 (1996). The agency found, on the basis of extensive scientific documentation in the record, that the nicotine in tobacco products "affect[s] the structure or any function of the body" because it causes and sustains addiction, results in other psychoactive effects (such as sedation and stimulation), and affects weight. *Id.* at 44630, 44664-85. In short, nicotine affects the brain in precisely the same way as other addictive drugs regulated by FDA, such as amphetamines. *Id.* at 44700. FDA also found that substantial new evidence establishes that these pharmacological effects are "intended" because: (i) a reasonable manufacturer could foresee that consumers will use tobacco to satisfy their nicotine addiction; (ii) consumers use tobacco nearly exclusively to obtain nicotine's pharmacological effects; (iii) manufacturers know that consumers use their tobacco products primarily for nicotine's pharmacological effects; and (iv) manufacturers have deliberately and carefully designed tobacco

products to deliver pharmacologically active doses of nicotine. *Id.* at 44630, 44686-45204.

Based on the voluminous record evidence showing the intended pharmacological effects of nicotine — none of which is disputed here — FDA concluded that the nicotine in cigarettes and smokeless tobacco is a drug. *Id.* at 45207. FDA further found that such products are not simply packaged nicotine, but rather "'a highly engineered product'" with "device" components that "have been carefully designed to deliver controlled, pharmacologically active doses of nicotine" to the user. *Id.* at 45209; *see also id.* at 45213-14. Thus, FDA determined that cigarettes and smokeless tobacco fall squarely within the definitions of drug, device, and "combination products." *Id.* at 45208-16.

Having concluded that these products are within its jurisdiction, FDA found that regulation of these products is warranted because of the serious threat to public health caused by tobacco use. *Id.* at 44398. Moreover, given the large number of Americans who are currently addicted to nicotine and the adverse health consequences of withdrawing tobacco products from the market, including the likely creation of black markets that would provide products that are potentially more dangerous to health *(id.* at 44405, 44413), FDA decided on a regulatory approach tailored to the unique public health threats posed by tobacco use. Because over 80% of adult smokers started this addictive habit as children, and nearly 3,000 young people begin smoking each day *(id.* at 44398, 44422), FDA concluded that the most appropriate way to address the disease and death caused by tobacco products is to prevent minors from beginning use of tobacco products. Accordingly, the agency decided that adopting regulations that both limit minors' access to these products and restrict the advertising that makes cigarettes and smokeless tobacco so attractive to young people is the most effective way to accomplish the public health goals of the Act. *Id.* at 44398-99.

2. Tobacco companies, advertisers, and retailers challenged the regulations on statutory and constitutional grounds. They moved for summary judgment, arguing *inter alia*, that Congress has

withheld from FDA the authority to regulate cigarettes and smokeless tobacco products as customarily marketed. Applying *Chevron*, the district court held that FDA properly determined that tobacco products fit within the broad "drug" and "device" definitions of the Act and, therefore, are within the agency's jurisdiction. The court rejected plaintiffs' argument that, in other statutes, Congress had effectively precluded the application of the Act's product definitions to tobacco products. The district court therefore upheld the FDA regulations limiting the availability of cigarettes and smokeless tobacco to youth. *Coyne Beahm, Inc. v. FDA*, 966 F. Supp. 1374, 1379-97, 1400 (M.D.N.C. 1997). The district court ruled, however, that FDA's advertising restrictions were not authorized by 21 U.S.C. § 360j(e)(1), which allows FDA to condition the "sale, distribution, or use" of a device. 966 F. Supp. at 1397-1400. The district court thus did not reach plaintiffs' First Amendment objections to those restrictions. *Id.* at 1400 n.33.

The district court consequently denied summary judgment to plaintiffs on the issue of FDA's jurisdiction, but granted their motion with respect to the advertising regulations. The court also stayed implementation of certain access regulations that had not yet taken effect, even though it upheld the agency's authority to issue those regulations.

3. Both sides appealed. In a split decision, this Court reversed the district court and ruled that "FDA lacks jurisdiction to regulate tobacco products." Slip op. 14. It therefore struck down **all** of the access and advertising regulations aimed at deterring minors' use of tobacco. Citing *Chevron*, 467 U.S. at 842-43, the panel majority stated that it must "examine whether Congress intended to give the FDA jurisdiction over tobacco products," because "'the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress.' * * * [O]nly if the intent of Congress is ambiguous [do] we defer to a permissible interpretation by the agency." Slip op. 17. It emphasized, however (*id.* at 17-18):

> [T]he Supreme Court has stated that "[a] precondition to deference under *Chevron* is a congressional delegation of administrative authority." *Adams Fruit Co. v. Barrett*, 494 U.S. 638, 649 (1990). Accordingly, no deference is due the FDA's construction of the Act unless it is acting within the bounds of its congressionally-established authority.

To ascertain Congress's intent, the majority looked first to the Act's language and agreed that its "definitions provisions may appear to support the government's position that tobacco products fit within the Act's definitions of drugs or devices." Slip op. 20. But according to the majority, FDA and the district court "failed to examine the literal definitions in view of the language and structure of the Act as a whole." *Ibid.* The majority thus embarked on an independent analysis of numerous provisions of the Act and concluded that tobacco products fail to fit within the overall regulatory scheme for drugs and devices. *Id.* at 21-27.

Looking at what it termed "extrinsic evidence" of legislative intent, the majority concluded that "Congress did not intend to give the FDA jurisdiction over tobacco products in 1938 when it passed the Act," as subsequent events allegedly confirm. *Id.* at 28. The majority relied on the fact that a number of bills have been introduced, but not enacted, in Congress over the years that would have explicitly given FDA jurisdiction over tobacco products. *Id.* at 33-34. The majority also concluded that other statutes that address tobacco-related matters provide "corroborating evidence" of Congress's intent that FDA not regulate tobacco products. *Id.* at 34.[1]

Judge Hall dissented. He concluded that "[t]obacco products fit comfortably in the [Act's] definitions of 'drug' and 'device,'" and, even if the "search for legislative intent [is expanded] beyond the words of the statute, the evidence falls far short of demonstrating that Congress intended to deny or withdraw jurisdiction over tobacco from the FDA." Dissent 45. He noted that "[t]he majority

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[1] The panel majority expressed no opinion on the district court's decision holding that FDA has no statutory authority to restrict the advertising of devices. Slip op. 44 n.29.

devote[d] approximately three paragraphs to the words that form the heart of the FDA's jurisdictional claim" and essentially "conced[ed] that tobacco products fit the [Act's] 'literal' definition of drug." *Id.* at 46. Judge Hall rejected the notion that allowing the continued sale (to adults) of tobacco products that FDA has found to be unsafe is at odds with the statute, thus requiring invalidation of the regulations as wholly beyond FDA's jurisdiction to adopt. He explained that "*[h]ow* the FDA has chosen to regulate tobacco has no bearing on the question of *whether* that agency has the authority to regulate it at all[.] * * * It is no argument to say the FDA can do nothing because it could have done more." *Id.* at 49.

The dissent also disagreed with the majority's other conclusions. Judge Hall concluded that, if legislative inaction "may be interpreted as 'ratification' of the FDA's prior (no tobacco jurisdiction) position," then Congress's inaction in the three years since FDA proposed the tobacco regulations "would more than offset any ratification effect to be gleaned from the earlier inaction." *Id.* at 49 n.1. Examining the Act overall, he pointed out that "Congress did not 'intend' that any particular product be included"; indeed, the Act "was written broadly enough to accommodate both new products and evolving knowledge about existing ones, and it was written that way on purpose," leaving it to the "expert — the FDA —" to decide which products fall within the scope of the Act. *Id.* at 50, 56. With respect to FDA's prior decision not to regulate tobacco products, the dissent expressed the long-standing principle that an agency is free to change its position, especially when new facts come to light, as was true here, where FDA responded "to the increasing level of knowledge about the addictive nature of nicotine and the manufacturer's deliberate design to enhance and sustain the addictive effect of tobacco products." *Id.* at 51. Judge Hall also examined in detail the other statutes considered by the majority and concluded that, far from establishing a comprehensive federal tobacco program, they address narrow concerns and do not reveal evidence of an intent to preclude

FDA from exercising jurisdiction over tobacco products. *Id.* at 52-56.[2]

ARGUMENT

The district court's opinion and Judge Hall's dissent, along with the necessarily abbreviated discussion herein, demonstrate that major administrative law issues are at stake in this case of the utmost importance to the nation's public health. Rehearing is therefore warranted.

The fundamental flaw in the majority's decision is its failure to follow the analytical course prescribed by *Chevron*. The Supreme Court explains that the initial question in analyzing an agency's construction of the statute it administers is "always" "whether Congress has **directly spoken** to the **precise** question at issue. If the intent of Congress is clear, that is the end of the matter; for the court, as well as the agency, must give effect to the **unambiguously expressed** intent of Congress." *Chevron*, 467 U.S. at 842-43 (emphases added).

The panel majority did not — and could not — find that Congress has "directly" addressed "the precise question" here, *i.e.*, whether tobacco products fall within FDA's jurisdiction. In fact, Congress has not named any particular items within FDA's jurisdiction. *See* 21 U.S.C. § 321 (defining broad categories of products such as "food," "drug," and "device"). Thus, like *Chevron* itself, this case presents a situation in which "the statute is silent or ambiguous with respect to the specific issue." 467 U.S. at 843. According to the Supreme Court, the question is then "whether [FDA's] answer is based on a permissible construction of the statute." *Ibid.* Significantly, a permissible construction need not be the only one possible, or the one that the Court itself would adopt "if the question initially had arisen in a judicial proceeding." *Id.* at 843 n.11.

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[2] Judge Hall further concluded that FDA's choice to regulate tobacco products as "combination products," under its "device" authority, was permissible. He would also reverse the district court's determination that FDA lacks authority to restrict tobacco advertising. Dissent 56-59.

Rather than examining whether FDA's interpretation of the Act is "permissible," the panel majority undertook a *de novo* analysis of numerous provisions of the Act and a wide range of "extrinsic evidence," contrary to *Chevron's* command of deference to the agency. Moreover, the majority began its analysis by stating that "no deference is due the FDA's construction of the Act unless it is acting within the bounds of its congressionally-established authority." Slip op. 18.

To the extent that the majority believed that an agency is not entitled to *Chevron* deference for its jurisdictional interpretations, its ruling is contrary to both Supreme Court and Circuit precedent. *See, e.g., Mississippi Power & Light Co. v. Mississippi ex rel. Moore*, 487 U.S. 354, 380-82 (1988) (Scalia, J., *concurring*) (collecting cases); *Board of Governors of the Univ. of N.C. v. United States Dep't of Labor*, 917 F.2d 812, 816 (4th Cir. 1990), *cert. denied*, 500 U.S. 916 (1991); *see also Oklahoma Natural Gas Co. v. FERC*, 28 F.3d 1281, 1283-84 (D.C. Cir. 1994). *Adams Fruit Co. v. Barrett*, 494 U.S. 638 (1990), on which the majority relies, addresses a different situation. At issue in *Adams* was whether state workers' compensation laws bar private rights of action under a federal migrant workers statute. The Supreme Court declined to give deference to a regulation of the Labor Department (which was not a party to the suit) because "it would be inappropriate to consult executive interpretations * * * to resolve ambiguities surrounding the scope of [a] judicially enforceable remedy." *Id.* at 650. In contrast, here FDA has interpreted the scope of its own authority under the very law Congress directed that agency to administer, and that interpretation is entitled to *Chevron* deference.

The majority's decision is likewise in error to the extent it can be read to invalidate FDA's regulations under step one of the *Chevron* analysis. Based on extensive evidence of the effects of nicotine on the function of the human body, FDA determined that tobacco products fall within the

Act's definitions of "drug" and "device." The majority did not set aside that conclusion by FDA,[3] and, indeed, it proceeded in the remainder of its opinion on the assumption that FDA was correct on the definitions' coverage of tobacco products. *See* Slip op. 20. FDA's jurisdictional determination should have been sustained under the panel majority's assumption, because "Congress fully intended that the Act's coverage be as broad as its literal language indicates." *Bacto-Unidisk*, 394 U.S. at 798.

The fallacy in the majority's approach is further revealed by its conclusion that "Congress did not intend to give the FDA jurisdiction over tobacco products in 1938 when it passed the Act." Slip op. 28. As Judge Hall notes, "[t]he [Act] was written broadly enough to accommodate both new products and evolving knowledge about existing ones, and it was written that way on purpose." Dissent 50. In fact, Congress has not identified any particular product that is included within the definition of "drug" or "device," thus necessarily leaving "a gap for [FDA] to fill." *Chevron*, 467 U.S. at 843. Further, legislation concerned with matters of science and technology, such as the Act, cannot be given a static interpretation if its public health goals are to be realized. The Supreme Court therefore recognized long ago that, given the Act's purpose to protect the public health, it should be treated "as a working instrument of government." *United States v. Dotterweich*, 320 U.S. 277, 280 (1943). *See also Brogan v. United States*, 118 S. Ct. 805, 809 (1998) (the reach of a statute's unqualified language often exceeds the precise matter to which it was originally directed).

Exemptions from the Act's individual product definitions are also instructive. *See* 61 Fed.

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[3] Although the majority did not reject FDA's finding that the effects of nicotine on the body are "intended," it stated that no other court has ever found that a product is "intended to affect" the body, without an explicit manufacturer's claim in that respect. Slip op. 20. Many courts, however, have stated that FDA may rely on evidence other than manufacturers' express claims in determining intended use. *See* 61 Fed Reg. at 45160-66 (discussing cases). And, as Judge Hall points out, "[n]o other court * * * has been confronted with the type and quantity of evidence collected during the rulemaking process in this case" — evidence that is undisputed for purposes of plaintiffs' summary judgment motion. Dissent 47; *see* Slip op. 14.

Reg. at 45254. Most notably, in 1994, Congress exempted "tobacco" from the definition of "dietary supplement." 21 U.S.C. § 321(ff)(1). Many dietary supplements had previously been regulated under FDA's "drug" authority. The explicit exemption of tobacco from dietary supplements, but not from the "drug" or "device" definitions, shows that Congress "knows how to exempt tobacco" (Dissent 52 n.3) and has chosen not to do so elsewhere in the Act.

Despite the broad and clear statutory text, the majority concluded that Congress could not have intended that FDA regulate tobacco products because, the majority believed, the regulatory program adopted by FDA for such products does not fit neatly into the Act's overall scheme for drugs and devices (*e.g.*, the device classification and cease-distribution provisions). Slip op. 20-27. The majority erred, however, in failing to defer to the expert judgment of the agency Congress charged with administering the Act concerning the appropriate regulatory approach for tobacco products. FDA interpreted the Act as providing it the discretion to decide how best to regulate these products. For example, 21 U.S.C. § 360f(a) provides that FDA "may" initiate a proceeding to ban a device after determining whether the device presents "an unreasonable and substantial risk of illness or injury." This section plainly "gives the agency ample discretion to balance the unique circumstances surrounding [tobacco] product[s]." 61 Fed. Reg. at 44413. To be sure, in determining the safety and effectiveness of a device for certain purposes under the Act, FDA is to weigh "any probable benefit to health from the use of the device against any probable risk." 21 U.S.C. § 360c(a)(2)(C). The Act, however, does not dictate what balance the agency is to strike or how its goals should be achieved.

Thus, FDA explained that, although "tobacco products are unsafe, as that term is conventionally understood, * * * the determination as to whether there is a 'reasonable assurance of safety' involves consideration of 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." 61 Fed. Reg. at 44412-13. FDA weighed the risks of leaving tobacco products on the market against the significant health risks to addicted adults that could result from the products' sudden withdrawal. *Id.* at 44413 (noting that health care systems could be overwhelmed, available pharmaceuticals may be unable to treat withdrawal symptoms of many tobacco users, and black markets with even more dangerous products could develop). The agency therefore chose not to ban tobacco products entirely, but rather to attack this public health problem when it begins, by prohibiting the sale and promotion of such products to children and adolescents. *Ibid.* Consistent with its usual practice, FDA also chose not to defer regulation of tobacco products pending classification. *Id.* at 44412.

In any event, as the dissent correctly and succinctly points out, "whether the regulations contravene the statute is a question wholly apart from whether *any* regulations could be issued." Dissent 49. FDA's decision to regulate tobacco products in a particular manner (*e.g.*, to promulgate restrictions before classifying, and not to take action under the Act's misbranding and cease distribution provisions) cannot, as a matter of law, mandate the conclusion that the agency has no jurisdiction over the product at all.[4] Rather, it raises the entirely separate question whether, because FDA has jurisdiction to regulate tobacco products, the Act compels the agency to ban such products. Thus, the majority has incorrectly used FDA's expert scientific and public health decision not to order the drastic measure of removing tobacco products from the market as a legal ground for finding that the agency has no regulatory authority whatsoever in this area.

The majority also relies heavily on FDA's prior position that it did not have jurisdiction to

[4] The fact that administrative enforcement decisions are not judicially reviewable underscores FDA's wide discretion in this area. *See Heckler v. Chaney*, 470 U.S. 821, 835 (1985).

regulate tobacco products unless the manufacturer made therapeutic claims about the product's effect on the body. But the majority fails to acknowledge the voluminous, undisputed factual record compiled in this rulemaking of the changed circumstances supporting FDA's current position. No mention is made of the new scientific evidence discussed in detail in the statement accompanying the final regulations, establishing that nicotine is highly addictive, most persons use tobacco products to satisfy that addiction, and "manufacturers design their products to sustain such addiction." Dissent 52. This is precisely the circumstance foreseen by the D.C. Circuit in *ASH v. Harris*, 655 F.2d 236, 239 (D.C. Cir. 1980), which upheld FDA's former position, but expressly recognized that FDA could obtain evidence in the future to support its jurisdiction over tobacco products. The D.C. Circuit therefore cautioned that "[n]othing in this opinion should suggest that [FDA] is irrevocably bound" by its prior declination of jurisdiction. *Id.* at 242 n.10. *See Rust v. Sullivan*, 500 U.S. 173, 186-87 (1991).[5] Indeed, the broad language of the Act contemplates that FDA will have the flexibility to adopt suitable regulatory measures as knowledge evolves.

The majority nevertheless determined that FDA's statutory authority to respond to new information and to protect public health as necessary is impliedly curtailed because Congress has not enacted bills that would have given FDA explicit jurisdiction to regulate tobacco products. In its view (Slip op. 33), this case presents a "strong case of legislative acquiescence" equal to that recognized in *Bob Jones Univ. v. United States*, 461 U.S. 574 (1983), where the Supreme Court

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[5] It is also difficult to square the majority's reasoning on this point with *Larus & Brother Co. v. FCC*, 447 F.2d 876 (4th Cir. 1971), in which this Court upheld the FCC's reversal of its earlier requirement that broadcasters provide equal time to tobacco companies to respond to anti-smoking messages. This Court noted that "[t]he fairness doctrine requires a current judgment, and it would lose its vitality if the [FCC] and licensees could not reasonably determine on facts before them that an issue is no longer controversial." *Id.* at 881. FDA should be no less entitled to change its position on an important public health matter when, as here, substantial new evidence compels it.

construed Congress's inaction as ratification of an agency's position. But unlike FDA's prior decision not to exercise jurisdiction over tobacco, *Bob Jones* involved agency action, followed immediately and consistently over many years by not only Congress's failure to act, but also affirmative manifestations of congressional acquiescence in enacted law. *Id.* at 599-602. *Cf. Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 45 (1983) (while an agency interpretation may be ratified by Congress, "even an unequivocal ratification — short of statutory incorporation * * * would not connote approval or disapproval of an agency's later decision to rescind the regulation"). Moreover, legislative inaction can just as readily imply that FDA already has authority to regulate tobacco products. *See Central Bank of Denver v. First Interstate Bank of Denver*, 511 U.S. 164, 187 (1994); *see also* Dissent 49 n.1; *United States v. Estate of Romani*, 118 S. Ct. 1478, 1487-88; *id.* at 1488-89 (1998) (Scalia, J., *concurring*).

The majority found the last indication of congressional intent to deny FDA jurisdiction over tobacco products in "tobacco-specific" legislation, such as the Federal Cigarette Labeling and Advertising Act ("Labeling Act"), Comprehensive Smokeless Tobacco Health and Education Act, and Alcohol, Drug Abuse, and Mental Health Administration Reorganization Act. According to the majority, these statutes are "comprehensive" and "address[] many of the activities that the FDA now attempts to regulate." Slip op. 41. However, Judge Hall correctly explained that these tobacco-specific statutes reveal no Congressional intent to preclude FDA action. Dissent 52; *see id.* at 53-56. Further, both the Supreme Court and this Court have given the Labeling Act a similarly narrow construction. *See Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 518 (1992); *Penn Advertising of Baltimore, Inc. v. Mayor of Baltimore*, 63 F.3d 1318, 1324 (4th Cir. 1995), *vacated and remanded on other grounds*, 518 U.S. 1030 (1996), *readopted and modified on remand*, 101 F.3d 332 (4th Cir. 1996), *cert. denied*, 117 S. Ct. 1569 (1997).

The majority's reliance on unenacted bills and the evolution of other laws extended well beyond the scope of inquiry that is proper under *Chevron* step one. Because the statutory text most directly relevant to the jurisdictional inquiry — the definitions of "drug" and "device" — unambiguously supports FDA, the other provisions of the Act and materials that the majority believed pointed in a different direction could, at most, only introduce ambiguity. It is precisely at that point that *Chevron* deference was owed to FDA.

CONCLUSION

For the foregoing reasons, this petition should be granted, and these appeals should be reheard by the panel or the Court *en banc*.

Respectfully submitted,

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SEPTEMBER 1998

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need 6, no matter how many recusals

Murnaghan
Ervin
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Michael
Motz

} any recusals?

If go en banc, Hall is eligible to sit.

Civil – prefer to go en banc – 2nd life as appeal
also, if 4th Cir takes en banc, helps to get cert no matter what result.

Tobacco - Litigation

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Subject: 4th Circuit -- background document

You guys probably know all this already, but in case its helpful

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Cynthia Dailard
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Record Type: Record

To: Cynthia A. Rice/OPD/EOP

cc:
Subject: 4th Circuit -- background document

FDA_CASE.W This may be helpful internally for background information.

4th Circuit Decision -- Background:

FDA Rule: Asserting its authority over tobacco products, the FDA in June 1996 issued regulations which prohibited the sale of tobacco products to minors. Specifically, the Rule establishes:

1) Youth Access Restrictions
- Sets minimum age of purchase at 18 years
- Requires age verification by photo ID for anyone 26 or younger
- Requires face-to-face sales (except for mail order sales)
- Bans vending machines and self-service displays except in facilities where only adults are permitted

2) Advertising Restrictions
- Bans outdoor advertising within 1000 feet of schools and public playgrounds
- Restricts advertising to black-and-white text only (publications, outdoor, point of purchase, direct mail, etc.), except in publications with a predominant adult readership or at adult only facilities
- Prohibits sale or giveaways of products like caps or gym bags that carry cigarette or smokeless tobacco product brand names or logos
- Prohibits brand-name sponsorship of sporting or entertainment events, but permits it in the corporate name

3) Point of Purchase Restrictions
- Prohibits sales of single cigarettes or "loosies"
- Bans free samples
- Sets minimum package size at 20 cigarettes
- Restricts all point of purchase advertising and labeling to black-and-white text only, except in adult only facilities

District Court: In April 1997, responding to the tobacco industry's challenge to the 1996 FDA rule, the US District Court for the Middle District of North Caroline upheld the FDA's jurisdiction to regulate tobacco products. The Judge also upheld the 1996 Rule's age and access restrictions, as well as the labeling requirements. However, the court said that the FDA did not have the authority to regulate the advertising and promotion of tobacco products.

Pending appeal, the court delayed implementation of those provisions of the FDA rule which had not yet gone into effect. Thus, only the age restriction and photo ID check requirement remained in effect; the court enjoined implementation of all of the other provisions pending further action by the court (i.e., the youth access restrictions other than age and photo ID checks, labeling and point of purchase restrictions).

4th Circuit Appeal: Immediately following the District Court decision, both the Federal government and the tobacco industry filed an appeal. The government appealed the District Court's decision that FDA lacked authority to regulate the promotion and advertising of tobacco products, as well as the Court's decision to enjoin certain provisions of the FDA rule. The industry appealed the Court's decision to affirm FDA authority.

