No. 98-1152

IN THE SUPREME COURT OF THE UNITED STATES

FOOD AND DRUG ADMINISTRATION, ET AL.,
Petitioner

v.

BROWN AND WILLIAMSON TOBACCO CORP., ET AL.,
Respondent

BRIEF OF *AMICUS CURIAE* PRODUCT LIABILITY ADVISORY COUNCIL, INC. IN SUPPORT OF RESPONDENTS

Filed September 10, 1999

QUESTION PRESENTED

Whether the Food and Drug Administration's claim of jurisdiction to regulate tobacco products under the Federal Food, Drug, and Cosmetic Act is entitled to deference under *Chevron U.S.A., Inc.* v. *Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984).

TABLE OF CONTENTS

TABLE OF CONTENTS

TABLE OF AUTHORITIES

TABLE OF AUTHORITIES — Continued

Page(s)

TABLE OF AUTHORITIES — Continued

Page(s)

TABLE OF AUTHORITIES — Continued

Page(s)

Statutes

TABLE OF AUTHORITIES — Continued

Page(s)

Miscellaneous

TABLE OF AUTHORITIES — Continued

Page(s)

TABLE OF AUTHORITIES — Continued

Page(s)

INTEREST OF THE *AMICUS CURIAE*

Amicus curiae Product Liability Advisory Council, Inc. ("PLAC") is a non-profit corporation whose membership consists of 123 major corporations engaged in a wide range of business activities in federally-regulated industries, including activities regulated by the Food and Drug Administration ("FDA") pursuant to the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq.*[1] In the course of their business activities, PLAC's members are subject to numerous agency actions for which deference is claimed under *Chevron U.S.A., Inc.* v. *Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984).

The FDA's argument before this Court rests on an extraordinarily expansive view of *Chevron* that would require judicial deference for virtually every agency action. PLAC therefore has a substantial interest in the outcome of this case and believes that the Court would be materially aided by an in-depth analysis of the *Chevron* doctrine and its applicability to the FDA's claim of regulatory authority over tobacco.

SUMMARY OF ARGUMENT

This Court's decision in *Chevron U.S.A., Inc.* v. *Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984), requires judicial deference to an agency's actions where Congress has delegated authority to the agency to interpret and enforce a statute. But this rule is subject to a key limitation: no deference is warranted where Congress has *not* delegated authority to an agency in a particular area. Before applying *Chevron* deference, therefore, a court must determine whether Congress intended to permit the agency to act in a given field. This review serves the vital purpose of ensuring that Congress, rather than the agency, makes the

---

[1] Pursuant to Supreme Court Rule 37, letters from the parties consenting to the filing of this brief have been filed with the Clerk of the Court. This brief was funded entirely by PLAC and was written entirely by its counsel.

major policy decisions, in order to further the political accountability necessary for a well-functioning administrative state.

The FDA's plea for *Chevron* deference to its jurisdictional claim over tobacco products cannot be reconciled with this fundamental limitation on the doctrine. The agency's assertion that Congress intended it to have regulatory authority over tobacco is based on isolated fragments of statutory text, read in a vacuum. It glosses over, or simply ignores, the overwhelming evidence to the contrary, all of which is relevant at the first step of the *Chevron* analysis. And it justifies its actions with a cramped and unsupported reading of *Chevron* that would mandate deference for virtually all agency actions. In sum, the government seeks to use *Chevron* — a doctrine that protects an agency's gap-filling authority where Congress has not spoken to an interstitial issue — to annex regulatory authority over an entire industry in a manner that raises political, economic, and social issues of enormous consequence. *Chevron* cannot be stretched so far.

The FDA's invocation of *Chevron* deference ignores two other essential limits on the doctrine's applicability. First, deference may not be appropriate where an agency is interpreting the scope of its own jurisdiction, rather than acting within its settled authority. Here, the FDA's jurisdictional claim rests on no special agency expertise, reflects an effort to expand its own power, and depends on the agency's interpretation of statutes that it has not been delegated authority to enforce. Second, deference may not be warranted for an agency position that is flatly at odds with a longstanding and contemporaneous construction of its statute. Here, the FDA's newly-minted position is based on an unexplained changed interpretation of congressional intent and infringes unduly on substantial reliance interests. Under these circumstances, it is unreasonable to assume that Congress intended the courts to defer to the FDA.

ARGUMENT

I. THE FDA IS NOT ENTITLED TO *CHEVRON* DEFERENCE BECAUSE CONGRESS DID NOT INTEND TO DELEGATE TO IT THE AUTHORITY TO REGULATE TOBACCO PRODUCTS

In *Chevron U.S.A., Inc.* v. *Natural Resources Defense Council, Inc.*, this Court set out a two-step analysis for reviewing an "agency's construction of the statute which it administers." 467 U.S. at 842. At step one, a court must determine "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." *Id.* at 842-843. If Congress's intent is not clear, then the court must determine "whether the agency's answer is based on a permissible construction of the statute." *Id.* at 843.

Judicial deference to an agency's statutory interpretation "reflects a sensitivity to the proper roles of the political and judicial branches." *Pauley* v. *BethEnergy Mines, Inc.*, 501 U.S. 680, 696 (1991). But *Chevron* is not intended to give an agency *carte blanche* to decide when and how to regulate. *Chevron* is based on the premise that an agency is entitled to deference where Congress has delegated to it interpretive authority; "[f]rom this congressional delegation derives the [agency]'s entitlement to judicial deference." *Id.* at 698; see also *Adams Fruit Co.* v. *Barrett*, 494 U.S. 638, 649 (1990) ("A precondition to deference under *Chevron* is a congressional delegation of administrative authority."); *Bowen* v. *Georgetown Univ. Hosp.*, 488 U.S. 204, 208 (1988).

In ascertaining the scope of an agency's delegated power, a court may not lightly presume that Congress intended to grant major policymaking authority. "An implied delegation of a law-declaring function is especially likely where * * * the question is interstitial, involves the everyday administra-

tion of the statute, implicates no special judicial expertise, and is unlikely to affect broad areas of the law." *St. Luke's Hosp.* v. *Secretary of Health & Human Servs.*, 810 F.2d 325, 331 (1st Cir. 1987) (Breyer, J.). Conversely, the larger the question at stake, and the more significant its impact, the less likely it is that Congress intended to authorize the agency to decide it. See *MCI Telecomms. Corp.* v. *AT&T Co.*, 512 U.S. 218, 231-232 (1994); *Mayburg* v. *Secretary of Health & Human Servs.*, 740 F.2d 100, 106 (1st Cir. 1984) (Breyer, J.).

Meaningful review of congressional intent at *Chevron*'s step one is essential to ensure against "'unauthorized assumption by an agency of major policy decisions.'" *Bureau of Alcohol, Tobacco & Firearms* v. *FLRA*, 464 U.S. 89, 97 (1983) (quoting *American Ship Bldg. Co.* v. *NLRB*, 380 U.S. 300, 318 (1965)); see also *Ernst & Ernst* v. *Hochfelder*, 425 U.S. 185, 214 n.33 (1976) (refusing to accept agency interpretation that would "rais[e] serious policy questions not yet addressed by Congress"). *Chevron* deference is intended to *further* political accountability in regulatory policymaking, not to countenance an agency's unwarranted usurpation of legislative power. By asking whether Congress intended to permit an agency to exercise authority in a given area before giving deference to the agency's decision, a court applying *Chevron*'s step one "ensures to the extent consistent with orderly governmental administration that important choices of social policy are made by Congress, the branch of our Government most responsive to the popular will * * *." *Industrial Union Dep't, AFL-CIO* v. *American Petroleum Inst.*, 448 U.S. 607, 685 (1980) (Rehnquist, J., concurring).

As this analysis demonstrates, *Chevron*'s step one — the determination whether Congress has given an "express" or "implicit" "delegation of authority to the agency to elucidate a specific provision of the statute by regulation," 467 U.S. at 843-844 — serves a critically important *judicial* function. It comes as no surprise, therefore, that in assessing congressional intent under *Chevron*'s step one, this Court gives no deference to the agency's position. See *Pauley*, 501 U.S. at 696-698; *Dole* v. *United Steelworkers of Am.*, 494 U.S. 26, 32-44 (1990); *Chevron*, 467 U.S. at 845; see also *Federal Election Comm'n* v. *Democratic Senatorial Campaign Comm.*, 454 U.S. 27, 31-32 (1981).