Tobacco - litigation

Q&A on Tobacco Court Decision
8/14/987

Q: Isn't the 4th Circuit tobacco decision a major set-back for the Administration?

A: The Department of Justice is examining the opinion right now. We should be able to state our intentions shortly regarding seeking further judicial review.

The President is firmly committed to the FDA's rule and its role in protecting our children. Reaffirming the FDA authority over tobacco products is necessary to help stop young people from smoking before they start by stopping advertising targeted at children and curbing minors' access to tobacco products. Currently, nearly 90 percent of people begin smoking before age 18, despite the laws that make it illegal to sell cigarettes to minors. Almost 3,000 young people become regular smokers each day, and 1,000 will die as a result.

If the leadership in Congress would act more like parents and less like politicians, it could enact bipartisan comprehensive tobacco legislation to reaffirm the FDA's authority. Instead the GOP leadership has done the bidding of Big Tobacco.

Tobacco - Litigation

STATEMENT BY THE PRESIDENT

The Solicitor General has today authorized the filing of a petition in the Court of Appeals for the Fourth Circuit seeking rehearing en banc of the three-judge panel's decision regarding FDA regulation of tobacco products. I am firmly committed to the FDA's rule and its role in protecting our children from tobacco. Confirming the FDA's authority over tobacco products is necessary to help stop young people from smoking before they start by stopping advertising targeted at children and curbing minors' access to tobacco products. Almost 3,000 young people become regular smokers each day, and 1,000 of them will die prematurely as a result. If the leadership in Congress would act responsibly, it would enact bipartisan comprehensive tobacco legislation to confirm the FDA's authority and take this matter out of the courtroom.

smokeless tobacco, products that are (under the assumed facts) actually designed to exert powerful and quintessentially drug-like effects on the users, should escape FDA regulation because the products are marketed as essential accoutrements of a more exciting or more sophisticated lifestyle.

II

Tobacco products, then, come squarely within the plain terms of the FDCA. If the words of a statute are plain, "absent any 'indication that doing so would frustrate Congress's clear intention or yield patent absurdity, our obligation is to apply the statute as Congress wrote it.'" Hubbard v. United States, 514 U.S. 695, 703 (1995) (quoting BFP v. Resolution Trust Corporation, 511 U.S. 531, 570 (1994) (Souter, J., dissenting)), quoted in Dunn v. Commodity Futures Trading Commission, 117 S. Ct. 913, 916 (1997). The questions, then, should be: Does upholding FDA jurisdiction over tobacco frustrate clear congressional intent to withhold such jurisdiction? Is it patently absurd? Does it "conflict with any other section of the Code, or with any important state or federal interest, [or] is a contrary view suggested by the legislative history[?]" Ron Pair, 489 U.S. at 243. In other words, given the plain language used in § 321(g)(1)(C), the question should be whether the intent manifested by the words used — that tobacco products are "drugs delivery devices" subject to FDA regulation — is trumped by evidence to the contrary.

The majority seeks to show that the "context" of these readily understood words demonstrates that Congress really meant something else where tobacco is concerned. This search for context takes us into "the overall regulatory scheme created by Congress" (Maj. op. at 20) and "the history of evolving congressional regulation in the area" (Maj. op. at 19) (citation omitted), the legislative history of the FDCA and related statutes, and even congressional inaction. I will address each avenue explored by the majority.

A

The majority opens with this argument: The FDA's mandate is to prevent the marketing of any drug or device that is found to be unsafe; tobacco products are unsafe; to allow the continued sale of

cigarettes is completely at odds with such mandate; ergo, the regulations must be struck down. But whether the regulations contravene the statute is a question wholly apart from whether any regulations could be issued. How the FDA has chosen to regulate tobacco has no bearing on the question of whether that agency has the authority to regulate it at all, particularly when it is agreed that the power to regulate under the FDCA includes the power (under the assumed facts) to ban tobacco products completely. The FDA made an eminently reasonable decision to focus on preventing addiction among children while permitting sales to adults. See Fed. Reg. 44398-99, 44412-13. It is no argument to say that the FDA can do nothing because it could have done more.

B

The majority's analysis of the "extrinsic evidence" of congressional intent stands on three legs: The lack of any mention of tobacco in the statute itself or the legislative history of the 1938 Act; the FDA's consistent disavowal of any intention of taking jurisdiction over tobacco, and, concomitantly, the general assumption that the agency was right; and the series of tobacco-related statutes enacted over the last thirty years.1

The FDCA

In construing remedial legislation, we must be ever mindful of the salutary purpose of the statute.

> The historical expansion of the definition of drug, and the creation of a parallel concept of devices, clearly show, we

1 As a corollary to this third point, the majority also relies on congressional refusal to enact legislation that would have expressly given the FDA the authority it now claims. See Maj. op. at 32-34. To whatever extent this inaction may be interpreted as "ratification" of the FDA's prior (no tobacco jurisdiction) position, it would appear that Congress's continued inaction in the face of all that has followed the FDA's announcement of the proposed rule three years ago (see 60 Fed. Reg. 41314) would more than offset any ratification effect to be gleaned from the earlier inaction.

> think, that Congress fully intended that the Act's coverage be as broad as its literal language indicates--and equally clearly, broader than any strict medical definition might otherwise allow. [W]e are all the more convinced that we must give effect to congressional intent in view of the well-accepted principle that remedial legislation such as the Food, Drug, and Cosmetic Act is to be given a liberal construction consistent with the Act's overriding purpose to protect the public health . . . .

United States v. An Article of Drug . . . Bacto-Unidisk, 394 U.S. 784, 798 (1969).2 The majority starts off on the wrong foot when it asks "whether Congress intended to delegate jurisdiction over tobacco products to the FDA." Maj. op. at 19.

Congress did not "intend" that any particular product be included; as the district court noted, "[r]ather than itemize each product subject to regulation under the FDCA, Congress defined these categories broadly so that each encompasses a wide range of products." Coyne Beahm v. FDA, 966 F. Supp. at 1380. An exhaustive list of covered products was neither feasible nor necessary; effective regulation required flexibility within broad parameters.

Pointing out the obvious -- that the FDCA was not originally directed at tobacco -- gets us nowhere. No one contends that Congress foresaw in 1938 that tobacco was or might someday be included as a "drug" under the FDCA. The operative congressional intent at the outset was simply to confer broad discretionary powers on the FDA to regulate "drugs" and "devices." The FDCA was written broadly enough to accommodate both new products and evolving knowledge about existing ones, and it was written that way on purpose.

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2 Justice Frankfurter put it this way:

> The purposes of this legislation [FDCA] thus touch phases of the lives and health of people which, in the circumstances of modern industrialism, are largely beyond self-protection. Regard for these purposes should infuse construction of the legislation if it is to be treated as a working instrument of government and not merely as a collection of English words.

United States v. Dotterweich, 320 U.S. 277, 280 (1943).

FDA's Prior Position

Until the rulemaking began in 1995, the FDA had interpreted the FDCA to include tobacco products only when health claims were made. See Maj. op. at 29-30. The agency's refusal even extended to opposing citizens' petitions to regulate cigarettes on essentially the same basis that is used in the regulations today. See, e.g., ASH, 655 F.2d 236. The agency's current position is a response to the increasing level of knowledge about the addictive nature of nicotine and the manufacturer's deliberate design to enhance and sustain the additive effect of tobacco products. When the early tobacco-specific statutes were being debated in Congress, the essential link between tobacco and illness had not yet been proven to the satisfaction of all. For instance, during the floor debate on amendments to the FCLAA, Rep. Perkins stated that

> [I]t is my feeling that not one of the tobacco farmers in my district would knowingly produce any commodity which, when consumed, would cause the dread diseases which have been claimed to be associated with tobacco. But the claims . . . are not proved. Tobacco has been impeached in passion but it had not been convicted in fact. Facts, cold hard facts are the basis upon which congress should legislate.

Cigarette Labeling and Advertising: Hearings Before the House Comm. on Interstate and Foreign Commerce, 91st Cong. 16 (1969). Well, the "cold hard facts" are now in.

It is a familiar canon of administrative law that an agency can change its view of what action is possible or necessary, particularly when new facts come to light. See Rust v. Sullivan, 500 U.S. 173, 186-87 (1991) ("An agency . . . must be given latitude to adapt its rules and policies to the demands of changing circumstances") (citations and internal quotation marks omitted). Even when upholding the FDA's earlier denial of its own power to regulate tobacco, the court added the following caveat:

> Nothing in this opinion should suggest that the[FDA] is irrevocably bound by any long-standing interpretation and representations thereof to the legislative branch. An admin-

> istrative agency is clearly free to revise its interpretations.... The very structure of the [FDCA] which the FDA must administer, moreover, calls for case-by-case analysis. Should an agency depart from its prior interpretations, however, it must provide a reasoned explanation for its action. . . . [citations omitted].

ASH, 655 F.2d at 242 n.10.

Under the facts found by the FDA during the rulemaking process, it is now a scientific certainty that nicotine is extremely addictive and that a large majority of tobacco users use the product to satisfy that addiction; even more important to my mind is the new evidence that the manufacturers design their products to sustain such addiction. The administrative record in this case is a perfect illustration of why an agency's opportunity to adopt a new position should remain open.

The Tobacco Statutes

As products of the democratic process, each tobacco-specific statute is a balance of health, economic, and other concerns. The majority cites this body of legislation as "corroborating evidence of established congressional intent" to withhold jurisdiction over tobacco from the FDA. Maj. op. at 34. Again, I think the majority's approach ignores the fundamental source of intent, the words of the statute itself. Nevertheless, closer examination of these tobacco statutes reveals that they form something less than Congress's "comprehensive program" to address the tobacco problem. Absent a discernable intent to exclude future FDA action,3 that these statutes were written with knowledge that the FDA foreswore jurisdiction over tobacco does not supply that intent.

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3 Congress certainly knows how to exempt tobacco. The only mention of tobacco in the FDCA was added in 1994 to explicitly remove tobacco from the new exemption of "dietary supplements" from the definition of "drug." See Pub. L. No. 103-407, § 3(a), 108 Stat. 4325, 4327 (codified at 21 U.S.C. § 321(ff)). The criminal laws regarding narcotics incorporate the definition of "drug" found in the FDCA, see 21 U.S.C. § 802(12), but the definition of "controlled substance," which includes "a drug," specifically excludes tobacco. See 21 U.S.C. § 802(6).

The first in this series, the Federal Cigarette Labeling and Advertising Act (FCLAA),4 was enacted in response to the Surgeon General's groundbreaking 1964 report linking smoking to health problems. The companies describe it as a statute that "set the boundaries of the federal regulatory role," "clearly expresses a congressional intent that precludes FDA jurisdiction over tobacco products," "embodied the view that Congress, itself, should retain all policy making authority as to tobacco, even in areas open to regulation," "ratified the established understanding that FDA does not have jurisdiction over tobacco products," "ruled out any later reading of the FDCA as an 'implicit' delegation to FDA . . . of authority to decide whether or how to regulate tobacco products and whether to ban them." Companies' Opening br. 13, 18-20. An examination of the statute reveals something considerably more modest, something that will not bear anything approaching the weight placed upon it by the companies or the majority.

The majority's focus is § 1331, which reads:

> It is the policy of the Congress, and the purpose of this chapter, to establish a comprehensive Federal program to deal with cigarette labeling and advertising with respect to any relationship between smoking and health, whereby--
>
> (1) the public may be adequately informed about any adverse health effects of cigarette smoking by inclusion of warning notices on each package of cigarettes and in each advertisement of cigarettes; and
>
> (2) commerce and the national economy may be (A) protected to the maximum extent consistent with this declared policy and (B) not impeded by diverse, nonuniform, and confusing cigarette labeling and advertising regulations with respect to any relationship between smoking and health.

This is a far cry from a comprehensive federal tobacco program; it is

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4 The Comprehensive Smokeless Tobacco Health and Education Act, 15 U.S.C. §§ 4401-4407, more or less mirrors the FCLAA.

little more than a mild response to one of the earliest official recognitions of an emerging health issue.

The narrowness of the FCLAA was emphasized in Banzhaf v. FCC, 405 F.2d 1082 (D.C. Cir. 1968), where the court was confronted with a post-FCLAA ruling by the FCC that required radio and television stations that carried cigarette commercials to devote significant broadcast time to permit the case to be made against smoking. Then, as they do today, the tobacco companies argued that the FCLAA embodied a clear congressional intent to preclude intrusions into the regulation of tobacco by any agency. See id. at 1088. Judge Bazelon, however, saw things differently:

> [T]here are positive indications that Congress's "comprehensive program" was directed at the relatively narrow specific issue of regulation of "cigarette labeling and advertising." . . . Nothing in the [FCLAA] indicates that Congress had any intent at all with respect to other types of regulation by other agencies-- much less that it specifically meant to foreclose all such regulation. If it meant to do anything so dramatic, it might reasonably be expected to have said so directly . . . .

Id. at 1089 (footnotes omitted) (quotations in original).5 The next thirty years would see several more small steps that, even when considered together, fall far short of a comprehensive program, and even shorter of a demonstration that Congress intended to preclude the exercise of jurisdiction now being asserted by the FDA.

Following the FCLAA, the next step in what the companies characterize as Congress's ongoing program was the Public Health Cigarette Smoking Act of 1969, which amended the FCLAA in response to proposed incursions into the field by the FCC and FTC by way of proposed regulations that would have restricted tobacco advertising.

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5 In Cippolone v. Liggett Group, Inc., 505 U.S. 504, 514 (1992), the Court described the purposes of the FCLAA as informing the public of the health risks and "protecting the national economy from the burden imposed by diverse, nonuniform, and confusing cigarette labeling advertising regulations" [footnote omitted].

Again, Congress addressed only advertising, this time in the electronic media, and short-circuited the roles proposed by the agencies for themselves.

Thirteen years later, Congress enacted the Alcohol and Drug Abuse Amendments of 1983, which simply directs the Secretary of HHS to report to Congress every three years on "the health consequences of drug abuse in the United States [and] current research findings made with respect to drug abuse, including current findings on . . . the addictive property of tobacco" and to include recommendations for "legislation and administrative action as the Secretary may deem appropriate." 42 U.S.C. § 290aa-2(b). This does not, as the majority asserts, "evidence[ ] Congress' . . . intent to retain control over further regulatory action." Maj. op. at 39. It is more an acknowledgment that because the HHS (and the FDA), as the experts in the complex field of drug abuse, had and would continue to have a crucial role to play, the Secretary was required to ask Congress for any additional tools it needed get to perform that role effectively.

The Alcohol, Drug Abuse, and Mental Health Administration Reorganization Act of 1992 [ADAMHA], the last brick in the purported congressional tobacco program, provides financial incentives to the States to enforce their own restrictions on access to tobacco by minors. The majority argues that the FDA regulations would conflict with this congressional determination that the States should take an active role in addressing the youth access problem because the FDCA preempts any different restrictions on devices. See 21 U.S.C. § 360k(a). This overstates the case.

ADAMHA restructured block grant programs aimed at substance abuse and mental health services; only a few provisions relate to underage smoking. See 42 U.S.C. § 300x-26. ADAMHA does not demonstrate an intent on Congress's part that the states "take the primary role" in addressing the problem of underage smoking, and it certainly does not "establish" a regulatory role for the states. Maj. op. at 42-43. Although the FDA's proposed regulations would preempt some state laws, the exercise of FDA authority over tobacco would not "prohibit the States from addressing the problem of youth access." Id. The proposed rule can co-exist with most of the states' separate laws prohibiting sales to minors and imposing other restrictions on

tobacco sales. Even the few more stringent state or local restrictions that are preempted by the FDA's proposed regulations (see 61 Fed. Reg. 44548-50) might qualify for an exemption from preemption, thereby further minimizing conflicts. See 21 U.S.C. § 360k(b). An overlap between two regulatory systems does not require wholesale jettisoning of one in favor of the other. See Connecticut Nat'l Bank v. Germain, 503 U.S. 249, 253 (1992) ("Redundancies across statutes are not unusual events in drafting, and so long as there is no 'positive repugnancy' between two laws, a court must give effect to both") (internal citation omitted).

C

Tobacco is different from the articles commonly associated with the word "drugs," the FDA regulations are indeed the result of turn-around in agency thinking, and tobacco was most probably not on anyone's mind when the FDCA was enacted. But the FDCA was broadly worded by design. In an area in which complex new products (and old products, seen in the light of new evidence) pose the potential for grievous harm, Congress deemed it necessary to delegate to an expert – the FDA – the job of monitoring drugs. Cigarettes and smokeless tobacco clearly fit within the literal terms of the FDCA. Absent a showing that following these statutory terms would be absurd or somehow frustrate congressional intent, we are bound to uphold FDA jurisdiction.

The FDA's denials that it had any authority over tobacco were certainly part of the background against which Congress passed tobacco-related legislation in the thirty years following the Surgeon General's 1964 report, but this series of statutes is hardly an argument for "legislative ratification" (Maj. op. at 32 n.18) of the FDA's prior position that the agency was powerless to act. It is agreed, moreover, that an agency is permitted to change its mind, particularly in response to new facts, so the real question is whether all that has gone before – the tobacco statutes, the consistent denials by the FDA – is sufficient to demonstrate a clear intent on Congress's part to preclude FDA jurisdiction. The evidence offered by the companies falls far short.

III

Having decided that the FDA has no jurisdiction over tobacco products, the majority had no reason to address whether cigarettes and

smokeless tobacco were "devices" and whether the choice of regulatory regime -- as a combination product, pursuant to the device authorities -- was permissible. I agree with and adopt the district court's reasoning on these points entirely. See Coyne Beahm, 966 F. Supp. at 1393-97.

IV

Another issue not reached by the majority is whether the FDA may restrict the advertising of tobacco products.6 On this point, I disagree with the district court's conclusion that the advertising regulations exceeded the FDA's statutory authority.

The FDA found that "cigarette and smokeless tobacco use begins almost exclusively in childhood and adolescence." 61 Fed. Reg. 45239. Minors are particularly vulnerable to Madison Avenue's exhortations, plastered on racing cars and outfield fences, to be cool and smoke, be manly and chew, and the FDA found "compelling evidence that promotional campaigns can be extremely effective in attracting young people to tobacco products." Id. at 45247.7 The FDA chose to attack the problem by attempting to reduce the pressures to start using tobacco in the first place.

The pertinent portion of the of the 1976 Medical Device Amendments, 21 U.S.C. § 360j(e), provides:

> The Secretary may by regulation require that a device be restricted to sale, distribution, or use . . . [by prescription]

6 In view of its ruling on statutory grounds, it was unnecessary for the district court to reach the companies' constitutional objections to the advertising restrictions. Coyne Beahm, 966 F. Supp. at 1400 n.33. Because neither party has briefed the First Amendment issue, I do not discuss it here.

7 For example, one study cited in the rulemaking record found that "30% of 3-year-olds and 91% of 6-year-olds could identify Joe Camel as a symbol for smoking." Id. at 45246 (citing Fischer, Schwartz & Richards, Brand Logo Recognition by Children Aged 3 to 6 Years. Mickey Mouse and Old Joe the Camel, Journal of the American Medical Association, 1991).

> or upon such other conditions as the Secretary may prescribe in such regulation, if, because of its potentiality for harmful effect or the collateral measures necessary to its use, the Secretary determines that there cannot otherwise be reasonable assurance of its safety and effectiveness.

The FDA relies on this section as authority for the regulations restricting the advertising of tobacco products, its rationale being that the authority to restrict the "sale" of or to impose "other conditions" on a product includes within it the authority to restrict the means by which such sales are generated.

Examples of obviously permissible restrictions of the "sale" of a product are regulations regarding where, when, by whom, and to whom a product can be sold. But is a restriction on advertising a restriction of the "sale" of a product? The district court found that the plain meaning of the words precluded advertising restrictions: "Both as ordinarily defined and as used in the phrase 'may . . . be restricted to sale, distribution, or use,' the word 'sale' does not encompass the advertising or promotion of a product." Coyne Beahm, 966 F. Supp. at 1398 (footnote omitted). But even the dictionary entry cited in the district court's opinion defines "sale" as "the act of selling"; the term "sales" is defined as "[a]ctivities involved in the selling of goods and services." Id. at n.23. Under a Chevron step-two analysis — "if the statute is silent or ambiguous with respect to the specific issue, the question is whether the agency's answer is based on a permissible construction of the statute[.]" Chevron, 467 U.S. at 843 (footnote omitted) — we need only find that the agency construction is a reasonable one, not the best one. See id. at n.11. I believe the term "sale" is ambiguous enough to encompass the concept of "offer for sale."

The district court also distilled an intent to withhold the authority asserted by the FDA from the use of the terms "offer for sale" and "advertising" elsewhere in 1976 legislation. See Coyne Beahm, 966 F. Supp. at 1398-99. However, while the "language and design of the statute as a whole" (K Mart Corp. v. Cartier, Inc., 486 U.S. 281, 291 (1988)) might raise a question about the extent of the FDA's authority in this area, it does not mandate a conclusion that Congress intended to foreclose the FDA from imposing advertising restrictions. There is simply no conclusive evidence of intent either way; the phrase is sim-

ply ambiguous, both in isolation and with reference to the context in which it is used.

The term "sale, distribution and use," which is used only once in the entire FDCA, can reasonably be construed to include all aspects of a product's journey from the factory to the store and to the home. As I have noted above, tobacco is different from the run-of-the-mine drugs and devices in the FDA's bailiwick, and the nature of the differences dictate new approaches to fight the dangers posed. Because the precise approach chosen might not have been considered by the drafters of the statute does not necessarily preclude it. The interpretation is a reasonable one and, therefore, we must defer to the agency.

V

I would affirm the district court's judgment to the extent that it denies summary judgment to the tobacco companies on the issues of the FDA's authority to regulate tobacco products under the FDCA and to regulate such products as "combination products." I would vacate the judgment below to the extent it grants summary judgment to the companies on the issue of the FDA's authority to regulate the advertising of tobacco products.

Tobacco - Litigation

PUBLISHED

UNITED STATES COURT OF APPEALS

FOR THE FOURTH CIRCUIT

BROWN & WILLIAMSON TOBACCO CORPORATION; LORILLARD TOBACCO COMPANY; PHILIP MORRIS, INCORPORATED; RJ REYNOLDS TOBACCO COMPANY,
Plaintiffs-Appellants,

and

COYNE BEAHM, INCORPORATED; LIGGETT GROUP, INCORPORATED,
Plaintiffs,

v.

FOOD & DRUG ADMINISTRATION; DAVID A. KESSLER, M.D., Commissioner of Food and Drugs,
Defendants-Appellees,

No. 97-1604

ATTORNEYS GENERAL OF THE STATE OF MINNESOTA; STATE OF ALASKA; STATE OF ARIZONA; STATE OF ARKANSAS; STATE OF COLORADO; STATE OF CONNECTICUT; STATE OF FLORIDA; STATE OF HAWAII; STATE OF ILLINOIS; STATE OF INDIANA; STATE OF IOWA; STATE OF LOUISIANA; STATE OF KANSAS; STATE OF MAINE; STATE OF MARYLAND; STATE OF MASSACHUSETTS; STATE OF MICHIGAN; STATE OF MISSISSIPPI; STATE OF MISSOURI; STATE OF MONTANA; STATE OF NEVADA;

Argued: June 9, 1998

Decided: August 14, 1998

Before WIDENER, Circuit Judge, HALL, Senior Circuit Judge, and MICHAEL, Senior United States District Judge for the Western District of Virginia, sitting by designation.

Reversed by published opinion. Judge Widener wrote the opinion, in which Senior Judge Michael joined. Senior Judge Hall wrote a dissenting opinion.

COUNSEL

ARGUED: Gerald Cooper Kell, Civil Division, UNITED STATES DEPARTMENT OF JUSTICE, Washington, D.C., for Government. Richard Melvyn Cooper, WILLIAMS & CONNOLLY, Washington, D.C.; Larry Bruce Sitton, SMITH, HELMS, MULLISS & MOORE, L.L.P., Greensboro, North Carolina; John L. Oberdorfer, PATTON BOGGS, L.L.P., Washington, D.C.; William C. McLeod, COLLIER, SHANNON, RILL & SCOTT, Washington, D.C., for Private Parties. ON BRIEF: Frank W. Hunger, Assistant Attorney General, Walter C. Holton, Jr., United States Attorney, Stephen W. Preston, Deputy Assistant Attorney General, George J. Phillips, Counselor to the Assistant Attorney General, Eugene M. Thirolf, Douglas N. Letter, Scott R. McIntosh, Christine N. Kohl, Civil Division, UNITED STATES DEPARTMENT OF JUSTICE, Washington, D.C.; Margaret Jane Porter, Chief Counsel, Karen E. Schifter, Patricia J. Kaeding, Associate Chief Counsel, FOOD & DRUG ADMINISTRATION, Rockville, Maryland, for Government. Robert R. Marcus, SMITH, HELMS, MULLISS & MOORE, L.L.P., Greensboro, North Carolina; Norwood Robinson, ROBINSON & LAWING, L.L.P., Winston-Salem, North Carolina; John R. Jordan, Jr., JORDAN, PRICE, WALL, GRAY & JONES, Raleigh, North Carolina; John F. Fithian, G. Kendrick Macdowell, PATTON BOGGS, L.L.P., Washington, D.C.; Eric Rowe, PATTON BOGGS, L.L.P., Greensboro, North Car-

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OPINION

WIDENER, Circuit Judge:

On August 28, 1996, the Food and Drug Administration (FDA) published a final rule entitled "Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents." 61 Fed. Reg. 44,396 (1996) (to be codified at 21 C.F.R. pt. 801, et al.). In general, this rule set out regulations restricting the sale and distribution of cigarettes and smokeless tobacco (collectively referred to as tobacco products) to minors and limiting the advertising and promotion of tobacco products. Plaintiffs (cigarette and smokeless tobacco manufacturers, convenience store retailers, and advertisers) filed these consolidated actions in federal district court, challenging the FDA's jurisdiction over tobacco products and seeking declaratory and injunctive relief.1 Plaintiffs then filed a

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1 When the complaint was filed on August 10, 1995, the FDA had only issued a Notice of Proposed Rulemaking. 60 Fed. Reg. 41,314 (1995). Following a comment period, the FDA adopted the proposed rule in modified form. 61 Fed. Reg. 44,396 (1996). Unless noted otherwise, all references in this opinion are to the final version of the rule published in the Federal Register on August 28, 1996. Where italics appear here within a quotation, they have been added for emphasis unless otherwise indicated.

motion for summary judgment in the district court, alleging that, as a matter of law: (1) Congress has withheld from the FDA the jurisdiction to regulate tobacco products as marketed by plaintiffs; and (2) the Federal Food, Drug, and Cosmetic Act (Act) does not permit the FDA to regulate tobacco products either as drugs or as devices. In denying plaintiffs' motion for summary judgment in part and granting the motion in part, the district court held that Congress did not "[intend] to withhold from FDA" the jurisdiction to regulate tobacco products. Coyne Beahm, Inc. v. FDA, 966 F. Supp. 1374, 1388 (M.D.N.C. 1997). The district court also concluded that the FDA had authority to regulate tobacco products under the device provision of the Act, but disapproved the FDA's restrictions on advertising as inconsistent with its statutory authority. Coyne Beahm, 966 F. Supp. at 1393-1400. Finally, the district court stayed implementation of the majority of the FDA's regulations pending appeal.2 Coyne Beahm, 966 F. Supp. at 1400-01. The district court certified its order for immediate interlocutory appeal pursuant to 28 U.S.C. § 1292(b), Coyne Beahm, 966 F. Supp. at 1401, and by order dated May 13, 1997, this court granted the § 1292(b) petitions for immediate appeal filed by two of the plaintiff groups and the FDA. In addition, the FDA had filed its Notice of Appeal dated May 2, 1997 from the partial injunction granted by the district court. Jurisdiction over the consolidated appeals is proper in this court under 28 U.S.C. §§ 1292(a)(1) and 1292(b).

Because this case arises from a motion for summary judgment, we review the judgment of the district court de novo. Myers v. Finkle, 950 F.2d 165, 167 (4th Cir. 1991). For purposes of these appeals, plaintiffs do not dispute the factual findings of the FDA. Based on our review of the record and the relevant legal authorities, we are of opinion that the FDA lacks jurisdiction to regulate tobacco products. For the reasons set forth below, all of the FDA's August 28, 1996 regulations of tobacco products are thus invalid. Accordingly, we reverse the judgment of the district court.

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2 The district court left in place the FDA's proof of age requirement for tobacco sales and the restrictions on sales to persons under age 18, which had already gone into effect. Coyne Beahm, 966 F. Supp. at 1400. However, all 50 States have already banned the sale of tobacco to minors under state law. See 61 Fed. Reg. at 44,419 (citing a joint letter from 25 state attorneys general and other comments submitted to the FDA).

I. FDA's Asserted Basis for Jurisdiction

The FDA3 has authority to regulate products only if they fall within one of the categories defined by Congress in the Act.4 In the jurisdictional determination attached to its August 28, 1996 regulations, the FDA asserted jurisdiction over tobacco products under the drug5 and device6 definitions in the Act. 61 Fed. Reg. at 44,628. According to the FDA, tobacco products fit within these definitions because they are "intended to affect the structure or any function of the body." More specifically, the FDA concluded that tobacco products are "combination products consisting of nicotine, a drug that causes addiction and other significant pharmacological effects on the human body, and device components that deliver nicotine to the body."7 61

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3 On most occasions, the Act refers to the authority of the Secretary of the Department Health and Human Services (HHS) to take certain actions. However, the Secretary acts through the Commissioner of Food and Drugs. 21 U.S.C. § 393(d)(2). For simplicity, we will refer to any legislative delegation as if made directly to the FDA.

4 The categories of products subject to regulation by the FDA are food, drugs, devices, and cosmetics. 21 U.S.C. § 321.

5 The Act defines "drug" in pertinent part as "articles (other than food) intended to affect the structure or any function of the body of man or other animals." 21 U.S.C. § 321(g)(1)(C).

6 In relevant part, "device" is defined as an article which is:

> intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes

21 U.S.C. § 321(h)(3).

7 A combination product is described as a product that contains a combination of a drug, device, or biological product. 21 U.S.C. § 353(g). Neither party contends that tobacco products contain any "biological product," as that term is used in the Act. See 42 U.S.C. § 262(I) (defining a biological product as a "virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or analogous product . . . applicable to the prevention, treatment, or cure of a disease or condition of human beings").

Fed. Reg. at 44,628, 44,649-650. Based on its classification of tobacco products as combination products, the FDA claimed that it could exercise its discretion in deciding whether the drug provisions or device provisions of the Act should apply. 61 Fed. Reg. at 44,400. Although finding that tobacco products function primarily as drugs, 61 Fed. Reg. at 45,209-218, the FDA concluded that tobacco products are most properly regulated under the device provisions of the Act, in particular the restricted devices section, 21 U.S.C. § 360j(e).8 61 Fed. Reg. at 44,400. The FDA's jurisdictional determination encompasses over 600 pages in the Federal Register; however, its basic premise can be fairly summarized in one sentence. That is, the FDA asserted jurisdiction over tobacco products based on its conclusion that tobacco products fit within the literal definitions of drug and device as set forth in the Act. In short, the FDA's inquiry began and ended with the definitions section of the Act.

We are of opinion that the FDA's limited, mechanistic inquiry is insufficient to determine Congress' intent. Therefore, as directed by Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc., 467 U.S. 837 (1984), we employ the traditional tools of statutory construction to ascertain congressional intent regarding whether the FDA has authority to regulate tobacco products.

II. Jurisdictional Analysis

We begin with the basic proposition that agency power is "not the

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8 Section 360j(e) provides in relevant part:

> (1) The Secretary may by regulation require that a device be restricted to sale, distribution, or use –
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> . . .
>
> (B) upon such other conditions as the Secretary may prescribe in such regulation,
>
> if, because of its potentiality for harmful effect or the collateral measures necessary to its use, the Secretary determines that there cannot otherwise be reasonable assurance of its safety and effectiveness.

21 U.S.C. § 360j(e).

power to make law. Rather, it is 'the power to adopt regulations to carry into effect the will of Congress as expressed by the statute.'" Ernst & Ernst v. Hochfelder, 425 U.S. 185, 213-14 (1976) (quoting Manhattan Gen. Equip. Co. v. Commission, 297 U.S. 129, 134 (1936)). Thus, our initial inquiry is whether Congress intended to delegate to the FDA authority to regulate tobacco products as "customarily marketed."[9] The district court framed the issue as "whether Congress has evidenced its clear intent to withhold from FDA jurisdiction to regulate tobacco products as customarily marketed." Coyne Beahm, 966 F. Supp. at 1380. However, we are of opinion that the issue is correctly framed as whether Congress intended to delegate such jurisdiction to the FDA. See Bowen v. Georgetown Univ. Hosp., 488 U.S. 204, 208 (1988) (stating that "[i]t is axiomatic that an administrative agency's power to promulgate legislative regulations is limited to the authority delegated by Congress"); INS v. Chadha, 462 U.S. 919, 953 n.16, 955 n.19 (1983) (providing that agency action "is always subject to check by the terms of the legislation that authorized it; and if that authority is exceeded it is open to judicial review" and "Congress ultimately controls administrative agencies in the legislation that creates them"). This fundamental misconception by the district court of the principal issue in the case unavoidably skewed the remainder of its analysis.

Applying the principles set forth by the Supreme Court in Chevron, we examine whether Congress intended to give the FDA jurisdiction over tobacco products. Under Chevron, we first consider the intent of Congress because "[i]f the intent of Congress is clear, that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress." Chevron, 467 U.S. at 842-43. It is only if the intent of Congress is ambiguous that we defer to a permissible interpretation by the agency. Chevron, 467 U.S. at 843. And we note, with emphasis, that the Supreme Court has stated that "[a] precondition to deference under Chevron is a congressional delegation of administrative authority." Adams Fruit Co. v.

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9 Plaintiffs use the term "customarily marketed" in their briefs to indicate tobacco products marketed with customary claims such as smoking pleasure as opposed to tobacco products marketed with specific therapeutic claims such as weight loss. Unless indicated otherwise, all references in this opinion are to tobacco products as customarily marketed.

Barrett, 494 U.S. 638, 649 (1990). Accordingly, no deference is due the FDA's construction of the Act unless it is acting within the bounds of its congressionally-established authority. If the court can ascertain Congress' intent on a particular question by applying the traditional rules of statutory construction, then it must give effect to that intent. Chevron, 467 U.S. at 843 n.9; see also Cabell Huntington Hosp., Inc. v. Shalala, 101 F.3d 984, 986 (4th Cir. 1996) (stating that "[t]he goal of statutory interpretation is to implement congressional intent"). We also note that ascertaining congressional intent is of particular importance where, as here, an agency is attempting to expand the scope of its jurisdiction. See, e.g., Adams Fruit Co., 494 U.S. at 650 (quoting Federal Maritime Comm'n v. Seatrain Lines, Inc., 411 U.S. 726, 745 (1973)) (warning that "an agency may not bootstrap itself into an area in which it has no jurisdiction"); ACLU v. FCC, 823 F.2d 1554, 1567 n. 32 (D.C. Cir. 1987) (stating that "[w]hen an agency's assertion of power into new arenas is under attack, therefore, courts should perform a close and searching analysis of congressional intent, remaining skeptical of the proposition that Congress did not speak to such a fundamental issue"), cert. denied, 485 U.S. 959 (1988); Hi-Craft Clothing Co. v. NLRB, 660 F.2d 910, 916 (3d Cir. 1981) (noting that "[t]he more intense scrutiny that is appropriate when the agency interprets its own authority may be grounded in the unspoken premise that government agencies have a tendency to swell, not shrink, and are likely to have an expansive view of their mission").

Although the task of statutory construction generally begins with the actual language of the provision in question, Mead Corp. v. Tilley, 490 U.S. 714, 722 (1989), the inquiry does not end there.10 The Supreme Court has often emphasized the crucial role of context as a tool of statutory construction. For example, the Court has stated that when construing a statute, courts "must not be guided by a single sentence or member of a sentence, but look to the provisions of the whole

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10 In fact, if application of the plain language of a statute "would produce a result demonstrably at odds with the intent of Congress . . . the intent of Congress rather than the strict language controls." Maryland State Dep't of Educ. v. U.S. Dep't of Veterans Affairs, 98 F.3d 165, 169 (4th Cir. 1996) (citing United States v. Ron Pair Enter., Inc., 489 U.S. 235, 242 (1989)), cert. denied, 118 S. Ct. 43 (1997).

law, and to its object and policy." United States Nat'l Bank of Or. v. Independent Ins. Agents of America, Inc., 508 U.S. 439, 455 (1993) (quoting United States v. Heirs of Boisdore, 49 U.S. (8 How.) 113, 122, (1849)); see also Regions Hosp. v. Shalala, 66 U.S.L.W. 4125, 4129 n.5 (U.S. Feb. 24, 1998) (No. 96-1375); Massachusetts v. Morash, 490 U.S. 107, 115 (1989). Thus, the traditional rules of statutory construction to be used in ascertaining congressional intent include: the overall statutory scheme, Offshore Logistics, Inc. v. Tallentire, 477 U.S. 207, 220-221 (1986) (directing courts to examine the language of the statute as a whole); legislative history, Atherton v. FDIC, 65 U.S.L.W. 4062, 4067 (U.S. Jan. 14, 1997) (No. 95-928); "the history of evolving congressional regulation in the area," Dunn v. CFTC, 65 U.S.L.W. 4141, 4144 (U.S. Feb. 25, 1997) (No. 95-1181); and a consideration of other relevant statutes, United States v. Stewart, 311 U.S. 60, 64 (1940) (explaining that"all acts in pari materia are to be taken together as if they were one law") (italics in original). With these general principles in mind, we begin our inquiry into the issue of whether Congress intended to delegate jurisdiction over tobacco products to the FDA.

A. Intrinsic Evidence

The FDA correctly contends that the language of the statute must be the starting point of our analysis. We agree that the first step of statutory construction is determining the plain meaning of the statutory text. In fact, the Court instructs that the inquiry ends with the statutory language when the language is unambiguous and "the statutory scheme is coherent and consistent." Robinson v. Shell Oil, 65 U.S.L.W. 4103, 4104 (U.S. Feb. 18, 1997) (No. 95-1376) (quoting Ron Pair Enter., 489 U.S. at 240).

However, the flaw in the limited approach suggested by the FDA and taken by the district court is that they examine only the literal meaning of the statutory definitions of drug and device.11 See FDA

11 For example, in its jurisdictional analysis, the district court purported to examine the "Text of the Federal Food, Drug, and Cosmetic Act." Coyne Beahm, 966 F. Supp. at 1380. However, the court mentioned only the definitions sections of the statute and ignored the text of all of the mandatory operative provisions of the Act.

Red Br. at 34 (stating that "the jurisdictional inquiry is at an end with the conclusion that cigarettes and smokeless tobacco are 'intended to affect the structure of any function of the body' within the meaning of the Act's drug and device provisions"); see also Coyne Beahm, 966 F. Supp. at 1380.

A mechanical reading of only the definitions provisions may appear to support the government's position that tobacco products fit within the Act's definitions of drugs or devices. However, an initial problem with the government's theory is that the definitions of drug and device require not only that the article "affect the structure or any function of the body," but also that these effects be intended. 21 U.S.C. §§ 321(g)(1)(C), 321(h)(3). As noted by the district court, "no court has ever found that a product is 'intended for use' or 'intended to affect' within the meaning of the [Act] absent manufacturer claims as to that product's use." Coyne Beahm, 966 F. Supp. at 1390. Even the FDA does not contend that tobacco manufacturers make any such claims. Coyne Beahm, 966 F. Supp. at 1389 n.14.

Even if we were to accept the FDA's position that no other inquiry is permissible if tobacco products fall within the literal definition of drug or device, the jurisdictional inquiry would not end there. Both the FDA and the district court failed to examine the literal definitions in view of the language and structure of the Act as a whole. Such holistic approach to statutory construction is well-supported by the case law. See, e.g., Robinson, 65 U.S.L.W. at 4104 (stating that statutory language must be examined by "reference to the language itself, the specific context in which that language is used, and the broader context of the statute as a whole"); Gustafson v. Alloyd Co., 513 U.S. 561, 570 (1995) (instructing that acts of Congress "should not be read as a series of unrelated and isolated provisions"); United States Nat'l Bank, 508 U.S. at 455 (quoting United Savings Ass'n of Texas v. Timbers of Inwood Forest Assoc., Ltd., 484 U.S. 365, 371 (1988)) (explaining that statutory interpretation is a "holistic endeavor" that must include, at a minimum, an examination of the statute's full text, its structure, and the subject matter). Accordingly, our task is to examine whether tobacco products fit into the overall regulatory scheme created by Congress.

According to FDA Deputy Commissioner Schultz, "[a] fundamental precept of drug and device regulation in this country is that these

products must be proven safe and effective before they can be sold." Statement by FDA Deputy Commissioner William B. Schultz before the Senate Comm. on Labor and Human Resources, 104th Cong., p. 8 (Feb. 22, 1996). In fact, the FDA's congressionally-established mission statement provides that the FDA is charged with protecting the public health by ensuring that human drugs are "safe and effective" and that "there is a reasonable assurance of the safety and effectiveness of devices intended for human use." 21 U.S.C. § 393(b)(2)(B), (C). During its rulemaking, the FDA found that tobacco products are "dangerous," "unsafe," and the cause of "great pain and suffering from illness such as cancer, respiratory illnesses, and heart disease." 61 Fed. Reg. at 44,412. In addition, the FDA determined that over 400,000 people die each year from tobacco use. 61 Fed. Reg. at 44,412. Yet, the FDA has proposed to regulate tobacco products under a statutory provision that requires conditions on sale and distribution which provide a reasonable assurance of safety. 21 U.S.C. § 360j(e). According to the FDA, a determination of safety under the Act requires consideration of the risks of a product compared to the "countervailing effects of use of that product, including the consequences of not permitting the product to be marketed." 61 Fed. Reg. at 44,412-13. Thus, the FDA concluded that withdrawal of tobacco from the market poses significant health risks to addicted adults which outweigh the risks of leaving tobacco products on the market. 61 Fed. Reg. at 44,405, 44,412-44,413.

But that test is contrary to the statute. The statutory provision, 21 U.S.C. § 360c(a)(2)(C), provides that safety and effectiveness are to be determined by "weighing any probable benefit to health from the use of the device against any probable risk of injury or illness from such use." See also United States v. Rutherford, 442 U.S. 544, 556 (1979) (stating that "a drug is unsafe if its potential for inflicting death and physical injury is not offset by the possibility of therapeutic benefit"). According to the language of § 360c(a)(2)(C), the FDA's obligation is to strike a balance between the risks and benefits of the use of a certain product, not to weigh the risks of leaving a product on the market against the risks of taking a product off the market. The FDA is unable to state any real health benefit derived from leaving tobacco products on the market. This is not to say that there are not other public policy reasons, such as impact on the national economy and the potential for a black market, weighing against a ban on

tobacco products. However, this type of decision involving countervailing national policy concerns is just the type of decision left for Congress. By statute, the FDA's authority is limited to the balancing of health benefits and risks. 21 U.S.C. § 360c(a)(2)(C). Thus, its attempted analogy between tobacco products and chemotherapy drugs is not well taken. 61 Fed. Reg. at 44,413. These cancer-fighting drugs may be considered high-risk, but they have not been deemed "unsafe" by the FDA. Under the Act, the key to allowing these drugs to remain on the market is that their use produces affirmative health benefits which outweigh their risks. 21 U.S.C. § 360c(a)(2)(C). According to the FDA's own findings, tobacco products do not meet this test, for there is no health benefit from the use of tobacco. The FDA's inquiry into whether the risks of removing tobacco products from the market are greater than the risks of leaving them on the market is irrelevant under § 360c(a)(2)(C).

In the proposed regulations, the FDA characterized tobacco products as combination products containing drug and device components, but purported to regulate tobacco products as restricted devices under § 360j(e) of the Act. Section 360j(e) permits the FDA to place restrictions on the sale, distribution or use of a product which are necessary for a "reasonable assurance of safety" of the product. 21 U.S.C. § 360j(e). However, based on the FDA's characterization of tobacco products as unsafe, it is impossible to create regulations which will provide a reasonable assurance of safety. Thus, the FDA cannot comply with the terms of the very statutory provision it has chosen as its basis for regulation. In addition to the fundamental conflicts described above, at least six internal inconsistencies arise when tobacco products are forced into the drug or device regulatory schemes of the Act.

First, § 355(a) of the Act requires that all new drugs be approved by the FDA before marketing. 21 U.S.C. § 355(a). The Act requires the FDA to disapprove applications for new drugs 12 if the drug is

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12 In relevant part, the Act defines a "new drug" as:

> Any drug . . . the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof . . .

21 U.S.C. § 321(p)(1).

deemed unsafe or if there is not substantial evidence of its effectiveness. 21 U.S.C. § 355(d). This mandatory approval process presents an insurmountable problem for the FDA with respect to tobacco products because of the FDA's finding that they are unsafe. 61 Fed. Reg. at 44,412. In fact, the FDA has conceded that under the mandatory approval provisions, tobacco products would constitute unapproved new drugs. 60 Fed. Reg. 41,348 (1995) (FDA Proposed Rulemaking). As such, the Act would require the prohibition of the distribution and marketing of tobacco products. 21 U.S.C. §§ 331(d), 355(a).

The FDA attempts to avoid the problem inherent in the new drug approval requirement by classifying tobacco products as combination products and then choosing to regulate them as devices rather than as drugs. The Act directs the FDA to determine the primary mode of action of a combination product. 21 U.S.C. § 353(g)(1). If the FDA determines that the primary mode of action is that of a drug, then it must assign "primary jurisdiction" over the product to the persons charged with premarket review of drugs. 21 U.S.C.§ 353(g)(1)(A), (B). The FDA concedes that the "primary mode of action" of tobacco products is that of a drug.13 FDA Red Br. at 26 (citing 61 Fed. Reg. at 45,209-18; 44,400-03). Yet, it chose to regulate tobacco products devices under § 360j(e) of the Act. This transparent action by the FDA, obvious sophistry, taken in order to avoid the new drug provisions of the Act, reinforces the conclusion that regulation of tobacco products under the Act was not intended by Congress. However, the FDA's classification of tobacco products as devices could not avoid similar problems caused by other provisions of the Act.

Section 331(a) of the Act prohibits the introduction into or delivery in interstate commerce of any drug or device that is misbranded. 21 U.S.C. § 331(a). Under § 352(j), a drug or device is deemed to be misbranded if it is dangerous to health when used in the manner suggested in the labeling. 21 U.S.C. § 352(j). The FDA has concluded that the use of tobacco products is dangerous to health. 61 Fed. Reg.

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13 Interestingly, the FDA chose to regulate tobacco products as devices even though it has regulated the nicotine products within its jurisdiction - nicotine patches, nicotine gum, and nicotine nasal sprays - as drugs. Approved Drug Products with Therapeutic Equivalence Evaluations, 1762 Food Drug Cosm. L. Rep. (CCH) 3-220, 221 (FDA May 29, 1996).

at 44,412. Thus, it is impossible for the labeling of tobacco products to suggest a nondangerous use. Accordingly, #8E8E # 331(a) and 352(j) operate to make the continued marketing of tobacco products illegal.

A drug or device is also considered misbranded, and thus prohibited under § 331(a), if it does not include "adequate directions for use." 21 U.S.C. § 352(f)(1). According to the FDA, the requirement of adequate directions for use means "directions under which the layman can use a device safely and for the purposes for which it is intended." 61 Fed. Reg. at 44,464. The FDA can exempt drugs and devices from § 352(f)(1)'s directions requirement, but only if the information is "not necessary for the protection of public health." 21 U.S.C. § 352(f). The FDA has previously interpreted § 352(f) to mean that an exemption from the direction requirements may be granted when other circumstances (such as a physician's prescription) can reasonably assure safe use of the drug or device. 21 C.F.R. §§ 201.100-201.129, 801.109-801.127 (1996).