A. The Text, Structure, And Legislative History Of The FDCA And Tobacco-Related Statutes Show That Congress Intended That The FDA Would Not Have Regulatory Authority Over Tobacco Products

Under *Chevron*'s step one, it is clear that Congress did not intend to give the FDA the power to regulate tobacco products.[2] Because the terms of the FDCA, when interpreted in light of the Act's structure and legislative history, as well as the structure and history of tobacco-related statutes, reveal Congress's contrary intent, the FDA's interpretation of the Act is not entitled to deference under *Chevron*.

We will not burden the Court with a lengthy recitation of the powerful evidence showing that Congress did not intend to delegate to the FDA the authority to regulate cigarettes and other tobacco products. Under the FDCA, the agency is authorized to regulate only those products whose "intended use," as determined by the manufacturer's or distributor's claims, is to affect a body's structure or function. See Brief of Respondent R.J. Reynolds Tobacco Co. at 11-21; Brief of Respondent Brown & Williamson Tobacco Corp. at 6-27 (discussing meaning of "intended use"). Furthermore, the statute's delegation of authority to regulate "drugs" and "devices" is limited to products with a real or claimed

---

[2] By referring to the regulation of tobacco or tobacco products, PLAC intends to encompass only tobacco or tobacco products as customarily marketed. We do not dispute that the FDA would have authority to regulate tobacco products (or any other products) for which therapeutic claims are made.

medical or therapeutic effect on the body. See Brief of Respondents United States Tobacco Co., *et al.*, at 9-20 (discussing meaning of "drug" and "device"). Clearly, tobacco products as commonly marketed do not fall within the terms of the statute.[3]

The legislative history of the FDCA and the tobacco-related statutes supports this reading of the plain language. Congress has been regulating the packing, labeling, marketing, and production of tobacco for nearly 100 years. See, *e.g.*, Pub. L. No. 57-237, 32 Stat. 714 (1902); Pub. L. No. 61-5, 36 Stat. 108-111 (1909); Pub. L. No. 73-483, 48 Stat. 1275 (1934); Pub. L. No. 74-314, 49 Stat. 731 (1935); Pub. L. No. 75-430, 52 Stat. 31 (1938). Nothing in the FDCA, enacted in 1938, suggests an intent to include tobacco — at that time (as now) a significant and discrete industry, governed by tobacco-specific federal statutes — within its reach. See Brief of Respondents Philip Morris Incorporated, *et al.*, at 6-11 (discussing evidence of congressional intent).

[3] Although the government argues that the "plain language" of the FDCA supports its exercise of jurisdiction, the FDA has conceded that under its literal interpretation it would also have regulatory jurisdiction over such products as thermal pajamas, exercise equipment and home air conditioners (see Appellee and Reply Brief for FDA in the Fourth Circuit at 20), a result that cannot be squared with the intended scope of the FDCA. Furthermore, the FDA's interpretation of the "plain language" would require a ban on the off-label use of many drugs, a consequence that would have serious adverse health effects. See Brown & Williamson Br. at 27-31. Thus, even if the "plain language" of the statute were otherwise clear, these absurd consequences would warrant an examination of the legislative history of the FDCA and other evidence of congressional intent. See *Green* v. *Bock Laundry Mach. Co.*, 490 U.S. 504, 509-510 (1989); *id.* at 527 (Scalia, J., concurring); Breyer, *On the Uses of Legislative History in Interpreting Statutes*, 65 S. CAL. L. REV. 845, 849 (1992) (use of legislative history to prevent absurd results "seems uncontroversial").

Beginning shortly after 1938, the year that the FDCA was enacted, the FDA consistently represented that it did not have regulatory jurisdiction over tobacco. See Philip Morris Br. at 10-14, 18-19, 22-31 (describing repeated statements by FDA officials). To the extent that the FDA's interpretation of the FDCA provides evidence of its intended scope, the agency's interpretation contemporaneous with the statute's enactment is far stronger evidence than the agency's unexplained, opposite interpretation decades later. See *Aluminum Co. of Am.* v. *Central Lincoln Peoples' Util. Dist.*, 467 U.S. 380, 390 (1984); *Zenith Radio Corp.* v. *United States*, 437 U.S. 443, 450 (1978); Scalia, *Judicial Deference to Administrative Interpretations of Law*, 1989 DUKE L.J. 511, 518.