The FDA now contends that an exemption for tobacco products is appropriate, 61 Fed. Reg. at 44,410, because everyone knows how to use tobacco products and thus directions are not needed. See 61 Fed. Reg. at 44,465 (stating that tobacco products are "one of the most readily available consumer products on the market today. Consequently, the way in which these products are used is common knowledge."). However, the FDA violated its own interpretation of the Act by exempting tobacco products under § 352(f) without any assurances of safety. Because of the FDA's finding that tobacco products are unsafe, 61 Fed. Reg. at 44,412, it is impossible to provide directions for safe use as required by the statute. In addition, the exemption is inapplicable because no assurance of safety can be given for inherently unsafe products such as tobacco. Again, the FDA's need to apply the statutory exemption demonstrates that the Act does not and cannot apply to tobacco products.

Similarly, a drug or device is also considered misbranded, and thus prohibited by § 331(a), if it fails to bear "adequate warnings against use . . . by children where its use may be dangerous to health." 21 U.S.C. § 352(f)(2). Unlike § 352(f)(1), this section does not permit any exemptions from the warning requirement. In support of its proposed regulations, the FDA cited widespread use of tobacco products

by minors and focused on controlling youth use as a means of decreasing tobacco-related illnesses and deaths. See 61 Fed. Reg. at 45,238-243 (characterizing youth use of tobacco products as a "pediatric disease"). The FDA concluded that the warnings mandated by other federal statutes satisfy the Act's requirement for adequate warnings to children even though none of the statutorily-prescribed warnings address the particular dangers of youth use repeatedly emphasized by the FDA. See 15 U.S.C. § 1333, 4402 (requiring Surgeon General warnings about health risks posed by tobacco products); see also 61 Fed. Reg. at 44,465. The FDA was constrained to find that the warnings mandated by other federal statutes are sufficient because the applicable federal statutes do not permit federal agencies to add to or modify the congressionally-mandated warnings. 15 U.S.C. §§ 1334(a), 4406(a). Again, the contortions that the FDA has gone through demonstrate that Congress did not intend its jurisdictional grant to the FDA to extend to tobacco products.

Furthermore, under 21 U.S.C. § 360c(b)(1), all devices intended for human use must be classified into one of three categories, Class I, II, or III, based on ascending degrees of dangerousness. Placement is appropriate in the class that will provide a "reasonable assurance of the safety and effectiveness of the device." 21 U.S.C. § 360c(a)(1)(A)-(C). As discussed above, safety and effectiveness are determined by "weighing any probable benefit to health from the use of the device against any probable risk of injury or illness from such use." 21 U.S.C. § 360c(a)(2)(C). Three years after it first introduced the proposed regulations, the FDA has yet to place tobacco products into one of the three categories. However, the agency's own findings with respect to dangers to health require classification of tobacco products as a Class III device subject to premarket approval because they "[present] a potential unreasonable risk of illness or injury." 21 U.S.C. § 360c(a)(1)(C)(ii)(II); see also 61 Fed. Reg. at 44,398, 44,412 (discussing dangers of tobacco use). Under the premarket approval process, tobacco products could not be approved without a showing that there is a reasonable assurance of safety and effectiveness of the products when used in the manner suggested by the labeling. 21 U.S.C. § 360c(a)(1)(C). The FDA contends that it will classify tobacco products at some point in the future and that the long delay is consistent with both the statutory framework and the agency's prior actions for other devices. 61 Fed. Reg. at 44,412; FDA Red Br. at 45.

However, the real problem with attempting a classification is that all three categories of devices require reasonable assurances of safety and effectiveness for the product. 21 U.S.C. § 360c(a)(1). As discussed earlier, the FDA cannot provide reasonable assurances of safety for a product that it has found to be inherently unsafe and dangerous. Thus, it has not, and more importantly, cannot comply with Congress' statutory classification directive because complying with the statute would trigger a ban on tobacco products, a result not intended by Congress.

Finally, the Act requires the FDA to issue an immediate cease-distribution order for all products found to cause "serious, adverse health consequences or death." 21 U.S.C. § 360h(e)(1).14 This order begins an agency process that may ultimately result in a recall order for the device. 21 U.S.C. § 360h(e)(2). The FDA has found that "tobacco use is the single leading cause of preventable death in the United States. 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." 61 Fed. Reg. at 44,398 (citations omitted). According to the terms of the Act, these findings, standing alone, mandate that the FDA issue a cease-distribution order for tobacco products. Nevertheless, the FDA has no intention of complying with the requirements of the Act. See 61 Fed. Reg. at 44,419 (stating that the FDA will not ban tobacco products). The necessity of the FDA's avoidance of the statutory directives again demonstrates that Congress did not intend that the Act regulate tobacco products. A faithful application of the statutory language would lead to a ban on tobacco products - a result not intended by Congress.

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14 In relevant part, § 360h(e)(1) provides:

> If the [FDA] finds that there is a reasonable probability that a device intended for human use would cause serious, adverse health consequences or death, the [FDA] shall issue an order requiring the appropriate person (including the manufacturers, importers, distributors, or retailers of the device) -
>
> (A) to immediately cease distribution of such device;
>
> . . .

21 U.S.C. § 360h(e)(1).

The FDA makes a linguistic argument in an attempt to avoid the problem presented by this section. The statute provides that if the FDA finds there is a reasonable probability that a device will cause health problems or death, then the FDA "shall issue an order requiring . . . [the immediate] cease distribution of such device." 21 U.S.C. § 360h(e)(1)(A). However, the FDA contends that "shall" should be interpreted to mean "may." FDA Red Br. at 42-43. Even if we were to adopt this interpretation, the substance of our analysis would not change. As discussed above, the FDA has made the requisite finding of dangerousness under the statute. Thus, even if "shall" were interpreted as "may," the FDA still could exercise its discretion under the statute and ban tobacco products. And a failure to ban a product as dangerous as is tobacco, by the FDA's own findings, would necessarily be an abuse of discretion. But because an absolute ban falls outside the scope of congressional intent, construing the Act to cover tobacco products would be inconsistent with the will of Congress.

As demonstrated by the examples provided above, the FDA's need to maneuver around the obstacles created by the operative provisions of the Act reflects congressional intent not to include tobacco products within the scope of the FDA's authority. The FDA argues that even if it has misapplied the Act, this error does not bear on the jurisdictional issue. However, the point is not merely that the FDA misapplied the Act, but these examples demonstrate the FDA's need to ignore and misapply the operative provisions of the Act before it can attain its end, not the end contemplated by Congress. Cf. United States v. Two Plastic Drums, 984 F.2d 814, 819 (7th Cir. 1993) (rejecting another recent attempt by the FDA to enlarge its jurisdiction and stating that "the only justification for this Alice-in-Wonderland approach is to allow the FDA to make an end-run around the statutory scheme"). The fact is that Congress did not equip the FDA with tools appropriate for the regulation of tobacco because it had no intention that the Act apply to tobacco products.

We do not dispute in this case that Congress has charged the FDA with protecting the public health and that tobacco products present serious health risks for the public. However, the Supreme Court has warned that "[i]n our anxiety to effectuate the congressional purpose of protecting the public, we must take care not to extend the scope of the statute beyond the point where Congress indicated it would stop."

62 Cases of Jam v. United States, 340 U.S. 593, 600 (1951). Based on our examination of the regulatory scheme created by Congress, we are of opinion that the FDA is attempting to stretch the Act beyond the scope intended by Congress.

B. Extrinsic Evidence

Pursuant to Chevron's instruction to employ the traditional tools of statutory construction, we now examine the events surrounding the 1938 passage of the Act as well as subsequent statements and actions by Congress and the FDA. These individual events are like pieces of a puzzle in that no single event is outcome determinative. However, when viewed as a whole, it is clear that Congress did not intend to give the FDA jurisdiction over tobacco products in 1938 when it passed the Act. See MCI Telecomm. Corp. v. AT&T, 512 U.S. 218, 228 (1994) (stating that relevant time for determining congressional intent on meaning of statute is when controlling statute enacted). As discussed above, the fact that the operative provisions of the Act simply cannot accommodate tobacco products is a clear indication of congressional intent. Cf. Gustafson, 513 U.S. at 569 (explaining that an operative provision of the Securities Act of 1933 does not define prospectus, the term at issue, but "does instruct us what a prospectus cannot be if the Act is to be interpreted as a symmetrical and coherent regulatory scheme"). Subsequent events outside the language of the statute only confirm our understanding of Congress' intent.

1. Historical Actions of the FDA

From 1914 until the present rulemaking attempt, the FDA had consistently stated that tobacco products were outside the scope of its jurisdiction. And, as early as 1898, the Supreme Court of Tennessee acknowledged the dangerous nature of tobacco products, characterizing cigarettes as "wholly noxious and deleterious to health," "inherently bad, and bad only," and "widely condemned as pernicious altogether." Austin v. State, 48 S.W. 305, 306 (Tenn. 1898). Yet, the statute preceding the Act, the Pure Food and Drugs Act of 1906, Pub. L. No. 59-384, 34 Stat. 768 (1906), did not mention tobacco. As early as 1914, the FDA's predecessor agency stated that it had authority to regulate tobacco products if their labeling indicated use for "the cure, mitigation, or prevention of a disease," but not if labeled or used for

"smoking or chewing or as snuff and not for medicinal purposes." Bureau of Chemistry, U.S. Dept. of Agriculture, 13 Service and Regulatory Announcements 24 (Apr. 2, 1914). Enacted in 1938, the present Act expanded the definition of drug from the definition provided in the Pure Food and Drugs Act of 1906 and also granted the FDA new authority to regulate "devices." Food, Drug, and Cosmetic Act, Pub. L. No. 75-717, 52 Stat. 1040 (1938). However, neither the Act nor its legislative history mention tobacco products.15

In the 60 years following the passage of the Act, the FDA has repeatedly informed Congress that cigarettes marketed without therapeutic claims do not fit within the scope of the Act. Ever since its beginning in the 1930s, the FDA has taken the position and made statements indicating that the Act did not apply to cigarettes marketed without specific health claims. FDA/Dep't of Justice Brief in ASH v. Harris (No. 79-1397), at 16. Again, in 1963, an FDA Bureau of Enforcement Guideline stated that "[t]he 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 in the Food, Drug, and Cosmetic Act for food, drug, device or cosmetic." Letter to Directors of Bureaus and Divisions and Directors of Districts from FDA Bureau of Enforcement (May 24, 1963), reprinted in Public Health Cigarette Amendments of 1971: Hearings Before the Consumer Subcomm. of the Senate Comm. on Commerce on S. 1454, 92d Cong. 240 (1972). When Congress later examined the issue of the FDA's jurisdiction during its consideration of tobacco-specific legislation, FDA Commissioner Charles Edwards testified regarding the FDA's lack of authority over cigarettes and stated that"if cigarettes were to be classified as drugs, they would have to be removed from the market because it would be impossible to prove they were safe for their intended [use]."16 Hearings on S. 1454 at 239. The Commissioner

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15 Two of the main supporters of the Act were representatives from the two leading tobacco States - Senator Bailey (D-NC) and Representative Chapman (D-KY). See 83 Cong. Rec. 9094 (1938). In fact, Sen. Bailey and Rep. Chapman were among Senate and House managers of the Act in the Conference Committee. Had there been any indication that the Act might apply to tobacco products, we can only assume that such members of Congress would have expressed opposition to the Act.

16 The Commissioner cited several cases in support of the FDA's conclusion that it lacked authority over cigarettes as customarily marketed.

took the position that the Federal Cigarette Labeling and Advertising Act, discussed in greater detail below, reinforced that "the regulation of cigarettes is to be the domain of Congress." Hearings on S. 1454 at 242. The Commissioner then concluded that "labeling or banning cigarettes is a step that can be take[n] only by Congress. Any such move by the FDA would be inconsistent with the clear congressional intent." Hearings on S. 1454 at 242.

In 1977, Action on Smoking and Health (ASH), a public health group, petitioned the FDA to regulate cigarettes. ASH claimed that cigarettes were drugs because they contain nicotine which produces addiction in many smokers, and particularly in youth. Citizen Petition, FDA Docket No. 77P-0185, at 4-11 (May 26, 1977)[G. Br. Att. 77]. In rejecting ASH's petition,17 the FDA cited a 1953 Second Circuit opinion, FTC v. Liggett & Myers Tobacco Co., 203 F.2d 955 (2d Cir. 1953), affirming on opinion below, 108 F. Supp. 573 (S.D.N.Y. 1952), for the proposition that cigarettes marketed without health claims by the vendor are not within the FDA's jurisdiction. Specifically, the FDA quoted with approval the following language from the court's opinion:

> The legislative history, such as it is, coupled with indications of contemporaneous administrative interpretation leads me to the conclusion that Congress, had the matter been considered, would not have intended cigarettes to be

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See, e.g., FTC v. Liggett & Myers Tobacco Co., 203 F.2d 955 (2d Cir. 1953), affirming on opinion below, 108 F. Supp. 573 (S.D.N.Y. 1952); United States v. 354 Bulk Cartons . . . Trim Reducing-Aid Cigarettes, 178 F. Supp. 847 (D.N.J. 1959); United States v. 46 Cartons . . . Fairfax Cigarettes, 113 F. Supp. 336 (D.N.J. 1952).

17 A federal appeals court upheld the FDA's denial of jurisdiction. See ASH v. Harris, 655 F.2d 236 (D.C. Cir. 1980). In upholding the FDA's denial of jurisdiction, the court emphasized the relevance of the remarks of the district court in Liggett. In construing the identical language of the definitions in the Federal Trade Commission Act, the Liggett court stated: "[s]urely, the legislators did not mean to be as all-inclusive as a literal interpretation of [the definitions] would compel us to be." ASH, 655 F.2d at 240 (quoting Liggett & Myers, 108 F. Supp. at 576).

> included as an article "intended to affect the functions of the body of man" or in any other definition of "drug."

See Letter from FDA Commissioner Donald Kennedy to John F. Banzhaf, III, at 3 (Dec. 5, 1977) (quoting Liggett & Myers, 108 F. Supp. at 577) (stating that the FDA's consistent position has been that cigarettes marketed without health claims by vendors are not drugs within the Act).

In 1978, ASH filed a second petition, claiming that cigarettes were devices under the Act and thus were within the scope of the FDA's jurisdiction. Citizen Petition, FDA Docket No. 78P-0338 (Oct. 2, 1978). After reviewing the legislative history of the Act, the FDA stated that "[i]nsofar as rulemaking would relate to cigarettes or attached filters as customarily marketed, we have concluded that FDA has no jurisdiction under [the definition of device]. Therefore, no rulemaking is permissible as a matter of law." Letter from FDA Commissioner Jere E. Goyan to John F. Banzhaf, III and Peter N. Georgiades, at 12 (Nov. 25, 1980). In considering the effect of the Medical Device Amendments of 1976 which modified the definition of device to its current formulation, the FDA Commissioner stated:

> Specifically, there is no evidence in the legislative history that Congress intended to include cigarettes within the definition of "device" nor does the legislative history contain any discussion of a possibility that cigarettes were "devices" within the prior definition.
>
> The amendments were thoroughly considered, and the legislative history discusses the types of products intended to be regulated and the types of health hazards with respect to which the amendments were intended to provide authority. Cigarettes are not mentioned even though Congress was aware of the considerable public discussion of the health hazards of cigarette smoking. It is, therefore, not reasonable to consider cigarettes as "devices" when there was no discussion in the legislative history of congressional intent to provide jurisdiction over cigarettes or to provide authority suitable to the regulation of cigarettes.

Goyan/Banzhaf Letter, at 3. The FDA's holdings and statements that the Act fails to provide "authority suitable to the regulation of cigarettes" are consistent with part II.A's conclusion, supra, that the Act's regulatory scheme simply cannot accommodate tobacco products.

Again in 1989, the FDA Commissioner stated that:"it doesn't look like it is possible to regulate [tobacco products] under the Food, Drug and Cosmetic Act even though smoking, I think, has been widely recognized as being harmful to human health." Hearings Before the Subcomm. on Rural Development, Agriculture, and Related Agencies of the House Comm. on Appropriations, 100th Cong., 2d Sess. 409 (1989). The above statements evidence the FDA's position from 1914 until the present rulemaking attempt that, as a matter of law, it did not have jurisdiction to regulate tobacco products as customarily marketed. The FDA's public, consistent, and longstanding interpretation[18] of the Act gains even more significance when viewed in conjunction with the actions of Congress during the same time period.

2. Congressional Inaction

We recognize the general reluctance of courts to rely on congressional inaction as a basis for statutory interpretation. See Brecht v. Abrahamson, 507 U.S. 619, 632 (1993) (noting that "[a]s a general matter, 'we are reluctant to draw inferences from Congress's failure to act'") (quoting Schneidewind v. ANR Pipeline Co., 485 U.S. 293, 306 (1988)). However, under certain circumstances, inaction by Congress may be interpreted as legislative ratification of or acquiescence to an agency's position. See Bob Jones Univ. v. United States, 461 U.S. 574, 601 (1983) (stating that "[i]n view of its prolonged and acute awareness of so important an issue, Congress' failure to act on the bills proposed on this subject provides added support for conclud-

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18 We do not mean to suggest that an agency is always irrevocably bound by its prior interpretations of a statute. However, we note that an agency's interpretation of a statutory provision that conflicts with the agency's earlier interpretation is "'entitled to considerably less deference' than a consistently held agency view." Good Samaritan Hosp. v. Shalala, 508 U.S. 402, 417 (1993) (quoting Watt v. Alaska, 451 U.S. 259, 273 (1981)). In addition, the evidence of legislative ratification also weighs against the FDA's actions in the present case.

ing that Congress acquiesced in the IRS rulings"). In Bob Jones, the Court examined Congress' failure to modify two IRS rulings when the public and Congress were well aware of the position of the IRS. Bob Jones, 461 U.S. 599-602. In finding legislative acquiescence to the IRS position, the Court emphasized: extensive hearings held by Congress on the issue; the introduction and failure of numerous bills in Congress introduced to overturn the IRS's interpretation of the Internal Revenue Code; and Congress' awareness of the IRS position when enacting other, related legislation. Bob Jones, 461 U.S. at 599-601; see also United States v. Riverside Bayview Homes, Inc., 474 U.S. 121, 137 (1985) (finding legislative acquiescence and explaining that "a refusal by Congress to overrule an agency's construction of legislation" is particularly relevant "where the administrative construction has been brought to Congress' attention through legislation specifically designed to supplant it").

We are of opinion that the matter before us presents an equally strong case of legislative acquiescence.19 As noted by the district court, Congress has introduced numerous bills that would have granted the FDA jurisdiction over tobacco products. See Coyne Beahm, 966 F. Supp. at 1382 (stating that "members of Congress agreed with FDA's assertions that it lacked jurisdiction" and thus introduced bills expressly granting the FDA jurisdiction "in an effort to remedy the situation"). In fact, the district court listed 15 different bills introduced in Congress which would have expressly granted the FDA jurisdiction over tobacco products. Coyne Beahm, 966 F. Supp. at 1382. However, none of these bills were enacted. As discussed above, FDA officials have testified at many congressional hearings regarding the FDA's lack of jurisdiction over tobacco products. See also Coyne Beahm, 966 F. Supp. at 1381. Thus, Congress has been well aware of the FDA's position that it lacked jurisdiction over tobacco products since 1914. On several occasions, Congress has enacted legislation to deal specifically with the dangers of tobacco products, but has never enacted legislation to overturn the FDA's

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19 The district court attempted to distinguish the Bob Jones and Riverside Bayview cases by noting that they involved agency action rather than statements by an agency that it did not have jurisdiction to act. Coyne Beahm, 966 F. Supp. at 1383. We fail to see any real distinction and thus find the cases applicable.

interpretation of its jurisdiction under the Act. Accordingly, this is not a case where congressional inaction demonstrates "unawareness, preoccupation, or paralysis." See Zuber v. Allen, 396 U.S. 168, 185-86 n.21 (1969). We believe that the actions rejected and taken by Congress with respect to the regulation of tobacco provide strong evidence of congressional intent that it, and not the FDA, controls the regulation of tobacco products.

3. Congress' Tobacco-Specific Legislation

Under Chevron's instruction to apply the traditional rules of statutory construction, it is also appropriate to consider the provisions of the "whole law, and . . . its object and policy" in ascertaining the will of Congress. Dole v. United Steelworkers of America, 494 U.S. 26, 35 (1990) (quoting Pilot Life Ins. Co. v. Dedeaux, 481 U.S. 41, 51 (1987)). Having examined the Act and prior actions of the FDA and Congress, we now take a closer look at three statutes and related amendments (collectively referred to as the tobacco-specific legislation) enacted by Congress for the purpose of addressing public health concerns about the use of tobacco products.

The issue is not, in the words of the stalking horse set up by the government, whether these three statutes partially repeal or amend the Act to withhold jurisdiction over tobacco products from the FDA. FDA Red Br. at 57. Rather, we examine the tobacco-specific legislation as a part of our inquiry into congressional intent. As discussed above, we are of opinion that the statutory text, viewed as a coherent whole, clearly indicates that Congress did not intend the FDA's original jurisdictional grant to include tobacco products. Thus, the subsequent enactment of tobacco-specific legislation provides corroborating evidence of established congressional intent.

In January 1964, the publication of the first Surgeon General's report on smoking and health called the federal government's attention to the dangers of tobacco products. Dept. of Health, Education and Welfare, Smoking and Health: Report of the Advisory Committee to the Surgeon General of the Public Health Service (1964); see also H.R. Rep. No. 289, 91st Cong., 1st Sess., at 5 (characterizing the 1964 Surgeon General's Report as the "principal basis" for regulatory efforts). Shortly thereafter, the House Committee on Interstate and

Foreign Commerce initiated a series of hearings regarding the federal government's role in dealing with smoking-related health problems. Committee Chairman, Representative Oren Harris, stated that:

> The purpose of these hearings will be, if we can reach that point, to determine the extent of authority under existing law to deal with the various aspects of this general field, and to determine whether any action of the Congress is warranted in the interest of public health. In other words, we want to find out under our responsibility whether or not legislative action is necessary, and if so, what kind.

Hearings Before the Comm. on Interstate and Foreign Commerce on Bills Regulating the Labeling and Advertising of Cigarettes and Relating to Health Problems Associated with Smoking, 88th Cong., 2d Sess. 23 (1964).

During the course of these hearings, Congress considered and rejected the option of granting the FDA jurisdiction over tobacco products. Of the eleven bills submitted to the Committee, two would have expressly amended the Act to make it applicable to tobacco products. 1964 Hearings at 2-12. These two bills proposed expansion of the Act to cover tobacco products by creating a new category of products subject to FDA jurisdiction. See 1964 Hearings at 4-7 (suggesting creation of new category entitled "smoking products"). These two bills also proposed new operative provisions applicable only to "smoking products."20 1964 Hearings at 4-7. As part of the hearings, Surgeon General Terry was asked whether the Department of Health, Education, and Welfare (HEW), the FDA's parent department, had authority to regulate tobacco products. Dr. Terry's unqualified response was that his department did not believe that it had "such authority in existing laws governing the Public Health Service and Food and Drug Administration." 1964 Hearings at 56. Similar testimony was later provided by the Deputy Commissioner of the FDA. See Cigarette Labeling and Advertising: Hearings Before the House

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20 The fact that the two proposed bills created a new jurisdictional category and new operative provisions for tobacco products is consistent with our analysis in part II.A, supra, which concludes that the current structure of the Act cannot accommodate tobacco products.

Comm. on Interstate and Foreign Commerce, 89th Cong., 2d Sess. 193 (1965) (statement of Deputy Commissioner Rankin that "[t]he Food and Drug Administration has no jurisdiction under the Food, Drug, and Cosmetic Act over tobacco, unless it bears drug claims"); see also 111 Cong. Rec. 13431 (1965). In addition, the Secretary of HEW, Anthony J. Celebrezze, warned the Committee that giving the FDA jurisdiction over tobacco products "might well" lead to a ban and that such a ban would be contrary to the intent of Congress and the will of the American public. See 1964 Hearings at 18 (stating that a ban would be "contrary to what, we understand, is intended or what, in the light of our experience with the 18th amendment, would be acceptable to the American people").

Following the hearings and consideration of the various bills, Congress responded to the Surgeon General's report by enacting The Federal Cigarette Labeling and Advertising Act (Cigarette Labeling Act), Pub. L. No. 89-92, 79 Stat. 282 (1965) (codified at 15 U.S.C. §§ 1331 et seq.). In general, the Cigarette Labeling Act required manufacturers to place specific health-hazard warnings from the Surgeon General on cigarette packaging, advertising, and billboards. 15 U.S.C. § 1333. The Cigarette Labeling Act also set forth congressional policy regarding regulation of tobacco products:

> It is the policy of the Congress, and the purpose of this chapter, to establish a comprehensive Federal program to deal with cigarette labeling and advertising with respect to any relationship between smoking and health, whereby -
>
> (1) the public may be adequately informed about any adverse health effects of cigarette smoking by inclusion of warning notices on each package of cigarettes and in each advertisement of cigarettes; and
>
> (2) commerce and the national economy may be (A) protected to the maximum extent consistent with this declared policy and (B) not impeded by diverse, nonuniform, and confusing cigarette labeling and advertising regulations with respect to any relationship between smoking and health.

15 U.S.C. § 1331. Thus, the express goal of the Cigarette Labeling Act is to warn consumers about the health hazards of smoking while also protecting the national economy.

The district court apparently considered that the plaintiffs claimed that the separate preemption provision of the Cigarette Labeling Act precluded any further regulation of tobacco products except by Congress. See Coyne Beahm, 966 F. Supp. at 1385-1386. We do not think that the claim was so broad then, certainly it is not so broad now. While it is true that 15 U.S.C. § 1334, requires that no statement relating to smoking or health other than the statement required by § 1333, shall be required on any cigarette package, that is not a statement excluding other regulation of tobacco products. But the fact that Congress has, some 27 years after the establishment of the FDA in its present form, enacted the Cigarette Labeling Act, is strong evidence that Congress has reserved for itself the regulation of tobacco products rather than delegating that regulation to the FDA.

Congressional policy, as set out in the Cigarette Labeling Act, cannot be harmonized with the FDA's assertion of jurisdiction over tobacco products. First, by enacting the Cigarette Labeling Act rather than other proposed legislation, Congress clearly rejected the proposed regulatory role for the FDA. Next, the Act charges the FDA with protecting the public health, but does not authorize the FDA to consider protection of commerce and the national economy. Thus, by the terms of its enabling statute, the FDA is not capable of complying with Congress' stated policy regarding the regulation of tobacco products. In addition, the congressionally-established regulatory plan of the Cigarette Labeling Act directly contradicts the FDA's mandatory requirements set forth in the Act. As discussed supra in part II.A, the Act prohibits the sale or distribution of unsafe devices. See, e.g., 21 U.S.C. §§ 331(a), 352(j). In contrast, the Cigarette Labeling Act recognizes the unsafe and dangerous nature of cigarettes, but permits continued marketing with consumer warnings. 15 U.S.C. §§ 1331, 1333. The decision by Congress to allow continued marketing of unsafe products cannot be reconciled with the operative provisions of the Act, primarily because the Act does not allow FDA consideration of the factors involved in Congress' policy determination. See 15 U.S.C. § 1331(2) (establishing policy of protecting "commerce and the national economy").

Finally, in developing the Cigarette Labeling Act, Congress clearly considered and rejected a role for the FDA. The government does not produce any legislative history to the contrary. The legislative history of the Cigarette Labeling Act is thus important to understanding congressional intent because it reflects the historical context in which the Cigarette Labeling Act was developed. See Radowich v. United States Att'y, 658 F.2d 957, 961 (4th Cir. 1981) (stating that courts should look at the "clearly expressed intention as expressed without dissent in the legislative history" to be certain that their construction of a statute is consistent with the "manifest purpose as clearly mirrored in the legislative history"). Thus, the Cigarette Labeling Act and the context in which it was enacted provides evidence of Congress' intent that the FDA not have jurisdiction over tobacco products. Subsequent legislation by Congress reinforces our understanding of this expressed congressional intent.

The Cigarette Labeling Act's advertising and labeling regulations originally were set to expire on June 30, 1969. In response, the Federal Communications Commission (FCC) introduced a proposal to ban all television and radio cigarette advertising. 34 Fed. Reg. 1959 (1969). In addition, the Federal Trade Commission (FTC) renewed its proposed rule from 1964. See 34 Fed. Reg. 7917 (1969) (citing health hazards of smoking and proposing warning statements for cigarette packages and advertisements).21 Again, Congress debated the role of administrative agencies in the regulation of tobacco products. See generally Cigarette Labeling and Advertising: Hearings Before the House Comm. on Interstate and Foreign Commerce, 91st Cong., 1st Sess. (1969). The House Report stated:

> The regulations [proposed by the FCC and the FTC] raise basic constitutional questions and would affect the growing, sale, and manufacturing of tobacco for cigarettes and the persons involved in or affected by those activities. These activities cut across the whole spectrum of commercial and social life in the United States. It is therefore an area where the Congress, if anyone, must make policy.

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21 We note that the FDA took no action at this time.

. . .

> Aside from the questions of constitutional and statutory law which the two agencies' proposed rules raise, they are an assumption by these agencies of policymaking with respect to a subject matter on which the Congress has made policy . . ., [and] has stated its intention to be the exclusive policymaker on the subject matter . . . .

H.R. Rep. No. 289, at 4-5.

Following these debates and hearings, Congress amended the Cigarette Labeling Act by enacting the Public Health Cigarette Smoking Act of 1969, Pub. L. No. 91-222, 84 Stat. 87 (1970). Basically, the 1969 Act reenacted the Cigarette Labeling Act, but with several amendments.22 Notably, Congress did not amend or replace 15 U.S.C. § 1331, the provision setting out its policy determination regarding the regulation of tobacco products.

Congress showed a continuing interest in the regulation of tobacco products with the Alcohol and Drug Abuse Amendments of 1983, Pub. L. No. 98-24, 97 Stat. 175, 178 (1983) (codified at 42 U.S.C. §§ 290aa et seq.). These amendments require the Secretary of HHS, FDA's parent agency, to submit certain reports to Congress every three years. 42 U.S.C. § 290aa-2(b). The statute directs the Secretary to report to Congress current findings on "the addictive property of tobacco" and to recommend "legislation and administrative action as the Secretary may deem appropriate." 42 U.S.C.§ 290aa-2(b)(2)-(3). This statute evidences Congress' awareness of the addictive nature of tobacco products and its intent to retain control over further regulatory action.

In 1984, Congress again amended the Cigarette Labeling Act, but retained the basic regulatory approach established in 1965. See Com-

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22 For example, the 1970 amendments changed the wording of the warning to be included on cigarette packages, 15 U.S.C. § 1333; revised § 1334's express preemption provision; and made it unlawful to advertise cigarettes on electronic communications subject to FCC jurisdiction, 15 U.S.C. § 1335.

prehensive Smoking Education Act (Smoking Education Act), Pub. L. No. 98-474, 98 Stat. 2200 (1984) (amending the Cigarette Labeling Act). The Smoking Education Act required rotating warnings on cigarette packaging and advertising, 15 U.S.C. § 1333; established an Interagency Committee on Smoking and Health, including members from the FTC, the Department of Education, and the Department of Labor, but not from the FDA, 15 U.S.C. § 1341(b); and required annual disclosure of tobacco ingredients to the Secretary of HHS, 15 U.S.C. § 1335a. Quoting U.S. Surgeon General Dr. C. Everett Koop, the House Report recommending this legislation described cigarette smoking as "the most important public issue of our time." H.R. Rep. No. 805, 98th Cong., 2d Sess., at 12 (1984). Consistent with the prior actions of Congress discussed above, the House Report recognized that "[f]ederal laws that protect the public from hazardous food, drugs and consumer products do not apply to cigarettes." H.R. Rep. 805, at 12.

In 1986, Congress created a similar regulatory program for smokeless tobacco, but with some additions.[23] Comprehensive Smokeless Tobacco Health Education Act (Smokeless Tobacco Act), Pub. L. No. 99-252, 100 Stat. 30 (1986) (codified at 15 U.S.C.§§ 4401-4408). In general, the Smokeless Tobacco Act required specific health warnings in smokeless tobacco advertising and on packaging, 15 U.S.C. § 4402(a),(b); authorized the FTC to issue specified regulations regarding the content and form of label warnings, 15 U.S.C. § 4402(c); banned advertising on electronic communications subject to FCC jurisdiction, 15 U.S.C. § 4402(f); and required annual ingredient and nicotine-level reporting to the HHS Secretary, 15 U.S.C. § 4403. In addition, the Smokeless Tobacco Act authorized the Secretary of HHS to develop a program for informing the public of the health hazards caused by use of smokeless tobacco. 15 U.S.C. § 4401(a). Specifically, the Secretary is instructed to make this information available to school systems for educational purposes. 15 U.S.C. § 4401(a)(1)(B). The statute also provided for technical and financial assistance to States for their development of educational programs about the dangers of smokeless tobacco and for establishing

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23 It is worth noting that Congress adopted a very similar approach to the one taken in the Cigarette Labeling Act, even though it had expressly recognized the addictive nature of tobacco. 42 U.S.C. § 290aa-2(b)(2).

18 as the minimum age for purchasing smokeless tobacco. 15 U.S.C. § 4401(b).24 Finally, the Smokeless Tobacco Act requires the Secretary of HHS to submit biennial reports to Congress containing "a description of the effects of health education efforts," "an evaluation of the health effects of smokeless tobacco products," and "recommendations for legislation and administrative action." 15 U.S.C. § 4407(a).

Like the Cigarette Labeling Act, the Smokeless Tobacco Act also contains an express preemption provision. See 15 U.S.C. § 4406 (providing that "[n]o statement relating to the use of smokeless tobacco products and health, other than the statements required by section 4402 of this title, shall be required by any Federal agency to appear on any package or in any advertisement"). However, as discussed in relation to the Cigarette Labeling Act, this express preemption provision does not detract from our examination of the statute as a tool for determining congressional intent. In recommending passage of the Smokeless Tobacco Act, the House Report cited particular concerns about the popularity of smokeless tobacco with minors. See S. Rep. No. 209, 99th Cong., at 4 (1985), reprinted in 1986 U.S.C.C.A.N. 7, 10 (stating that "a major reason for the development of a legislative proposal is the alarming incidence of use by children"). Thus, in 1986, Congress considered the very issues that the FDA now purports to address in its proposed regulations.

Within the context of the FDA's repeated stated positions that it had no jurisdiction, Congress enacted comprehensive legislation addressing many of the activities that the FDA now attempts to regulate, based on the same concerns relating to youth use now cited by the FDA. The enactment of the Smokeless Tobacco Act in no way supports a conclusion that Congress intended to give the FDA jurisdiction over tobacco products. To the contrary, the detailed scheme created by Congress evidences its intent to retain authority over regulation of smokeless tobacco. Cf. Patterson v. McLean Credit Union,

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24 As discussed below, Congress built on the youth education and age limit provisions of the Smokeless Tobacco Act in the Alcohol, Drug Abuse, and Mental Health Administration Reorganization Act of 1992 (1992 Amendments), Pub. L. No. 102-321, 106 Stat. 394 (codified at 42 U.S.C. § 300x-26).

491 U.S. 164, 181 (1989) (stating that courts "should be reluctant . . . to read an earlier statute broadly where the result is to circumvent the detailed remedial scheme constructed in a later statute"). The FDA may not, without empowerment by Congress, construct what it believes is a "better" regulatory scheme. MCI, 512 U.S. at 234. If the FDA believed that additional regulation was needed, the Secretary should have recommended such action to Congress, as directed in the Smokeless Tobacco Act. 15 U.S.C. § 4407(a)(4).

In 1992, Congress again addressed the problem of youth access to tobacco products. The Alcohol, Drug Abuse, and Mental Health Administration Reorganization Act of 1992 (1992 Amendments), Pub. L. No. 102-321, 106 Stat. 394, focused on regulation at the state level by providing financial incentives to States which enact and enforce access restrictions for individuals under age 18. 42 U.S.C. § 300x-26.25

The 1992 Amendments express clear congressional intent that States exercise their traditional police powers and take a primary role in attacking the problem of youth access to tobacco products. However, the FDA's proposed regulatory scheme would preempt much state regulation in this area, including more stringent regulations than those proposed by the FDA. The Act prohibits States from imposing on devices any requirements "different from, or in addition to" those imposed by the FDA. 21 U.S.C. § 360k(a). Thus, if the Act applied to tobacco products, § 360k(a) would prohibit States from addressing the problem of youth access. The FDA responds, FDA Red Br. p. 67, n. 16, that States "might" qualify for exemptions from preemption under § 360k(b). However, the possibility of a discretionary exemption does not take away the inherent conflict between the state regula-

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25 More specifically, States are eligible for the financial incentives only if they: (1) prohibit sales to individuals under age 18, 42 U.S.C. § 300x-26(a)(1); (2) enforce the prohibition in a way that "can reasonably be expected to reduce the extent to which tobacco products are available to individuals under the age of 18," 42 U.S.C. § 300x-26(b)(1); (3) conduct "random, unannounced inspections" of retailers to check compliance, 42 U.S.C. § 300x-26(b)(2)(A); and (4) make annual reports to the HHS Secretary regarding the manner and success of state enforcement activities, 42 U.S.C. § 300x-26(b)(2)(B).

tory role established by Congress and the FDA's proposed scheme. In developing its regulatory scheme for tobacco products, Congress made a policy determination that state participation was necessary for effective regulation of youth access. Allowing the FDA to override this decision would be contrary to congressional intent.

Over the last 60 years, Congress has enacted numerous statutes and amendments for the regulation of tobacco products. Throughout this period, Congress was well aware of the dangers of tobacco products and of the FDA's consistent position that it had no jurisdiction over tobacco products. Yet, Congress took no steps to overturn the FDA's interpretation of the Act, that it had no jurisdiction over tobacco products as customarily used. In fact, Congress deliberately rejected a role for the FDA during its consideration of various legislation from 1965 through 1993.26 Instead, Congress developed a regulatory scheme whereby it retained the position of policymaker for the industry.27 In addition, it developed a scheme whereby designated agencies would periodically report any new information and recommendations for legislation or regulation to Congress.28 Taken together, these actions by Congress are relevant and corroborative evidence that Congress never intended to give the FDA jurisdiction over tobacco products.

III. Conclusion

This is not a case about whether additional or different regulations are needed to address legitimate concerns about the serious health problems related to tobacco use, and particularly youth tobacco use, in this country. At its core, this case is about who has the power to

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26 Between 1965 and 1993, at least 13 bills were introduced in Congress which would have given the FDA jurisdiction over tobacco products. None of these bills were enacted.

27 Although Congress has given the FTC limited authority to regulate advertising related to tobacco products, this power is limited by the tobacco-specific legislation. 15 U.S.C. §§ 1336m, 4404-06.

28 The HHS, FTC, and Interagency Committee are all directed to make periodic reports to Congress including information on the health effects of tobacco products, the addictive nature of tobacco products, cigarette advertising. See e.g., 15 U.S.C. §§ 1337(a), (b), 1341(a)-(c); 42 U.S.C. § 290aa-2.

make this type of major policy decision. As the Supreme Court has previously stated about a different agency and its enabling statute, neither federal agencies nor the courts can substitute their policy judgments for those of Congress. See MCI, 512 U.S. at 234 (stating that "our estimations, and the [FCC's] estimations, of desirable policy cannot alter the meaning of the federal Communications Act of 1934"). In rejecting the agency's interpretation of its enabling statute, the MCI Court characterized the agency's action as "effectively the introduction of a whole new regime of regulation . .. which may well be a better regime but is not the one that Congress established." MCI, 512 U.S. at 234. Accordingly, we do not, indeed cannot, pass judgment on the merits of the regulatory scheme proposed by the FDA. By its ultra vires action, the FDA has exceeded the authority granted to it by Congress, and its rulemaking action cannot stand.

We are thus of opinion that Congress did not intend to delegate jurisdiction over tobacco products to the FDA. Accordingly, the judgment of the district court is

REVERSED.29

HALL, Circuit Judge, dissenting:

The FDCA delegates to the FDA the duty of promulgating and enforcing regulations aimed at protecting the nation's citizens from misbranded and unsafe drugs and food. After years of considering an array of evidence, much of it only recently brought to light, the FDA

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29 This footnote is added to make clear that the judgment of the district court regarding the construction of 21 U.S.C. § 360j(e), Coyne Beahm, 966 F. Supp. at 1399-1400, is vacated. The district court's construction of § 360j(e) was based on its erroneous holding that the FDA had authority to promulgate regulations regarding tobacco products. Had the district court reached the correct conclusion on the jurisdictional issue, there would have been no occasion to address the construction of § 360j(e). Accordingly, we vacate the district court's decision on that issue which is the subject of the government's appeal. We express no opinion on that question, and our decision should not be construed as either agreeing with or disagreeing with the district court's decision on the construction of § 360j(e).

decided to regulate a product that is estimated to cause some 400,000 deaths a year. While not actually disputing that tobacco products deliver a drug, nicotine, into the body, the majority would deny to the FDA the authority to act to address this acknowledged health threat. I dissent.

Tobacco products fit comfortably into the FDCA's definitions of "drug" and "device." Inasmuch as cigarettes and smokeless tobacco are responsible for illness and death on a vast scale, FDA regulations aimed at curbing tobacco use by children cannot possibly be contrary to the general intent of the FDCA to protect the public health. But even when we expand our search for legislative intent beyond the words of the statute, the evidence falls far short of demonstrating that Congress intended to deny or withdraw jurisdiction over tobacco from the FDA. Therefore, on the major question before us, I would affirm the district court's denial of summary judgment to the companies to the extent such judgment turns on the issue of the FDA's authority to regulate tobacco products.

As a consequence of this view, I must also reach those subordinate issues not discussed by the majority. I would affirm the denial of summary judgment to the companies on the issue of the FDA's choice of the "combination-products" regulatory scheme. I believe, however, that the district court erred in ruling that the FDA cannot, as a matter of statutory law, restrict the advertising of tobacco pursuant to the agency's authority to regulate the "sale" of such products.

I

When reviewing an agency's construction of a statute, we must first ask "whether Congress has directly spoken to the precise question at issue." Chevron, U.S.A., Inc., v. Natural Resources Defense Council, Inc., 467 U.S. 837, 842 (1984). The usual rule is to enforce the plain language of a statute according to its terms. United States v. Ron Pair Enters., Inc., 489 U.S. 235, 241 (1989). Whether the language is plain is "determined by reference to the language itself, the specific context in which the language is used, and the broader context of the statute as a whole." Robinson v. Shell Oil Company, 519 U.S. 337, ___, 117 S. Ct. 843, 846 (1997). Here, the language is

plain, and the context does not command a result contrary to the plain meaning.

The majority devotes approximately three paragraphs to the words that form the heart of the FDA's jurisdictional claim: "[T]he term 'drug' means . . . articles (other than food) intended to affect the structure or function of the body." 21 U.S.C.§ 321(g)(1)(C). While as much as conceding that tobacco products fit the FDCA's "literal" definition of drug, the majority concentrates instead on what it believes is abundant evidence elsewhere demonstrating that Congress has never intended that tobacco come under FDA authority. Despite the apparent agreement about the "literal" meaning of "drug" and "device," a few words are necessary to set the stage before moving on to a discussion of the "context" of the FDCA.

A

The rulemaking record contains voluminous evidence of the pharmacological effects of nicotine; in addition to being highly addictive, nicotine acts as a stimulant, tranquilizer and appetite suppressant. See 61 Fed. Reg. 44665-66 (1996). Under these assumed facts, nicotine clearly "affect[s] the structure or function of the body of man . . .", and I do not understand the majority to be saying otherwise. The only arguable impediment to a complete fit between the terms of the statute and tobacco products is the word "intended."

B

Building on the conclusion that the nicotine in tobacco products is highly addictive, the FDA proffered four independent rationales to satisfy the additional requirement that tobacco products be "intended" to affect the body: (1) a reasonable manufacturer would foresee that consumers would use the product to satisfy addiction, see 61 Fed. Reg. 44634, 44701-39; (2) most consumers do in fact use tobacco products to satisfy addiction, see id. at 44233; (3) the manufacturers have long known that consumers use the products for the pharmacological effects, see id. at 44849; and (4) the manufacturers design the products to deliver active doses of nicotine, see id. at 44951. On reasoning with which I agree, the district court held that the FDA could proffer evidence in support of the first and second of these rationales.

Coyne Beahm, 966 F. Supp. at 1388-92. In addition, I would also permit the use of recently disclosed evidence, including heretofore-secret company documents, that establish that the companies have known about the addictive qualities of their products for years and that cigarettes are deliberately manipulated to create and sustain addiction to nicotine.

My dictionary contains the following definitions of"intend": "1. To have in mind: PLAN. 2a. To design for a particular purpose. b. To have in mind for a particular purpose." WEBSTER'S II NEW RIVERSIDE UNIVERSITY DICTIONARY (1984). As a matter of simple English, the resultant effect on the body – nicotine addiction– is intended when the manufacturer (as we are assuming for the purposes of this appeal) deliberately designs the product to have that effect. This meaning is the primary, literal, and most common one attached to the word "intend," and it is ordinarily the one we should use. See Asgrow Seed Co. v. Winterboer, 513 U.S. 179, 187 (1995) ("When terms used in a statute are undefined, we give them their ordinary meaning."). The majority's argument does not convince me that we should abandon this common sense rule in this situation.

Prior to these rules, the FDA had "asserted jurisdiction over cigarettes only when health claims were made by the vendors or manufacturers." Action on Smoking and Health v. Harris, 655 F.2d 236, 239 & n.7 (D.C. Cir. 1980) [hereinafter ASH] (citing as examples United States v. 354 Bulk Cartons . . . Trim Reducing-Aid Cigarettes, 178 F. Supp. 847 (D.N.J. 1959), in which cigarettes were marketed as weight reduction aids, and United States v. 46 Cartons . . . Fairfax Cigarettes, 113 F. Supp. 336 (D.N.J. 1953), in which cigarettes were marketed as helping to prevent respiratory diseases). No other court, however, has been confronted with the type and quantity of evidence collected during the rulemaking process in this case; the strength of nicotine's addictive qualities, the extent of the health problems created by tobacco products, and the complicity of the manufacturers bring us to a different place than we have been before.

Products deliberately designed to create and sustain addiction are not likely to be marketed as such; indeed, such products are more likely listed elsewhere in Title 21 among the illegal controlled substances. It strikes me as patently absurd to contend that cigarettes and

Tobacco - Litigation

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June 10, 1997

HAND DELIVERY TO THE FOLLOWING RECIPIENTS:

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Ms. Harriet Rabb
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Mr. Andy Hyman
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RE: Coyne Beahm, Inc.; Am. Advertising Federation; United States Tobacco Company and Nat'l Ass'n of Convenience Stores v. FDA M.D. N.C. (Osteen), Case Nos. 2:95CV00591, 2:95CV00706, 2:95CV00593 and 6:95CV00665

Dear Mr. Lindsey, Ms. Kagan, Ms. Drye, Mr. Burson, Ms. Rabb, and Mr. Hyman:

Enclosed is the government's opening brief that we are filing tomorrow in the Fourth Circuit in the case where the tobacco companies challenged FDA's regulation of tobacco products.

Sincerely,

George J. Phillips

Enclosure

No. 97-1604 (consolidated with Nos. 97-1581, 1605, 1606, & 1614)

IN THE UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

BROWN AND WILLIAMSON TOBACCO CORP., *et al.*,
Plaintiffs/Appellants/Cross-Appellees,

v.

FOOD AND DRUG ADMINISTRATION, *et al.*,
Defendants/Appellees/Cross-Appellants.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF NORTH CAROLINA

BRIEF FOR APPELLANTS FOOD AND DRUG ADMINISTRATION, *et al.*

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STATEMENT OF SUBJECT MATTER AND APPELLATE JURISDICTION

The district court had jurisdiction over this case under 28 U.S.C. § 1331. The district court entered an order on April 25, 1997, granting in part and denying in part summary judgment to the plaintiffs, and granting in part and denying in part an injunction; the court also certified its order for immediate interlocutory review under 28 U.S.C. § 1292(b).