The FDA's lack of regulatory authority over tobacco has been confirmed in the decades since 1938. Congress considered, and failed to enact, numerous bills that would have given the FDA the power to regulate tobacco products, manifesting Congress's understanding that the FDA did not already possess such authority under the FDCA. See Philip Morris Br. at 11-21, 28-31, 33-35 (listing failed legislative efforts). Congressional committee reports and members of Congress repeatedly stated that the FDA lacked regulatory authority over tobacco and that any further regulation of the industry must be accomplished by congressional action. See *ibid.* Agency officials acknowledged the correctness of this understanding as well, time and again disavowing any regulatory jurisdiction over tobacco. See *id.* at 12-14, 18-19, 22-31.

Finally, in reliance on this understanding, Congress has enacted numerous laws directly regulating tobacco or delegating enforcement authority to agencies other than the FDA or to the States. See Pub. L. No. 89-92, 79 Stat. 282 (1965); Pub. L. No. 91-222, 84 Stat. 87 (1970); Pub. L. No. 98-24, 97 Stat. 175, 178 (1983); Pub. L. No. 98-474, 98 Stat. 2200 (1984); Pub. L. No. 99-252, 100 Stat. 30 (1986); Pub. L. No. 102-321, 106 Stat. 323 (1992). This statutory ratification

of the FDA's longstanding position is compelling evidence that the agency's disclaimer of jurisdiction was correct. See, *e.g.*, *CFTC* v. *Schor*, 478 U.S. 833, 846 (1986) (where "Congress has not just kept its silence by refusing to overturn the administrative construction, but has ratified it with positive legislation, we cannot but deem that construction virtually conclusive") (quotation marks omitted). Moreover, the substantive terms of these statutes are in serious conflict with the FDA's claim of regulatory authority under the FDCA. See Philip Morris Br. at 35-43.[4]

Under *Chevron*'s step one, all of this evidence is relevant in determining whether Congress has spoken to the FDA's regulatory authority over tobacco. See *Chevron*, 467 U.S. at 843 n.9 ("traditional tools of statutory construction" and other evidence of legislative intent considered at step one); see also, *e.g.*, *MCI Telecomms. Corp.*, 512 U.S. at 231-234 (considering general purpose of statute and later-enacted legislation); *United States Nat'l Bank* v. *Independent Ins. Agents of Am., Inc.*, 508 U.S. 439, 455 (1993) (considering entire law, and its object and policy); *Dole*, 494 U.S. at 35-43 (considering legislative history and "language, structure, and purpose" of statute); *Chemical Mfrs. Ass'n* v. *Natural Resources Defense Council, Inc.*, 470 U.S. 116, 125-133 (1985) (considering statutory text, history, structure, and purpose).

And when examined, this evidence plainly shows that Congress has *not* authorized, and did *not* intend, the FDA to exercise regulatory authority over tobacco. Under step one of *Chevron*, therefore, the FDA's contrary conclusion (even if it might be deemed plausible) is not entitled to deference. See *Chevron*, 467 U.S. at 842-843; see also, *e.g.*, *Pittston Coal Group* v. *Sebben*, 488 U.S. 105, 113-115 (1988); *id.* at

[4] The FDA's tobacco regulations also cannot be reconciled with the operative terms of the FDCA, which would require the FDA to ban tobacco — a result directly at odds with congressional intent. See R.J. Reynolds Br. at 27-30; page 20, *infra*.

124 (Stevens, J., dissenting); *Sullivan* v. *Zebley*, 493 U.S. 521, 536-537 (1990); *id.* at 543 (White, J., dissenting).

B. The Government's Arguments for Deference Are Based On A Misapplication Of *Chevron*'s Step One

The most notable aspect of the government's analysis of *Chevron* is its near-total disregard of *Chevron*'s step one: the government makes little effort to show that the statutory text, statutory framework, legislative history, or other relevant sources demonstrate that Congress intended to delegate to the FDA the authority to decide whether tobacco products should be regulated under the FDCA. Instead, the government asserts that the case must be resolved at *Chevron*'s step two, and that the agency's assessment of its authority to regulate tobacco must be given deference, because "it simply is not possible to conclude that Congress specifically addressed the question and clearly denied FDA authority to regulate tobacco products." FDA Pet. Reply 3; accord FDA Br.16-17 (arguing that *Chevron* step two deference applies because Congress has not unambiguously expressed an intent about whether the FDA has authority to regulate tobacco as a "drug" or "device").

The government's elision of *Chevron*'s step one is especially curious given its arguments in the courts below. The agency told both the district court and the Fourth Circuit that the case could be decided at step one of the *Chevron* analysis because, "[b]y its plain terms, the [FDCA] encompasses these tobacco products as drugs and devices." FDA Appellee Br. 12; see also FDA Defendants' Brief in Opposition to Plaintiffs' Motions for Summary Judgment at 23 ("[T]his court need not proceed past step one of the *Chevron* analysis."). It is difficult to understand why, if Congress's intent was crystal-clear in the lower courts, it has suddenly become obscured. The government has provided no explanation for this striking about-face.

The FDA's cursory treatment of *Chevron*'s step one is also incompatible with *Chevron* itself. The government's approach to *Chevron* would turn nearly every statutory construction case into a step two reasonableness test, which the agency would almost invariably win. This simplistic analysis would render *Chevron*'s step one virtually meaningless and would undermine fatally its utility as a guard against undue delegation of major policymaking authority and agency usurpation of legislative power. *Chevron* does not mandate such abdication of the judicial role.

The government invokes deference because "Congress has conferred on FDA the authority to administer the [FDCA]." FDA Br. 16. But agencies always purport to act pursuant to statutes that they have been authorized to administer. Nonetheless, an agency's enforcement authority "only permits the [agency] to police within the boundaries of the Act; it does not permit the [agency] to expand its jurisdiction beyond the boundaries established by Congress." *Board of Govs. of Fed. Res. Sys.* v. *Dimension Fin. Corp.*, 474 U.S. 361, 373-374 & n.6 (1986). To grant deference whenever an agency claims to act under its enabling statute would ignore the fundamental limitation that no deference is warranted where congressional intent is clear. In any event, the government's argument is factually incorrect: the question of the FDA's jurisdiction to regulate tobacco not only turns on the meaning of the FDCA, but also implicates the meaning of other statutes that the FDA has *not* been directed by Congress to administer. See pages 7-8, *supra*.

In a related vein, the government asserts that *Chevron* deference applies because the FDA was delegated the authority to determine whether products are "drugs" or "devices" under the Act. See FDA Br. 17-18 & n.3; see also FDA Pet. 18. This, too, begs the question: in enacting the FDCA, did Congress intend the FDA to have authority to regulate tobacco products? The fact that the FDCA contains broad definitions of "drug" and "device" does not answer that

predicate question, nor does it mean that Congress intended to give the FDA limitless authority to regulate anything that might fall within a possible interpretation of the statutory definitions. A statute is not ambiguous simply because Congress has not, in so many words, answered a question on its face. *Chevron*'s step one requires an assessment of *all* probative evidence of congressional intent to delegate regulatory authority to the agency; as we have already explained, the evidence shows that Congress did *not* intend to authorize the FDA to regulate tobacco, notwithstanding its enactment of broad definitions of "drug" and "device." See pages 5-9, *supra*.[5]

The government also suggests that deference is proper because, in enacting the definitions of "drug" and "device," Congress did not "clearly den[y] FDA authority to regulate tobacco products." See FDA Pet. Reply 3; see also FDA Br. 16-17. But we have already explained that a statute is not

---

[5] The FDA's argument appears to be based on the premise that if Congress had known in 1938 what the FDA claims to know now, it would have included tobacco products within the FDCA. But if the FDA's lack of authority to regulate tobacco has become "an anachronism," "it is the responsibility of Congress" — not the agency — to change course. *Maislin Indus., U.S., Inc.* v. *Primary Steel, Inc.*, 497 U.S. 116, 136 (1990); see also *MCI Telecomms. Corp.*, 512 U.S. at 234 ("our estimations, and the Commission's estimations, of desirable policy cannot alter the meaning of the federal Communications Act of 1934"). As this Court has recognized, although agencies must be able to change position to meet new conditions arising *within* the scope of their authority, an expansion of the scope of agency authority based on changed circumstances must come from Congress itself. See *Board of Govs.*, 474 U.S. at 365, 373-375.