By order of May 13, 1997, this Court granted timely petitions for immediate appeal under Section 1292(b) filed by two of the plaintiff groups and the defendants. This Court also has jurisdiction over the Government's appeal under 28 U.S.C. § 1292(a)(1) because the Government filed a timely notice of appeal (on May 2, 1997) from the partial injunction granted. The Court has consolidated all appeals.

STATEMENT OF THE ISSUES

1. Whether the district court correctly held that, despite the Food and Drug Administration's authority under 21 U.S.C. § 360j(e) to restrict the "sale, distribution, or use" of tobacco products and to impose "other conditions," the agency lacked authority under that provision to regulate the promotion and advertising of such products in relation to minors.

2. Whether the district court validly enjoined Food and Drug Administration regulations governing access to tobacco products by minors and the labeling of these products, even though the court upheld the agency's authority to issue those regulations.

STATEMENT OF THE CASE

A. Nature Of The Case

On August 28, 1996, after conducting the most extensive notice-and-comment rulemaking in its history, the Food and Drug Administration (hereafter "FDA") published in the *Federal Register* "Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco

to Protect Children and Adolescents." 61 Fed. Reg. 44396 (1996) (reprinted in JA Exh. Vol.).[1] Annexed to and made part of this rule was the "Jurisdictional Determination," in which FDA explained its statutory authority to regulate tobacco products. 61 Fed. Reg. 44619 (1996).

In these regulations, FDA determined that the nicotine in cigarettes and smokeless tobacco is a "drug" within the meaning of the Federal Food, Drug, and Cosmetic Act (hereafter "the Act"), and that tobacco products contain components that are "devices" under the statute. The agency determined that cigarettes and smokeless tobacco contain both a drug (nicotine) and device components, and that they are "combination products" under the Act. The regulations are designed to reduce smoking by children by restricting access to tobacco products by minors, as well as the labeling, promotion, and advertising of these products.

Plaintiffs (tobacco companies, advertisers, and convenience store owners) filed this action in district court, challenging the validity of FDA's regulations. They sought summary judgment, claiming that, as a matter of law: (1) Congress has withheld from FDA the authority to regulate cigarettes and smokeless tobacco as marketed by plaintiffs; (2) the Act does not authorize FDA to regulate cigarettes and smokeless tobacco as drugs or devices; and (3) the restrictions that FDA placed on advertising and promotion of cigarettes and smokeless tobacco violate the First Amendment. In moving for summary judgment, plaintiffs accepted as true the facts found by FDA in its jurisdictional determination and the preamble to the tobacco regulations.

The district court partially granted and partially denied plaintiffs' motions. The court agreed with FDA that the agency has authority to regulate tobacco products under the Act, and

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[1] (JA __) citations refer to pages in the Joint Appendix filed with this brief. The FDA final regulations, preamble, and jurisdictional determination are included in the Joint Appendix as a separately bound Exhibit Volume with the original *Federal Register* pagination.

therefore can restrict access by minors to such products. The court further held, however, that 21 U.S.C. § 360j(e) does not authorize FDA to regulate promotion and advertising of tobacco products to minors, and, accordingly, it enjoined those restrictions. The court also enjoined many of the restrictions that it had ruled the agency had authority to impose.

B. The Statutory Scheme

In 1938, Congress passed the Federal Food, Drug, and Cosmetic Act, expanding the definition of "drug" in the Food and Drugs Act of 1906 to include articles "intended to affect the structure or any function of the body." 21 U.S.C. § 321(g)(1)(C). This expansion was intended to "amplif[y] and strengthen[]" the statutory scheme. H.R. Rep. No. 75-2139, at 2 (1938).

Congress also granted FDA the authority to regulate "devices," which include items intended to affect the structure or any function of the body. 21 U.S.C. § 321(h). The "expansion of the definition of the term 'drug' and the inclusion of devices are essential if the consumer is to be protected against a multiplicity of abuses not subject to the present law." S. Rep. No. 74-646, at 1 (1935). The Supreme Court described this legislative change:

> The historical expansion of the definition of drug, and the creation of a parallel concept of devices, clearly show, we think, that Congress fully intended that the Act's coverage be as ***broad as its literal language indicates*** — and equally clearly, ***broader than any strict medical definition might otherwise allow. * * * [R]emedial legislation such as the Food, Drug, and Cosmetic Act is to be given a liberal construction consistent with the Act's overriding purpose to protect the public health.***

United States v. An Article of Drug ...Bacto-Unidisk, 394 U.S. 784, 798 (1969) (emphases added).

As the Act now reads, "drug" includes, in relevant part, "articles (other than food) intended to affect the structure or any function of the body of man or other animals." 21 U.S.C. § 321(g)(1). (The relevant portions of the Act are reprinted in an addendum to this brief.) "Device" includes "an instrument, apparatus, implement, machine, contrivance, implant, in vitro

reagent, 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 of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes." *Id.*, § 321(h).

The Act imposes substantial restrictions regarding the design, content, manufacture, distribution, advertising, sale, and use of drugs and devices, and has also provided FDA with broad regulatory authority to protect public health.[2]

For example, the Act mandates that certain drugs may be dispensed only pursuant to a prescription. 21 U.S.C. § 353(b). A related, but more expansive provision for devices authorizes FDA to restrict the "sale, distribution, or use" of a device. 21 U.S.C. § 360j(e)(1) — the provision at the center of this case — provides, as pertinent, that FDA

> may by regulation require that a device be restricted to sale, distribution, or use — (A) only upon the written or oral authorization of a practitioner licensed by law to administer or use such device, or (B) upon such other conditions as [FDA] may prescribe in such regulation, if, because of its potentiality for harmful effect or the collateral measures necessary to its use, [FDA] determines that there cannot otherwise be reasonable assurance of its safety and effectiveness.

In addition, the Act bans the misbranding of drugs and devices *(see* 21 U.S.C. § 331(b)), and restricted devices are misbranded if their advertising is false or misleading, or if they are sold, distributed, or used in violation of regulations promulgated by FDA. *See* 21 U.S.C. § 352(q). The Act also requires that all advertisements for restricted devices include a statement of the intended uses of the device and relevant warnings regarding side effects, precautions, and

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[2] In the Act, Congress has made most delegations of authority to the Secretary of Health and Human Services through the Commissioner of Food and Drugs. 21 U.S.C. § 393(b)(2). For simplicity, we refer to the legislative delegations as being made to FDA.

contraindications. 21 U.S.C. § 352(r).

For products that constitute "a combination of a drug, device, or biological product," the Act provides that FDA shall determine "the primary mode of action of the combination product," which then determines which agency component will be assigned responsibility for premarket review of the product. 21 U.S.C. § 353(g)(1). The agency may regulate drug/device combination products using its drug authorities, device authorities, or both. 61 Fed. Reg. 44400-03.

In sum, the statutory scheme established by Congress provides for broad definitions of drugs and devices, allows for significant limits on the "sale, distribution, or use" of such products (as well as combinations of the two), and delegates to FDA substantial authority to establish by regulation the conditions under which devices may be made available to the public.

C. Statement Of The Facts

1. The Health Effects of Cigarettes and Smokeless Tobacco

FDA's extensive rulemaking record shows that tobacco use is the largest cause of preventable death in the United States. More than 400,000 people die each year from tobacco-related illnesses such as cancer, respiratory illnesses, and heart disease. Tobacco alone kills more Americans annually than AIDS, alcohol, car accidents, homicides, suicides, illegal drugs, and fires combined. The average tobacco user loses 15 years of life. 61 Fed. Reg. 44571.

Although death from tobacco use occurs among adults, FDA found in its rulemaking that tobacco use is a "pediatric disease" because most adult smokers become addicted to nicotine in tobacco during childhood. *Id.* at 44421. Over 80% of the adult smokers in the U.S. started to smoke as children or adolescents. Because nearly all first use of tobacco occurs before high school graduation, if adolescents can be kept tobacco-free, most will never start using tobacco. *Id.* at 44399. Most of the children and adolescents who now smoke already regret their decision to start

and say they want to quit, but cannot. *Id.* at 44398.

Approximately three million American children and adolescents now smoke; an additional one million adolescent males use smokeless tobacco. Every year, approximately one million children and adolescents begin to smoke — nearly 3,000 per day. FDA found that one of every three young tobacco users will eventually die from a tobacco-related disease. *Id.* at 44398, 44568.

In its rulemaking, FDA recognized that the problem of youth tobacco use is getting worse. The agency found that the percentage of eighth and tenth graders who smoke has risen for four consecutive years. The prevalence rates of adolescent smokers are 20% to 30% higher than in 1991. *Id.* at 44399. Based on these facts, FDA concluded that cutting in half the number of children and adolescents who start to use cigarettes and smokeless tobacco will have profound, beneficial effects on public health. *Id.* at 44568-69.

2. The Basis for the Assertion of FDA Jurisdiction

FDA has authority to address the serious public health problems caused by cigarettes and smokeless tobacco if they are "drugs" or "devices" under the Act. Historically, FDA has asserted jurisdiction over tobacco products when there was sufficient evidence to establish that the products were "intended" to affect the structure or function of the body. *See, e.g., United States v. 354 Bulk Cartons . . . Trim Reducing-Aid Cigarettes*, 178 F. Supp. 847 (D.N.J. 1959). Conversely, when the evidence failed to support a finding of intent to affect the structure or function of the body, FDA determined that it lacked jurisdiction to regulate cigarettes. 61 Fed. Reg. 45222-23.

Prior to this rulemaking, FDA last considered in the late 1970s whether it had jurisdiction over cigarettes for which no express therapeutic claims were made, when it rejected petitions by Action on Smoking and Health ("ASH") that urged FDA to regulate cigarettes as drugs or devices. The agency then concluded that the available evidence was insufficient to establish that cigarettes

were intended to affect the structure or function of the body. The D.C. Circuit deferred to FDA's judgment, but expressly left open the possibility that, in the future, FDA could obtain sufficient factual support to exercise jurisdiction generally over cigarettes and smokeless tobacco. *See ASH v. Harris*, 655 F.2d 236, 239-41, 242 n.10 (D.C. Cir. 1980).

In April 1988, the American Heart Association and other public health organizations again petitioned FDA to regulate cigarettes under the Act. FDA conducted an extensive investigation, issued a proposed rule with a jurisdictional analysis, and invited public comments. 60 Fed. Reg. 41314 (1995). The jurisdictional determination published on August 28, 1996, is the agency's decision on this issue. As summarized below, FDA has now found that cigarettes and smokeless tobacco fit the statutory definition of drugs and devices because they "affect the structure or any function of the body," and these effects are "intended" by the manufacturers.

a. The Evidence That Nicotine in Cigarettes and Smokeless Tobacco "Affect[s] the Structure or Any Function of the Body"

FDA's determination that nicotine in cigarettes and smokeless tobacco affects the "structure or any function of the body" is based on the key findings that nicotine in cigarettes and smokeless tobacco causes and sustains addiction. 61 Fed. Reg. 44630, 44665-66. Nicotine does so by exerting psychoactive, or mood-altering, effects on the brain, and by producing chemical reactions in the brain that motivate repeated, compulsive use and create dependence in the user. *Id.* at 44666. Nicotine directly affects a part of the brain known as the mesolimbic system, which rewards the repeated consumption of certain pleasurable substances. It is believed that amphetamine, cocaine, and nicotine all cause the compulsive drug-seeking behavior of drug addiction through the same mechanism: increasing the activity of the neurotransmitter dopamine within the mesolimbic system. *Id.* at 44700. In some cases, nicotine in cigarettes and smokeless

tobacco can have a sedating or tranquilizing effect on mood and brain activity, while in others, it can have a stimulant effect. *Ibid.* Further, clinical and animal studies indicate that nicotine causes weight loss, and that cessation of nicotine administration results in weight gain. *Ibid.*

FDA found that these effects on the structure and function of the body are significant, quintessentially drug-like, and the same as those that FDA has traditionally regulated in drugs such as stimulants, tranquilizers, appetite suppressants, nicotine replacement products, and narcotics used to treat addiction (*e.g.*, methadone). *Id.* at 44632, 44666-70.

b. The Evidence That the Pharmacological Effects of Nicotine in Cigarettes and Smokeless Tobacco Are "Intended"

FDA found that since it last examined its jurisdiction over tobacco products three independent categories of evidence have emerged, demonstrating that the pharmacological effects described above are "intended." 61 Fed. Reg. 45227.

Foreseeability. First, there has developed "a scientific consensus, on the basis of overwhelming scientific evidence, that nicotine in cigarettes and smokeless tobacco is highly addictive and produces significant effects on the structure and function of the body." 61 Fed. Reg. 45227. Before 1980, no major public health organization had determined that nicotine was an addictive drug. By 1995, however, all major public health organizations in the United States and abroad with expertise in tobacco or drug addiction, including the American Psychiatric Association (1980), the U.S. Surgeon General (1986 and 1988), the American Psychological Association (1988), the Royal Society of Canada (1989), the World Health Organization (1992), the American Medical Association (1993), and the Medical Research Council in the United Kingdom (1994), had concluded that nicotine is addictive. *Id.* at 44634, 45228-33. In addition, substantial evidence since 1980 has established that nicotine has other significant pharmacological effects, such as

changes in mood and alertness. *Id.* at 45229-32.

FDA determined that, with this scientific consensus, a reasonable manufacturer must now foresee that cigarettes and smokeless tobacco cause consumers to become addicted to nicotine and will be used by consumers for pharmacological purposes, including satisfying their addiction. *Id.* at 44634, 44701-39. Applying the legal principle that "every man intends the legitimate consequence of his own acts" (*Agnew v. United States*, 165 U.S. 36, 53 (1897)), the agency concluded that the manufacturers intend cigarettes and smokeless tobacco to result in addiction and thereby affect the structure and function of the body. 61 Fed. Reg. 44633-35, 44690-91.

Consumer Use. Second, FDA found in its rulemaking "scientific data establishing that the vast majority of consumers who use cigarettes and smokeless tobacco are addicted to them and use these products nearly exclusively to obtain the pharmacological effects of nicotine." 61 Fed. Reg. 45227. Scientific evidence accumulated since 1980 shows that over 75% of smokers, and as many as 75% of young regular smokeless tobacco users, are addicted to nicotine and use cigarettes and smokeless tobacco to satisfy their addiction and for their mood-altering effects. *Id.* at 45233. *See also id.* at 44635-36, 44807-08.

Manufacturers' Statements and Actions. Third, FDA relied upon "newly disclosed evidence showing that tobacco companies have in mind that their products will be used by consumers for pharmacological purposes and have designed their products to affect the structure and function of the body." 61 Fed. Reg. 45227. Although this evidence includes three decades of tobacco industry statements, research, and actions, virtually none of it was known to anyone other than the manufacturers, nor was it disclosed to FDA, until this material was recently revealed through the agency's investigation, congressional hearings, and disclosures by tobacco company officials and employees. *Id.* at 45235-36.

This newly found evidence led to two central findings regarding the manufacturers' intent. First, FDA determined that "[m]anufacturers of cigarettes and smokeless tobacco know that nicotine in their products causes pharmacological effects in consumers, including addiction to nicotine * * * and that consumers use their products primarily to obtain the pharmacological effects of nicotine." *Id.* at 44630. This finding was based in part on evidence that senior officials and researchers for the tobacco manufacturers had, for decades, consistently — but secretly — characterized nicotine as:

> "'*addictive*,'" *id.* at 44884 (quoting A.Y. Yeaman, general counsel of Brown & Williamson (1963)) (emphasis added);
>
> "'*a potent drug* with a variety of physiological effects * * * [and] *a habit-forming alkaloid*,'" *id.* at 44867 (quoting C.E. Teague, assistant director of research for R.J. Reynolds (1972)) (emphases added);
>
> "'*a powerful pharmacological agent* with multiple sites of action,'" *id.* at 44857 (quoting J.L. Charles, Philip Morris researcher (1980)) (emphasis added);
>
> "'*an extremely biologically active compound* capable of eliciting a range of pharmacological, biochemical and physiological responses,'" *id.* at 44888 (quoting BATCO researchers (1980)) (emphasis added).

FDA also relied upon "evidence show[ing] that the manufacturers have known for decades * * * that consumers use cigarettes primarily to obtain the pharmacological effects of nicotine, including satisfaction of their addiction." *Id.* at 44849. For example, researchers for R.J. Reynolds recognized in the 1970s that "'[t]he confirmed user of tobacco products is primarily seeking the physiological 'satisfaction' derived from nicotine'" (*id.* at 44868), and that "'[w]ithout any question, the desire to smoke is based upon the effect of nicotine on the body'" (*id.* at 44871). This knowledge of the researchers was communicated to the highest levels of the tobacco companies. As early as 1969, Philip Morris's vice president for research and development notified his board of directors that "'the ultimate explanation for the perpetuated cigaret[te] habit

resides in the pharmacological effect of smoke upon the body of the smoker.'" *Id.* at 44856.

Second, FDA found that "[m]anufacturers of cigarettes and smokeless tobacco design their products to provide consumers with a pharmacologically active dose of nicotine." *Id.* at 44630. In the case of cigarettes, FDA found:

> ***Manufacturers of commercially marketed cigarettes commonly manipulate nicotine deliveries to provide remarkably precise, pharmacologically active doses of nicotine to consumers.*** The principal techniques that are used to control and manipulate nicotine deliveries include: (1) the use of nicotine-rich tobacco blends in low-tar cigarettes; (2) the use of filtration and ventilation technologies that selectively remove more tar [than nicotine] from smoke * * * ; and (3) the use of chemical additives that increase the percentage of "free" nicotine in cigarette smoke.

Id. at 44951 (emphasis added). FDA further determined that smokeless tobacco manufacturers also manipulate nicotine deliveries. *Id.* at 45108.

Indeed, tobacco company documents in the rulemaking record revealed that senior industry officials and researchers expressly conceived of cigarettes and smokeless tobacco as:

> "'*a dispenser for a dose unit of nicotine*,'" *id.* at 44856 (quoting W.L. Dunn, Philip Morris researcher (1972)) (emphasis added);
>
> "'*a vehicle for delivery of nicotine*, designed to deliver the nicotine in a generally acceptable and attractive form,'" *id.* at 44868 (quoting C.E. Teague, assistant director of research for R.J. Reynolds (1972)) (emphasis added); and
>
> "'*the means of providing a nicotine dose in a metered fashion*,'" *id.* at 44890 (quoting BATCO researchers (1984)) (emphasis added).

c. The Evidence That Cigarettes and Smokeless Tobacco Are "Combination Products"

As noted earlier, products such as cigarettes and smokeless tobacco that are intended to affect the structure and function of the body can be drugs, devices, or combinations of the two under the Act. The critical distinction between these product types is that a device "does not achieve its primary intended purposes through chemical action within or on the body * * * and

* * * is not dependent upon being metabolized" to achieve its primary intended purposes. 21 U.S.C. § 321(h). A product that has both drug and device components can be regulated as a "combination product." 21 U.S.C. § 353(g). Combination products include drug delivery systems, such as preloaded inhalers or syringes, and adhesive patches containing nicotine to help relieve tobacco-related withdrawal symptoms. 61 Fed. Reg. 45210-11.

Based on the record evidence regarding the pharmacological effects and intended uses of nicotine, FDA concluded that the nicotine in cigarettes and smokeless tobacco is a drug. *Id.* at 45207. However, FDA further found that cigarettes and smokeless tobacco are not simply packaged nicotine, but rather "a highly engineered product" with device components that "have been carefully designed to deliver controlled, pharmacologically active doses of nicotine to the smoker." *Id.* at 45209. Similarly, FDA found that processed tobacco in smokeless tobacco "deliver[s] the nicotine to the cheek and gum tissue for absorption into the body." *Id.* at 45213-14. Thus, the agency determined that these components of cigarettes and smokeless tobacco meet the statutory definition of a device, and that cigarettes and smokeless tobacco are therefore combination products. *Id.* at 45208-16.

3. FDA's Tobacco Products Rule

Once FDA found that cigarettes and smokeless tobacco are combination products under the Act, the agency had to choose whether it would regulate these products as drugs, devices, or both. 61 Fed. Reg. 44400-03. The agency elected to use the Act's authority to regulate devices because that authority offers the agency "additional flexibility" to develop "careful, tailored solutions" to the unique safety concerns presented by tobacco products. *Id.* at 44404.

Considering the large number of Americans who are currently addicted to nicotine, FDA determined that a ban on cigarettes and smokeless tobacco would unlikely be effective in

protecting consumers from the serious risks of these products. Black markets and smuggling could develop, offering products that likely "would be even more dangerous than those currently marketed." *Id.* at 44413; *see also id.* at 44398, 44405. Furthermore, a ban could result in adverse health consequences for the millions of adults who are dependent on nicotine. *Id.* at 44413; *see also id.* at 44398, 44405.

FDA therefore concluded that, to address effectively the death and disease caused by cigarettes and smokeless tobacco, addiction to these products must be eliminated or substantially reduced. *Id.* at 44398, 44413. The agency found that this goal could be achieved best by preventing minors from beginning use of cigarettes and smokeless tobacco. *Id.* at 44399. Accordingly, FDA determined that "restrictions to reduce the use of cigarettes and smokeless tobacco by individuals under the age of 18 while leaving these products on the market for adults * * * is the available option that is the most consistent with both the [A]ct and the agency's mission to protect the public health." *Id.* at 44398.

The evidence before the agency demonstrated that the most effective way to achieve such a reduction is to limit both minors' access to cigarettes and smokeless tobacco and the attractiveness of such products. FDA thus invoked its "restricted device" authority (21 U.S.C. § 360j(e)), which authorizes it to impose conditions on the "sale, distribution, or use" of a device if "there cannot otherwise be reasonable assurance of its safety and effectiveness." Pursuant to Section 360j(e), FDA adopted regulations designed "to ensure that children and adolescents are unable to have access to cigarettes and smokeless tobacco," and "to prevent advertising by the manufacturers of cigarettes and smokeless tobacco from undercutting the access restrictions." 61 Fed. Reg. 44406.

FDA found that, despite state laws outlawing sales of tobacco products to minors,

adolescents have had little difficulty purchasing tobacco products. For instance, recent studies of over-the-counter sales showed that 67% of minors are able to purchase tobacco products illegally, and that a higher percentage (88%) is able to make such purchases from vending machines. *Id.* at 44426. *See* 60 Fed. Reg. 41325-26 (youth access to free samples and self-service displays).

Given this evidence and the extensive public comments, FDA adopted regulations designed to reduce these means of easy access to cigarettes and smokeless tobacco by minors, while permitting continued availability to adults. The access restrictions prohibit the sale of cigarettes and tobacco products to persons under age 18; require retailers to check the photographic identification of persons under age 27; ban distribution of free samples; and prohibit vending machine sales of cigarettes and smokeless tobacco and self-service displays except in predominantly adult locations. 61 Fed. Reg. 44616-17.

As for the effects of tobacco advertising on children and adolescents, FDA found that cigarettes and smokeless tobacco are "among the most heavily advertised and widely promoted products in America." *Id.* at 44475. In 1993 alone, the cigarette and smokeless tobacco industries spent over $6.1 billion to market and promote their products in diverse media, including "magazines, newspapers, outdoor advertising, point of purchase, direct mail, in-store, dissemination of nontobacco items with brand identification [such as t-shirts and hats], and sponsorship of cultural and sporting events." *Ibid.*

Two recent, comprehensive analyses by the National Academy of Science's Institute of Medicine and the Surgeon General found that tobacco advertising plays a significant role in the decisions of young people to use cigarettes and smokeless tobacco. *Id.* at 44487-88. In addition, as the nation's largest psychological association concluded, "color and imagery in advertisements are important components for young people" because they "generally have less

information-processing ability than adults, and they are less able or less willing to pay attention to the factual information in the advertisements," and tobacco advertising "plays directly to the factors" that are most appealing to youth. *Id.* at 44468, 44488; see also *id.* at 44485-86. Further, the Centers for Disease Control and Prevention demonstrated that more than twice as many children and adolescents (86%) than adults are likely to buy the three most heavily advertised brands. 60 Fed. Reg. 41332. This study demonstrated that minors' choices of cigarettes and smokeless tobacco are "directly related to the amount and kind of advertising." *Ibid.*

Advertising campaigns using appealing imagery "have been particularly effective with children." *Id.* at 44476. For instance, the "Joe Camel" campaign, featuring a fanciful cartoon figure, had a dramatic effect on Camel's share of the youth market, increasing it fourfold, between 1988, when "Joe Camel" was introduced, and 1992. During the same period, the campaign had no effect on Camel's share of the adult market. Moreover, 30% of three-year-olds and more than 90% of six-year-olds were able to identify "Joe Camel" as a symbol for smoking. *Id.* at 44476-78.

This record evidence led FDA to conclude that "young people * * * are also very impressionable and therefore vulnerable to the sophisticated marketing techniques employed by the tobacco industry, techniques that associate the use of tobacco products with excitement, glamour, and independence" (*id.* at 44398); "cigarette and smokeless tobacco advertising has a powerful appeal to children and adolescents" (*id.* at 44471); and "the pervasiveness and imagery used in industry advertising and promotional programs often obscure adolescent perceptions of the significance of the associated health risks and the strength of the addictive power of tobacco products" (*id.* at 44571). FDA additionally found that empirical evidence from the experiences of other countries shows that increases in advertising expenditures led to increases in smoking. *Id.* at 44487-93. Thus, the agency concluded, "the evidence in this proceeding demonstrates that

cigarette and smokeless tobacco advertising plays a material role in the decision of children and adolescents under the age of 18 to engage in tobacco use." *Id.* at 44489.

Internal tobacco company documents also provide "convincing evidence" of an intent "to attract young smokers and so-called presmokers" through advertising. *Id.* at 44480. *See, e.g., ibid.* (if R.J. Reynolds "'is to survive and prosper, over the long-term we must get our share of the youth market'"); *id.* at 44481 ("'[e]vidence now available * * * indicate[s] that the 14 to 18 year old group is an increasing segment of the smoking population. RJR must soon establish a successful new brand in this market if our position in the industry is to be maintained'").

Based on the record before it, FDA determined that advertising restrictions are necessary to "ensur[e] that the restrictions on access are not undermined by the product appeal that advertising for these products creates for young people," and that, "[t]o be effective, these restrictions must be comprehensive." *Id.* at 44465, 44489-90. FDA also decided that ***both*** access ***and*** advertising restrictions are necessary to meet public health goals, and it stressed the complementary nature of such restrictions: "The effectiveness of the restrictions on youth access would be substantially diminished if the manufacturers were free to entice children and adolescents to circumvent the access restrictions." *Id.* at 44406-07; *see also id.* at 44408. FDA's advertising restrictions directly address a critical component of underage cigarette and smokeless tobacco use that is largely beyond the reach of access restrictions: the development of the desire of children to use tobacco. FDA found that, without such restrictions, tobacco advertising will continue to contribute to the decisions of a significant percentage of young people to purchase and to use tobacco products, and thereby significantly undermine the effectiveness of the agency's access restrictions and result in continued sales to, and use by, minors. *See id.* at 44465-66.

FDA therefore developed restrictions on tobacco advertising that "retain the informational

function of advertising by permitting text-only advertising while removing color and imagery from those advertisements to which young people are unavoidably exposed." *Id.* at 44469. These restrictions include: the use of a black-and-white, text-only advertising format, except in adult publications and adult-only facilities; a ban on outdoor advertising of cigarettes and smokeless tobacco within 1,000 feet of schools and public playgrounds; a prohibition on the sale or distribution (by tobacco companies and distributors) of non-tobacco products (such as hats and t-shirts) bearing a tobacco product brand name or logo; and a prohibition on sponsoring athletic, cultural, or other events in a tobacco brand name. *Id.* at 44617-18.

In adopting these regulations, the agency explicitly addressed arguments that it lacks authority to regulate promotion and advertising under Section 360j(e), concluding that that statutory provision supplies the necessary authority. *See id.* at 44406-08. Further, consistent with its authority to promulgate restrictions under 21 U.S.C. § 360j(e)(1) that are necessary to provide "reasonable assurance of [a device's] safety and effectiveness," FDA found:

> Without effective restrictions on sale and distribution of cigarettes and smokeless tobacco to children and adolescents under 18, young people will continue to become addicted to these products and, once addicted, will as adults continue to use them in spite of their potential for harmful effects. * * * ***Thus, there can be no doubt that without the access and advertising restrictions imposed in this final rule, no finding that there is a reasonable assurance of safety for cigarettes and smokeless tobacco would be possible.***

61 Fed. Reg. 44407 (emphasis added).

4. The District Court's Rulings

On April 25, 1997, the district court issued an opinion and an order partially denying and partially granting plaintiffs' motions for summary judgment, and granting partial injunctive relief.

First, the court acknowledged that it must review FDA's construction of the Act pursuant to *Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984), and

determine whether the agency has given the statute a permissible interpretation. The court held that FDA properly determined that tobacco products fit within the broad "drug" and "device" definitions of the Act and, therefore, are within the agency's jurisdiction. The court rejected plaintiffs' argument that, in other statutes, Congress, in effect, repealed the Act's product definitions encompassing tobacco products. (JA 370-405.)

The court also concluded that FDA could limit access to these products pursuant to its power in Section 360j(e) to restrict the "sale, distribution, or use" of such devices. Consequently, the court ruled that "FDA's access restrictions will stand." (JA 413.)

The court ruled, however, that FDA exceeded its authority by regulating the advertising and promotion of tobacco products to minors under Section 360j(e). The court agreed that, under that section FDA may restrict the "sale, distribution, or use" of tobacco products because they are restricted devices. But the court determined that "sale," as ordinarily defined and as used in the Act, does not include promotion and advertising directed at making a sale. (JA 408.) In addition, the court ruled that, even if "sale" could be read to include the advertising and promotion of tobacco products, the authority in Section 360j(e) empowering FDA to impose "other conditions" on the sale of restricted devices still does not extend to regulation of such activities. (JA 409.)

The district court also concluded (JA 411-12) that Congress meant to limit FDA's power to regulate advertising and promotion of restricted devices to authorities elsewhere in the Act, in 21 U.S.C. §§ 352(q) and 352(r). (As explained earlier, in those provisions, Congress provided that a drug or device is misbranded if false or misleading advertising is used, and that advertisements for any restricted device must include certain information, such as the name and intended uses of the product.)

The district court thus struck down the advertising and promotion regulations at issue. (JA

412-13.) Because it so ruled on statutory grounds, the court did not reach plaintiffs' First Amendment claims. (JA 414 n.33.)

The district court consequently granted summary judgment to plaintiffs on the FDA restrictions concerning promotion and advertising, but it denied that motion as to the youth access and labeling requirements. Although the court allowed FDA to continue to implement the access restrictions that went into effect in February 1997 (those prohibiting sale of tobacco products to minors and requiring photographic identification for certain sales), it ordered FDA not to implement those access and labeling restrictions scheduled to go into effect on August 28, 1997, despite upholding FDA's authority to issue such regulations.[3] (JA 417-18.)

SUMMARY OF ARGUMENT

1. The district court correctly upheld FDA's jurisdictional determination that, under the clear and expansive terms of the Act, tobacco products are drug/device combination products within the agency's authority to regulate. However, after undertaking that thorough, careful review and giving appropriate deference to Congress's intent and FDA's reasonable interpretation of the Act (*see Chevron*), the court changed course; it adopted a narrow reading of 21 U.S.C. § 360j(e) — which allows FDA to restrict the "sale, distribution, or use" of devices by imposing "other conditions" thereupon — and substituted its own view of the Act for that of the agency. The court did so without any determination that FDA had adopted an impermissible interpretation of the Act when it concluded that Section 360j(e) authorizes conditions on device advertising and

[3] The court enjoined access restrictions that require a face-to-face exchange; prohibit individual or unpackaged cigarettes or tobacco products, self-service displays, and free samples of tobacco products; and limit vending machine sales to adult environments. *See* 61 Fed. Reg. 44616-17. The enjoined labeling restrictions require the established name on the product and its advertising and a statement of intended use — "Nicotine-Delivery Device for Persons 18 or Older." *See id.* at 44617.

promotion.

As the Supreme Court explained in *Chevron*, the function of the court was to determine first whether actions taken by FDA in regulating tobacco products as drug/device combination products were inconsistent with the clear, broad provisions of the Act. Where Congress has left ambiguity in the statute or delegated authority to FDA to enforce it, then the court's responsibility is to determine whether the agency has adopted an unreasonable construction of the statute. That the reviewing court itself might adopt a different reading of the statute is legally irrelevant; instead, the sole issue is the reasonableness of the agency's interpretation, which must be upheld as long as it is a permissible one.

Section 360j(e) delegates to FDA the authority to restrict the "sale, distribution, or use" of a device. Although Congress itself has precisely and technically defined many of the terms used in the Act, it did not define this phrase. Therefore, FDA was free to adopt a common sense definition of those terms, encompassing the full process of selling and distribution, of which promotion and advertising are integral parts.

FDA's approach was explicitly premised on a Supreme Court decision that recognizes and applies the link between advertising and sales in the First Amendment context, *Edenfield v. Fane*, 507 U.S. 761 (1993). FDA also based its application of the Act on the purposes of the statute, which the Supreme Court has recognized should be broadly construed for the protection of public health. Thus, FDA reasonably concluded that the statutory power to restrict sales of devices includes the ability to regulate promotion and advertising that generates those very sales.

Congress further delegated to FDA the authority to impose on the sale, distribution, or use of restricted devices "such other conditions" as the agency "may prescribe." Therefore, even if the phrase "sale, distribution, or use" is given a narrow reading, FDA's regulation of promotion

and advertising leading to these activities must be upheld because the agency has exercised the authority delegated to it to impose "conditions." FDA found that this explicit delegation includes the authority to restrict the promotion and advertising that helps to create demand for tobacco products among young people and that, despite the access restrictions, would result in continued sales to, and use by, minors. This agency determination is fully consistent with the language of Section 360j(e) and the regulatory goal of deterring minors from beginning to use tobacco products, and thereby becoming addicted to them, and is further consistent with the Act's overriding purpose of empowering FDA to protect the public health by regulating the way in which products subject to its jurisdiction are made available to the public.

As the district court recognized elsewhere in its opinion, it had an obligation to uphold FDA's construction of the Act unless there are compelling indications that it was contrary to what Congress intended. There are no such compelling indications here. Rather, the court gave Section 360j(e) a highly restrictive reading, even though nothing in the statutory language, other provisions of the Act, its legislative history, or common word usage establishes that FDA was barred from concluding that its authority to place conditions on the sale or distribution of a device includes the power to regulate promotion and advertising for that sale and distribution.

2. Finally, the district court erred in enjoining several important youth access and labeling restrictions imposed by FDA on tobacco products. The court *upheld* the agency's authority to promulgate those restrictions, and made no other findings regarding their impact on plaintiffs' businesses. Nonetheless, it enjoined those regulations.

ARGUMENT

I. FDA Is Authorized By The Act To Restrict The Advertising And Promotion Of Tobacco Products.

A. The Standard of Review.

This Court reviews grants of summary judgment and questions of statutory construction *de novo*. *Shafer v. Preston Memorial Hosp. Corp.*, 107 F.3d 274, 277 (4th Cir. 1997).

B. FDA Has Reasonably Interpreted 21 U.S.C. § 360j(e)(1) To Authorize Restrictions on Advertising and Promotion of Tobacco Products.

1. Section 360j(e)(1) Vests FDA with Broad Authority to Impose Conditions on the Sale, Distribution, and Use of Medical Devices.

21 U.S.C. § 360j(e)(1) provides FDA with a "broad grant of authority" (61 Fed. Reg. 44406) over the sale, distribution, and use of medical devices.[4] By its terms, Section 360j(e)(1) authorizes FDA to impose "such * * * conditions" on sale, distribution, or use "as [FDA] may prescribe," if "[FDA] determines that there cannot otherwise be reasonable assurance of [a device's] safety and effectiveness." Section 360j(e)(1) contains only two limitations on the "conditions" that FDA may impose, neither of which applies (or is claimed to apply) to FDA's regulations in this case (*see infra p.* 32). Apart from those two statutory limitations, Section 360j(e)(1) gives FDA unqualified authority — as a precondition to offering a device for sale to the public — to impose whatever conditions the agency determines are necessary because "there cannot otherwise be reasonable assurance of [a device's] safety and effectiveness." As FDA explained in the tobacco rule preamble:

Congress, rather than limiting [FDA's] options, left it to [FDA] to decide what

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[4] FDA's preamble to the final tobacco rule refers to Section 360j(e) as "section 520(e)." The Medical Device Amendments of 1976, Pub. L. No. 94-295, § 2, 90 Stat. 539, 567, amended the Act by adding Section 520(e), which is codified as 21 U.S.C. § 360j(e).

> conditions are necessary for a particular device. * * * Section [360j(e)] * * * is intended to authorize such conditions on the sale, distribution, or use of a device as are necessary to ensure that the device is not improperly used and without which a reasonable assurance of its safety and effectiveness cannot be provided. ***There is no basis on the face of the [A]ct or in the legislative history to conclude that Congress was trying to limit the conditions that FDA could impose to achieve that end*** * * * .

61 Fed. Reg. 44409 (emphasis added).

FDA has interpreted Section 360j(e)(1) as authorizing it to place restrictions on the advertising and promotion of medical devices in order to complement access restrictions, when there cannot otherwise be reasonable assurance of a device's safety and effectiveness. *See id.* at 44405-09. This interpretation fully accords with the broad terms of Section 360j(e)(1). As explained below, advertising is an essential component of "sale, distribution, and use," both as a textual matter and as a matter of Supreme Court precedent. Moreover, even if advertising were not itself an inextricable element of "sale, distribution, or use," Section 360j(e)(1)'s plenary grant of authority to place "conditions" on "sale, distribution, or use" permits FDA to limit advertising as a "condition" of offering a device for sale to the public. *See id.* at 44409. The only predicate that Section 360j(e)(1) requires for the exercise of this plenary authority is a "determin[ation] [by FDA] that there cannot otherwise be reasonable assurance of [a device's] safety and effectiveness." FDA has made that determination regarding the tobacco products at issue in this case. *Cf. United States v. Garfinkel*, 29 F.3d 451, 454-57 (8th Cir.1994) (finding nothing to indicate Congress intended to limit FDA's authority in similar provision of the Act that permits agency to impose conditions "within [its] discretion," and deferring to FDA's permissible interpretation).[5]

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[5] It is noteworthy that Congress, instead of merely authorizing FDA to act if "there cannot otherwise be reasonable assurance of [a device's] safety and effectiveness," gave FDA the authority to act "if [FDA] determines" that there cannot otherwise be such assurance. In gauging (continued...)

The district court nonetheless refused to accept FDA's interpretation of Section 360j(e)(1), holding that the provision does not permit any restrictions on advertising and promotion. The breadth of the district court's holding must be clearly understood. That holding is not, and does not purport to be, limited to tobacco products; instead, it denies FDA the authority to regulate advertising and promotion of ***any*** medical device under Section 360j(e)(1). Moreover, under the district court's reading, advertising and promotion of medical devices cannot be regulated under Section 360j(e)(1), even if it is undisputed that "there cannot otherwise be reasonable assurance of [a device's] safety and effectiveness."

In adopting this reading of Section 360j(e)(1), the district court abandoned the framework *Chevron* mandates for reviewing administrative interpretations of federal statutes, even though, in the preceding portions of its opinion, the district court repeatedly (and correctly) relied on *Chevron* to guide its review of FDA's interpretation of the Act.

As *Chevron* explains, "[i]f the intent of Congress [in a statute] is clear, that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress." 467 U.S. at 842-43. On the other hand, "if the statute is silent or ambiguous with respect to the specific issue, the question for the court is whether the agency's answer is based on a permissible construction of the statute." *Id.* at 843. A reviewing court should "not

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[5](...continued)
the discretion conferred on regulatory agencies by Congress, courts have attached great significance to this kind of textual "distinction between the objective existence of certain conditions and the [agency's] determination that such conditions are present." *Kreis* v. *Secretary of Air Force*, 866 F.2d 1508, 1513 (D.C. Cir. 1989). Indeed, Congress's use of "deeming" or "determining" language has been taken as strong evidence that Congress meant to preclude judicial review altogether. *See, e.g., Webster v. Doe*, 486 U.S. 592, 600 (1988) (statutory language authorizing termination of CIA employee when agency "*deem[s]* such termination necessary or advisable in the interests of the United States" "fairly exudes deference" (emphasis added)).

simply impose its own construction on the statute." *Ibid.* *See Young v. Community Nutrition Inst.*, 476 U.S. 974, 981 (1986) (upholding FDA interpretation of the Act, and noting that the "'view of the agency charged with administering the statute is entitled to considerable deference'"); *see also Medtronic, Inc. v. Lohr*, 116 S. Ct. 2240, 2255-56 (1996) (giving "substantial weight" to FDA's regulations interpreting preemptive effect of provision of the Act concerned with medical devices).

Moreover, where "Congress has explicitly left a gap for the agency to fill, there is an express delegation of authority to the agency to elucidate a specific provision of the statute by regulation. Such legislative regulations are given controlling weight unless they are arbitrary, capricious, or manifestly contrary to the statute." *Chevron*, 467 U.S. at 843-44.

This Court has repeatedly applied the *Chevron* analysis and deferred to agencies' interpretations of their own statutes, especially where "'a complex and highly technical regulatory program' entailing policy determinations that fall within the ambit of agency expertise" is involved. *Akindemowo v. INS*, 61 F.3d 282, 285 (4th Cir. 1995) (quoting *Pauley v. BethEnergy Mines, Inc.*, 501 U.S. 680, 697 (1991)).

Regulation of drugs and devices is indisputably a complex and highly technical program, dependent on agency expertise. As explained *infra*, FDA's interpretation of Section 360j(e), so as to permit the imposition of conditions on tobacco advertising and promotion as a key element of its program to reduce the harmful use of such products by children, reflects a permissible construction of the Act. As we now show, none of the district court's reasons for rejecting FDA's interpretation of the statute has merit. By substituting its own interpretation of Section 360j(e) for FDA's permissible interpretation, the district court acted contrary to *Chevron's* clear command.

2. Advertising and Promotion Are Integral Components of the "Sale, Distribution, or Use" of a Device.

a. In determining whether its authority to restrict "sale, distribution, or use" of medical devices under Section 360j(e)(1) includes authority over advertising and promotion, FDA explained that "[h]ow a device is sold involves many elements," including "how the device is represented to potential users. It is in the latter regard that advertising plays a role and may be restricted under" Section 360j(e)(1). 61 Fed. Reg. 44406. FDA relied on *Edenfield v. Fane*, 507 U.S. 761, 767 (1993), in which the Supreme Court noted the inextricable relationship between a commercial transaction and the commercial speech that proposes that transaction. *Accord Friedman v. Rogers*, 440 U.S. 1, 10 n.9 (1979) ("By definition, commercial speech is linked inextricably to commercial activity"). As a result, "the State's interest in regulating the underlying transaction may give it a concomitant interest in the expression itself." *Edenfield*, 507 U.S. at 767. FDA thus concluded that, "under section [360j(e)] of the [A]ct, the sale of a device is 'linked inextricably' to the advertising that promotes the sale, giving FDA concomitant authority to impose necessary restrictions on the advertising." 61 Fed. Reg. 44406.

The agency's view that a "sale" encompasses the necessarily predicate act of an "offer for sale" is reasonable and founded on common sense.[6] Moreover, in its commercial speech case law, the Supreme Court has repeatedly recognized the inextricable relationship between commercial transactions and advertising. Not only did the Court make this connection in *Edenfield*, 507 U.S. at 767, it did so in other cases by at least the mid-1970s, before Section 360j(e) was enacted. *See, e.g., Virginia State Bd. of Pharmacy v. Virginia Citizens Consumer Council, Inc.*, 425 U.S. 748,

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[6] The particular connection between advertising and the need for protection of the public through regulation of medical devices dates to the 1930s. See H.R. Rep. No. 94-853, at 6 (1976).

771-72 n.24 (1976) ("advertising is the *sine qua non* of commercial profits"); *Bigelow v. Virginia*, 421 U.S. 809, 826 (1975) (discussing relationship of advertising to regulated commercial activity); *Pittsburgh Press Co. v. Pittsburgh Comm'n on Human Relations*, 413 U.S. 376, 385 (1973) (same). When it enacted Section 360j(e) in 1976, Congress must be assumed to have been aware of the connection the Supreme Court had noted between sales transactions and advertising. *See Smith v. Reagan*, 844 F.2d 195, 201 (4th Cir.) (legislation is informed by the state of the law at the time of its enactment), *cert. denied*, 488 U.S. 954 (1988). It was thus clearly reasonable for FDA to rely on the Supreme Court's acknowledgment of that relationship.

b. The district court, however, summarily rejected FDA's interpretation of Section 360j(e) and looked instead to the *American Heritage Dictionary* definition of "sale." It found that this term "does not encompass the advertising or promotion of a product." (JA 408 & n.23.)

Contrary to the district court's suggestion, FDA's interpretation of the scope of Section 360j(e) *is* consistent with dictionary definitions of both "distribution" and "sale." *See Webster's Third New International Dictionary (Unabridged)* 660, 2003 (1981) ("distribution" includes "the marketing or merchandising of commodities"; "sale" includes an "exhibition for selling" and "an advertised disposal of marked-down goods," and "sales" is defined as "operations and activities involved in promoting and selling goods"); *Black's Law Dictionary* 1337 (6th ed. 1990) (referring to Investment Company Act: "'Sale', 'sell', 'offer to sell', or 'offer for sale' includes every contract of sale or disposition of, attempt or offer to dispose of, ***or solicitation of an offer to buy*** * * * ") (emphasis added). Indeed, even the dictionary used by the district court defines "sales" as "[a]ctivities involved in the selling of goods or services," which can reasonably be read to include advertising and promotion, and defines "distribution" as "[t]he process of marketing and supplying goods." *American Heritage Dictionary* 411, 1085 (2d ed. 1991).

The district court's decision is also internally inconsistent and overlooks that Section 360j(e) permits conditions on the "use" of a restricted device. Earlier in its opinion, the court recognized the relationship between the intended "use" of a product and its accompanying advertising and promotional materials. (JA 386-87.)

c. Relying on the "negative pregnant" rule of construction — *i.e.*, when Congress includes particular language in one section of a statute, but omits it in another, it is generally presumed to act intentionally in not including it in the second section — the district court found it significant that Congress used the terms "offer for sale" and "advertising" elsewhere in the Act, but not in Section 360j(e). (JA 408-09.) The Supreme Court, however, has cautioned against over-reliance on this method of statutory construction, especially when "common sense would balk" at the result. *Field v. Mans*, 116 S. Ct. 437, 442 (1995). Indeed, "[t]he rule is weakest when it suggests results strangely at odds with other textual pointers." *Id.* at 446.

Here, there is important textual evidence in tension with the district court's narrow interpretation of "sale." First, the pertinent statutory term is not simply "sale," but "sale, distribution, or use." The court, however, appears to have read "sale" in isolation, as if it were limited to a particular transaction, overlooking its broader application to the offering of a product to the marketplace at large. Had Congress intended to restrict FDA's authority to such a precise, technical concept of sale, it would not have used the broad phrasing that it did. Promotion and advertising can readily be considered part and parcel of "sale, distribution, or use." At the very least, had Congress not wanted FDA to engage in such reasoning, it would have used more restrictive and precise terminology, as it did elsewhere in the Act.

Second, Section 360j(e) authorizes FDA to restrict the "sale, distribution, or use" of a device "upon such other conditions as the [agency] may prescribe in such regulation." A narrow

construction of "sale distribution, or use" would be inconsistent with the exercise of the patently broad authority to impose "other conditions." *See infra* pp. 29-34.

Moreover, FDA addressed comments submitted during the rulemaking contending that advertising relates only to an "offer for sale," and that, if Congress had intended to authorize conditions on how devices are offered for sale, it would have said so explicitly. 61 Fed. Reg. 44408. The agency rejected this contention, noting that the Act uses the phrase "offer for sale" in several sections prohibiting specified conduct. *See, e.g.*, 21 U.S.C. §§ 331(m), 331(o), 353(c). As FDA explained, this fact simply reflects Congress's intent that a consummated sale would not be necessary in order for a prohibited act to fall within the ambit of the statute's enforcement provisions. *See* 61 Fed. Reg. 44408.

d. Finally, the district court's interpretation of "sale" produces a result at odds with common sense, which is to be avoided. *See Field*, 116 S. Ct. at 442. The court's ruling permits FDA to prohibit the "sale" of tobacco products at a convenience store to persons not old enough to purchase such products lawfully. But the court simultaneously found the agency powerless to prevent cigarette advertisements in displays at the store's candy counter or in children's magazines, using characters or animals designed to appeal to children or adolescents. This incongruous result created by the district court's narrow construction of the Act further demonstrates why the court should not have substituted its judgment for that of the expert agency charged with the statute's enforcement.

3. The Authority to Impose "Other Conditions" on the Sale, Distribution, or Use of Restricted Devices Authorizes FDA to Restrict the Advertising and Promotion of Tobacco Products to Children.

Even if the phrase "sale, distribution, or use" could be narrowly interpreted, the promotion and advertising restrictions must be upheld because they are the result of FDA's exercise of its

broad statutory authority to impose "other conditions" on the sale, distribution, or use of restricted devices. For plaintiffs to prevail, they must show that FDA adopted an impermissible interpretation of the Act because sale, distribution, or use must be construed narrowly, ***and*** that, despite the language Congress used, it meant to limit severely the types of conditions FDA may impose. No such showing can be made here.

a. The district court concluded that, even if "sale" within Section 360j(e) can be construed to encompass a product's advertising and promotion, FDA's authority to impose "other conditions" on the sale, distribution, or use of a restricted device nonetheless does not extend to such activities. The court stated that the "other conditions" provision must be construed in the overall context of Section 360j(e), which permits FDA to require a prescription for a restricted device, or to impose "other conditions necessary to provide a reasonable assurance of safety and effectiveness." (JA 409.) With no elaboration, the court concluded that "[t]he restriction on the advertising and promotion of a product does not fit within this framework." (JA 409.)

The district court also found that "other conditions" must be construed with respect to its "counterpart" for prescription drugs, 21 U.S.C. § 353(b). (JA 409.) Like Section 360j(e), Section 353(b) "authorizes FDA to restrict drugs to prescription sale." (JA 410.) While the court conceded that FDA's power under Section 360j(e) is broader than under Section 353(b) because of the additional authority to impose "other conditions," the court nonetheless concluded that "'other conditions' cannot be so broadly construed as to encompass conditions on advertising and promotion." (JA 410.)

Not only did the district court fail on this point to defer to FDA's interpretation of the statute, its own interpretation of the "other conditions" language in Section 360j(e)(1)(B) is at odds with both the Act's plain language and legislative history.

b. "[S]uch other conditions as [FDA] may prescribe in such regulation" (21 U.S.C. § 360j(e)(1)(B)), is the quintessential "gap" that "Congress has explicitly left * * * for the agency to fill" — *i.e.*, "an express delegation of authority to the agency to elucidate a specific provision of the statute by regulation." *Chevron*, 467 U.S. at 843-44. "Such legislative regulations are given controlling weight unless they are arbitrary, capricious, or manifestly contrary to the statute." *Id.* at 844. Thus, when Congress makes a delegation of authority as broad as that in Section 360j(e)(1)(B), the agency's implementation of such authority "merit[s] the greatest deference," especially when policy determinations are implicated. *ABF Freight System, Inc. v. NLRB*, 510 U.S. 317, 324 (1994) (upholding agency action pursuant to a delegation "'to take such affirmative action * * * as will effectuate the policies'" of the statute). *See also Schweiker v. Gray Panthers*, 453 U.S. 34, 44 (1981).

In *Doolin Sec. Sav. Bank, F.S.B. v. FDIC*, 53 F.3d 1395 (4th Cir.), *cert. denied*, 116 S. Ct. 473 (1995), a banking statute directed the FDIC to adopt risk-based assessment regulations to identify financial institutions likely to incur losses. The statute specified several factors that the agency was to consider in determining whether an institution would incur a loss, as well as "'any other factors the [FDIC] determines are relevant to assessing such probability.'" *Id.* at 1399. In upholding the FDIC's interpretation of the statute, this Court found that that provision "expressly gives the FDIC considerable discretion." *Id.* at 1400. The Court also declined to engage in policymaking, recognizing that that was the agency's function. *Id.* at 1400 n.8.

Similarly, at issue in *National Rifle Ass'n v. Brady*, 914 F.2d 475 (4th Cir. 1990), *cert. denied*, 499 U.S. 959 (1991), were agency regulations implementing certain amendments to the Gun Control Act. The statute originally provided that "'[t]he Secretary may prescribe such rules and regulations as he deems reasonably necessary to carry out the provisions of this chapter.'"

Id. at 478. The legislation was amended, however, to provide: "'The Secretary may prescribe only such rules and regulations as are necessary to carry out the provisions of this chapter.'" *Ibid.*

The plaintiff in *National Rifle Ass'n* argued that the amendment demonstrated Congress's intent to limit the agency's authority, but this Court disagreed. It held that the revised language was not intended to divest the agency (and transfer to the courts) the primary role of implementing the legislation. *Id.* at 479. This Court stressed that the agency was "better equipped than the courts for such an endeavor, having the technical expertise essential to determinations of statutory enforcement." *Ibid.*

c. The "such other conditions as [FDA] may prescribe" language of Section 360j(e)(1)(B) is at least as broad a grant of authority as was found in the various statutes at issue in *National Rifle Ass'n*, *Doolin*, *ABF Freight*, and *Gray Panthers*. Indeed, by the explicit terms of Section 360j(e), FDA's exercise of this authority is cabined in only three limited respects.

First, no condition "may restrict the use of a device to persons with specific training or experience * * * [or] in certain facilities unless [FDA] determines that such a restriction is required for the safe and effective use of the device." 21 U.S.C. § 360j(e)(1). Second, no condition "may exclude a person from using a device solely because the person does not have the training or experience to make him eligible for certification by a certifying board * * * or has not been certified by such a Board." *Ibid.* The tobacco advertising restrictions obviously do not violate those statutory proscriptions. And, presumably, if Congress had intended to foreclose FDA's authority to impose conditions on the sale, distribution, or use of restricted devices in any other respect, it would have so provided along with these two conditions.

The remaining limitation on FDA's authority to impose "other conditions" under Section 360j(e) is the requirement that FDA "determine[] that there cannot otherwise be reasonable

assurance of [the] safety and effectiveness" of the restricted device. *Ibid.* FDA made that determination and explained it in the rule's preamble. *See, e.g.*, 61 Fed. Reg. 44405 ("unless measures are taken now to prohibit the sale and promotion of these products to young people under the age of 18, there cannot otherwise be reasonable assurance of safety"), *id.* at 44406-07 (effectiveness of youth access restrictions "would be substantially diminished if the manufacturers were free to entice children and adolescents to circumvent the access restrictions"), *id.* at 44407 ("without the access and advertising restrictions imposed in this rule, no finding that there is a reasonable assurance of safety for cigarettes and smokeless tobacco would be possible").

d. The district court ignored FDA's determination that the advertising conditions are necessary if there is to be a "reasonable assurance" of safety and made no finding that the agency had rendered an impermissible construction of the statute. Instead, the court rendered its own interpretation of Section 360j(e): "The restriction on the advertising and promotion of a product does not fit within this framework." (JA 409.) Under *Chevron*, 467 U.S. at 844, however, a court is not free to set aside an agency's regulations pursuant to a broad delegation of authority, absent some indication that the regulations are "manifestly contrary" to the governing statute.

There are no such statutory markers here. Contrary to the district court's belief, 21 U.S.C. § 353(b) — which states that certain drugs "shall be dispensed only" by prescription — does not supply the proper context in which to construe the "other conditions" provision in Section 360j(e) pertaining to restricted devices. Although the two sections parallel one another in some respects, Section 353(b) requires prescriptions for certain drugs, whereas Section 360j(e)(1) gives FDA the discretion to issue regulations requiring a prescription for a restricted device. Moreover, Section 353(b) refers to how a drug is "dispensed," whereas Section 360j(e)(1) allows restrictions on a much wider range of activities — "sale, distribution, or use." More critically, as FDA

emphasized, Section 353(b) has "no counterpart to [the] 'other conditions' authority" in Section 360j(e). 61 Fed. Reg. 44406. "Congress, rather than limiting [FDA's] options, left it to [FDA] to decide what conditions are necessary for a particular device." *Id.* at 44409. The district court's opinion failed to attribute meaning to that key distinction between the two sections.

Moreover, the legislative history of Section 360j(e) supports FDA's interpretation of this broad delegation of authority. The House Report states that Section 360j(e) "supersede[d] and add[ed] to" FDA's then-existing authority to regulate devices. H.R. Rep. No. 94-853, at 24. It explains further that, under that section, the sale or distribution of a device may be restricted by prescription "or upon such other conditions as [FDA] may prescribe, except that no condition limiting the use of a device to categories of physicians defined by their training or experience may be imposed." *Ibid.* The report also notes that "conditions on sale or distribution *could include* use of [a restricted device] only within hospitals or clinics." *Id.* at 25 (emphasis added). Congress's use of the phrase "could include" indicates that this discussion was intended to be illustrative rather than exhaustive.

The Senate Report notes FDA's then "limited authority" to regulate medical devices and the need to provide greater protection for the public. S. Rep. No. 94-33, at 2 (1976), *reprinted in* 1976 U.S.C.C.A.N. 1070, 1071. In discussing the version of Section 360j(e) that was enacted, the House Conference Report makes no mention of any limitations on the "other conditions" authority, except those written into the law. H.R. Conf. Rep. 94-1090, at 62 (1976), *reprinted in* 1976 U.S.C.C.A.N. 1103, 1114.

4. Other Provisions of the Act Concerned with the Advertising of Devices Do Not Impair FDA's Authority to Restrict the Advertising and Promotion of Tobacco Products Under Section 360j(e).

a. The district court's final reason for striking down the restrictions on tobacco

advertising and promotion is that Sections 352(q) and 352(r) of the Act delegate FDA "limited authority" to restrict the advertising of devices, thus reflecting Congress's intent that FDA not use Section 360j(e) to restrict advertising and promotion. (JA 411-12.)

As discussed earlier, Section 352(q) provides that a restricted device is considered "misbranded" "if (1) its advertising is false or misleading in any particular, or (2) it is sold, distributed, or used in violation of regulations prescribed under section 360j(e)." 21 U.S.C. § 352(q). Section 352(r) provides that a restricted device is misbranded "unless the manufacturer, packer, or distributor thereof includes in all advertisements and other descriptive printed matter issued * * * with respect to that device (1) a true statement of the device's established name * * * and (2) a brief statement of the intended uses of the device and relevant warnings." *Id.*, § 352(r).

FDA interpreted Sections 352(q), 352(r), and 360j(e) as complementing one another and explained that these provisions are directed to different matters. 61 Fed. Reg. 44408. Not only did the district court's opinion fail to acknowledge and accord deference to this agency interpretation, its own reading again conflicts with the Act's plain language and legislative history.

Section 352(q) is an enforcement provision; it directs that any restricted device that is falsely advertised or sold, distributed, or used in violation of regulations prescribed under Section 360j(e) is "misbranded." 21 U.S.C. § 352(q). Misbranding is a "prohibited act." 21 U.S.C. § 331(b). The fact that Section 352(q)(1) makes "false or misleading" advertising a "misbranding" violation says nothing at all about whether advertising designed to attract underage purchasers of tobacco products may be restricted by FDA under ***other*** provisions of the Act. Nothing in the text of Section 352(q)(1) supports drawing the inference that the reference there to "false or misleading" advertising means that FDA may not otherwise impose conditions on the advertising of restricted devices. Indeed, limiting FDA's authority by reading such a negative implication into

Section 352(q)(1) would be inconsistent with Section 352(q)(2), which actually puts teeth into the regulations FDA "prescribe[s] under Section 360j(e)" — such as the tobacco advertising conditions here at issue.

Likewise, nothing in the text of Section 352(r) suggests a congressional intent that the ***only*** way in which the advertising of a device may be regulated is through the provisions of that paragraph, to the exclusion of other broader authority granted to FDA elsewhere in the Act. Rather, Section 352(r) simply establishes minimum information required in device advertising. Contrary to the district court's interpretation of Section 352(r), there is no indication, implicit or explicit, of any congressional intent to preclude additional conditions on advertising under Section 360j(e) that FDA might determine are necessary to provide a reasonable assurance of the device's safety. Moreover, the advertising restrictions in Section 352(r) pertain to information that will be provided to persons who can legally purchase the product. By contrast, Section 360j(e) permits conditions designed to prevent the use of a device by persons not competent to use it safely.

b. The legislative history of the Medical Device Amendments of 1976 also refutes the district court's narrow interpretation of Sections 352(q), 352(r), and 360j(e). The Senate Report makes clear that "[t]he basic intent of the legislation is to assure safe and effective devices and the Secretary is authorized to use ***all of the authorities contained in this Act in any combination deemed necessary to protect the public health and safety.***" S. Rep. 94-33, at 13, *reprinted in* 1976 U.S.C.C.A.N. 1082 (emphasis added).

Thus, the notion that, despite the broadly worded delegation of authority in Section 360j(e), that provision may not be invoked to restrict tobacco advertising because Sections 352(q) and 352(r) allow limited restrictions on device advertising, is mistaken. *See Young*, 476 U.S. at 983-84 (fact that two sections of the Act address the same matter, one in general and one in

specific terms, gives FDA a choice in how to regulate and does not render one section superfluous). Sections 352(q), 352(r), and 360j(e) are not mutually exclusive — as the district court seemed to believe — but rather complement one another, as FDA concluded. *See* 61 Fed. Reg. 44408.

c. Finally, in a footnote (JA 412 n.29), the district court offered its interpretation of the following sentence in Section 352(r): "Except in extraordinary circumstances, * * * no advertisement of a restricted device * * * shall, with respect to the matters specified in this paragraph or covered by regulations issued hereunder, be subject to the provisions of sections 52 through 55 of Title 15." The Federal Trade Commission (hereafter "FTC") enforces 15 U.S.C. §§ 52-55, which address false advertising and deceptive practices.

The district court concluded that this statement "reveals Congress' intention that the [FTC] have primary jurisdiction over advertising." (JA 412 n.29.) Although it did not elaborate, the court appeared to believe that, because Section 352(r) restricts device advertising in only two respects (the established name of the product and its intended use), the FTC alone has authority to regulate all other aspects of device advertising.

Once again, however, the plain language of the text points to no such interpretation. Section 352(r) simply states that, in general, insofar as the misbranding of a restricted device is concerned, the manufacturer or distributor thereof is subject only to FDA enforcement. There is no basis to infer from this limited statement that Congress intends for the FTC to have primary jurisdiction over advertising. Indeed, the legislative history of Section 352(r) suggests just the opposite. *See* S. Rep. No. 94-33, at 17, *reprinted in* 1976 U.S.C.C.A.N. 1086.

FDA's jurisdiction, in fact, overlaps that of the FTC in a number of areas. *See Thompson Medical Co. v. FTC*, 791 F.2d 189, 192-93 (D.C. Cir. 1986), *cert. denied*, 479 U.S. 1086 (1987).

That is neither surprising nor unusual. For example, the Department of Justice and the FTC share overlapping enforcement authority under the Sherman Act and Federal Trade Commission Act. *See FTC v. Cement Inst.*, 333 U.S. 683, 692-93 (1948); *United States v. Restland Funeral Home, Inc.*, 51 F.3d 56 (5th Cir.1995), *cert. denied,* 116 S. Ct. 772 (1996). Absent a clear congressional signal to the contrary, the existence of such overlapping jurisdiction is no cause to prevent the otherwise lawful exercise of FDA's authority.

In sum, because the district court failed to explain or find that FDA's interpretation of Section 360j(e) was impermissible, the agency's interpretation should have been upheld.

II. There Is No Basis For The District Court's Preliminary Injunction Against The Access And Labeling Regulations.

A. The Standard of Review.

An abuse of discretion standard of review applies to the grant of preliminary injunctive relief. *Rum Creek Coal Sales, Inc. v. Caperton*, 926 F.2d 353, 358 (4th Cir. 1991). As this Court has explained, however, a district court's discretion in this regard is "'not boundless'" and its decision will be overturned "'if made under an improper legal standard.'" *Ibid.* (citation omitted). Thus, the standard is "not a rule of perfunctory appellate review but one of careful scrutiny." *Direx Israel, Ltd. v. Breakthrough Medical Corp.*, 952 F.2d 802, 815 (4th Cir. 1991).

B. The Court Erred in Enjoining Implementation of Regulations That It Upheld.

The district court unequivocally upheld FDA's authority to regulate tobacco products as drugs, devices, and combination products under the Act. (JA 381-405.) The court also held that FDA is authorized by Section 360j(e) to impose conditions on access to tobacco products, and by Section 352(r) to impose labeling restrictions on such products. (JA 413-14.) In the order accompanying its opinion, however, the court enjoined FDA from implementing "any of the

additional Regulations set for implementation on August 28, 1997, pending further orders by the court." (JA 417.)

The injunction thus prevents implementation of not only the advertising and promotion regulations struck down by the court, but also those access and labeling conditions that had not yet gone into effect and that the court explicitly upheld. *See supra* note 3. In issuing this sweeping relief, the district court failed to address this Circuit's well established "hardship balancing test" for the grant of a preliminary injunction. See *Direx*, 952 F.2d at 811. Indeed, it provided no explanation at all for its injunctive order.

As this Court has explained, "the grant of interim relief [is] an extraordinary remedy involving the exercise of a very far-reaching power, which is to be applied 'only in [the] limited circumstances' which clearly demand it." *Ibid. (citation omitted).* Four factors are to be considered, in the following order:

> (1) the likelihood of irreparable harm to the plaintiff if the preliminary injunction is denied,
> (2) the likelihood of harm to the defendant if the requested relief is granted,
> (3) the likelihood that the plaintiff will succeed on the merits, and
> (4) the public interest.

Rum Creek, 926 F.2d at 359. Plaintiff bears the burden of establishing that these factors support an injunction. *Direx*, 952 F.2d at 812.

Plaintiffs here made no showing — let alone a "clear" one — of any irreparable harm that they would suffer if the access and labeling restrictions upheld by the court were allowed to take effect. The dearth of both evidence of harm and any findings by the court on this score compels vacating the injunction against those regulations.

On the other hand, the irreparable harm to defendants and the public interest from an injunction against the tobacco access and labeling restrictions ***is*** amply supported by the record.

The public and individual health concerns at stake are immediate and far-reaching. As previously noted, although death from tobacco use occurs among adults, FDA found that tobacco use is a "pediatric disease" because 80% of adult smokers became addicted to the nicotine in tobacco during childhood. 61 Fed. Reg. 44421, 44398. Every year, approximately one million children and adolescents begin to smoke — nearly 3,000 per day. One of every three of these individuals will later die from a tobacco-related disease. *Id.* at 44398, 44568.

Moreover, the problem of youth tobacco use is getting worse. FDA found that the percentage of eighth and tenth graders who smoke has risen for four consecutive years. *Id.* at 44399. Similar problems exist with underage use of smokeless tobacco products. *Ibid.* Thus, the record in this proceeding demonstrates that irreparable injury to public health will occur if implementation of FDA's restrictions on tobacco access and labeling is indefinitely delayed.

Because the balance of harms therefore clearly weighs in favor of the timely implementation of FDA's regulations, plaintiffs' probability of success on the merits need not even be addressed. In any event, the district court has already upheld FDA's jurisdiction to regulate tobacco products and has concluded — correctly — that the agency has the statutory authority to impose restrictions on the access and labeling of such products. That being so, preliminary injunctive relief against those regulations is without any support whatsoever and should be overturned.

CONCLUSION

For the foregoing reasons, the partial summary judgment in favor of the plaintiffs and the injunction entered by the district court against the FDA regulations at issue should be reversed and vacated.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on June 10, 1997, I transmitted eight copies of the foregoing "Brief for Appellants Food and Drug Administration, *et al.*" to the Clerk of the U.S. Court of Appeals for the Fourth Circuit by Federal Express. I also served two copies of this brief upon the following counsel on the date and in the manner indicated.

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Douglas N. Letter

21 U.S.C. § 321(g)(1)

(g)(1) The term "drug" means (A) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any article specified in clause (A), (B), or (C). A food or dietary supplement for which a claim, subject to sections 343(r)(1)(B) and 343(r)(3) of this title or sections 343(r)(1)(B) and 343(r)(5)(D) of this title, is made in accordance with the requirements of section 343(r) of this title is not a drug solely because the label or the labeling contains such a claim. A food, dietary ingredient, or dietary supplement for which a truthful and not misleading statement is made in accordance with section 343(r)(6) of this title is not a drug under clause (C) solely because the label or the labeling contains such a statement.

(h) The term "device" (except when used in paragraph (n) of this section and in sections 331(i), 343(f), 352(c), and 362(c) of this title) means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is—

(1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,

(2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or

(3) intended to affect the structure or any function of the body of man or other animals, and

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

21 U.S.C. § 331(b)

The following acts and the causing thereof are prohibited:

* * *

(b) The adulteration or misbranding of any food, drug, device, or cosmetic in interstate commerce.

(q) Restricted devices using false or misleading advertising or used in violation of regulations

In the case of any restricted device distributed or offered for sale in any State, if (1) its advertising is false or misleading in any particular, or (2) it is sold, distributed, or used in violation of regulations prescribed under section 360j(e) of this title.

(r) Restricted devices not carrying requisite accompanying statements in advertisements and other descriptive printed matter

In the case of any restricted device distributed or offered for sale in any State, unless the manufacturer, packer, or distributor thereof includes in all advertisements and other descriptive printed matter issued or caused to be issued by the manufacturer, packer, or distributor with respect to that device (1) a true statement of the device's established name as defined in subsection (e) of this section, printed prominently and in type at least half as large as that used for any trade or brand name thereof, and (2) a brief statement of the intended uses of the device and relevant warnings, precautions, side effects, and contraindications and, in the case of specific devices made subject to a finding by the Secretary after notice and opportunity for comment that such action is necessary to protect the public health, a full description of the components of such device or the formula showing quantitatively each ingredient of such device to the extent required in regulations which shall be issued by the Secretary after an opportunity for a hearing. Except in extraordinary circumstances, no regulation issued under this paragraph shall require prior approval by the Secretary of the content of any advertisement and no advertisement of a restricted device, published after the effective date of this paragraph shall, with respect to the matters specified in this paragraph or covered by regulations issued hereunder, be subject to the provisions of sections 52 through 55 of title 15. This paragraph shall not be applicable to any printed matter which the Secretary determines to be labeling as defined in section 321(m) of this title.

(g) Regulation of combination products

(1) The Secretary shall designate a component of the Food and Drug Administration to regulate products that constitute a combination of a drug, device, or biological product. The Secretary shall determine the primary mode of action of the combination product. If the Secretary determines that the primary mode of action is that of—

(A) a drug (other than a biological product), the persons charged with premarket review of drugs shall have primary jurisdiction,

(B) a device, the persons charged with premarket review of devices shall have primary jurisdiction, or

(C) a biological product, the persons charged with premarket review of biological products shall have primary jurisdiction.

(e) Restricted devices

(1) The Secretary may by regulation require that a device be restricted to sale, distribution, or use—

(A) only upon the written or oral authorization of a practitioner licensed by law to administer or use such device, or

(B) upon such other conditions as the Secretary may prescribe in such regulation,

if, because of its potentiality for harmful effect or the collateral measures necessary to its use, the Secretary determines that there cannot otherwise be reasonable assurance of its safety and effectiveness. No condition prescribed under subparagraph (B) may restrict the use of a device to persons with specific training or experience in its use or to persons for use in certain facilities unless the Secretary determines that such a restriction is required for the safe and effective use of the device. No such condition may exclude a person from using a device solely because the person does not have the training or experience to make him eligible for certification by a certifying board recognized by the American Board of Medical Specialties or has not been certified by such a Board. A device subject to a regulation under this subsection is a restricted device.

(2) The label of a restricted device shall bear such appropriate statements of the restrictions required by a regulation under paragraph (1) as the Secretary may in such regulation prescribe.

STATUTORY ADDENDUM