The FDA's "changed circumstances" argument also ignores the fact that Congress has already considered the possibility of "changed circumstances" with respect to tobacco regulation and has set out statutorily-mandated procedures pursuant to which agencies can bring new information about tobacco to Congress with proposals for legislative response. See 15 U.S.C. §§ 1337, 1341(a), (c), 4407.

ambiguous merely because it does not explicitly address a particular issue or explicitly withhold authority from the agency. Under the government's approach, an agency would be entitled to deference in every case unless Congress expressly prohibited the regulation of a particular product, industry, or field. Yet the more overreaching or unintended the agency's claim of regulatory power, the less likely it is that Congress would have expressly withheld authority — notwithstanding that it is precisely in these circumstances that Congress would not intend the agency to act. See Breyer, *Judicial Review of Questions of Law and Policy*, 38 ADMIN. L. REV. 363, 370-371 (Fall 1986). The government's approach would place an intolerable burden on Congress, which would be required to enact elaborate and heavily detailed definitional sections or risk the possibility that an agency's extravagant jurisdictional claim would be given judicial deference. And the government's position would impose an almost insurmountable barrier on private litigants challenging agency action as outside the scope of the agency's authority. Notably, the government offers no authority for its argument. See *Ethyl Corp.* v. *EPA*, 51 F.3d 1053, 1060 (D.C. Cir. 1995) ("To suggest * * * that *Chevron* step two is implicated any time a statute does not expressly *negate* the existence of a claimed administrative power * * * is both flatly unfaithful to the principles of administrative law * * * and refuted by precedent.").

Finally, the government contends that it is simply irrelevant that Congress repeatedly rejected bills designed to give the FDA the power it now seeks and instead enacted laws directly regulating tobacco and delegating enforcement authorities to other agencies. See FDA Br. 42-44. But Congress's conduct demonstrates not only its acquiescence in, but also its ratification of, the FDA's frequently-stated position that it lacked regulatory authority over tobacco. See pages 7-8, *infra*. The government's disregard of this highly

probative evidence cannot be squared with *Chevron*'s step one requirement to faithfully determine the intent of Congress.

II. THE FDA'S CLAIM THAT IT IS ENTITLED TO DEFERENCE IGNORES OTHER FUNDAMENTAL LIMITATIONS ON THE *CHEVRON* DOCTRINE

In addition to ignoring the clear intent of Congress, the FDA's argument for deference is based on a disregard of fundamental limits on the *Chevron* doctrine consistently recognized and applied by this Court. Two crucial features in this case — that the agency is interpreting the scope of its own jurisdiction, and that the agency's position breaks sharply and inexplicably with its longstanding interpretation of the FDCA — support a more skeptical and searching review of the agency's actions.

A. The FDA's Claim Of Jurisdiction Over An Entirely New Regulatory Area Does Not Involve Specialized Agency Expertise And Depends On The Interpretation Of Statutes The Agency Has Not Been Authorized To Enforce

As this Court has long recognized, an agency's determination of the scope of its own jurisdiction is not automatically entitled to judicial deference. See, *e.g.*, *Federal Maritime Comm'n* v. *Seatrain Lines, Inc.*, 411 U.S. 726, 745 (1973) (agency may not invoke discretion to "bootstrap itself into an area in which it has no jurisdiction"); *SEC* v. *Sloan*, 436 U.S. 103, 119 (1978) (same).

There are sound reasons for this principle. To begin with, an agency's claim of new regulatory authority "may be motivated by designs for agency aggrandizement rather than by a disinterested assessment of statutory authority and appropriate policy." Merrill, *Judicial Deference to Executive Precedent*, 101 YALE L.J. 969, 1024 (1992); accord Sunstein,

Constitutionalism After the New Deal, 101 HARV. L. REV. 421, 467 (1987) ("foxes should not guard henhouses").

Furthermore, the premise of *Chevron* is that Congress intends an agency to apply its technical and policymaking expertise within an area of delegated authority. See *Chevron*, 467 U.S. at 843-844. But as this case shows, an agency's interpretation of jurisdictional boundaries often does not implicate agency expertise. To the contrary, a jurisdictional limit may reflect a determination by Congress of the outer limit of the agency's abilities, "a direct refutation of the agency's expertise." Gossett, Comment, Chevron, *Take Two: Deference to Revised Agency Interpretations of Statutes*, 64 U. CHI. L. REV. 681, 694 (1997). Cf. *Leedom* v. *Kyne*, 358 U.S. 184, 190 (1958) ("This Court cannot lightly infer that Congress does not intend judicial protection of rights it confers against agency action taken in excess of delegated powers.").

Accordingly, it is unreasonable to assume that Congress deemed each piece of enabling legislation to be "an open book to which the agency could add pages and change the plot line." Gellhorn & Verkuil, *Controlling* Chevron-*Based Delegations*, 20 CARDOZO L. REV. 989, 1011 (1999). It is especially unlikely that Congress intended to allow an agency to define the limits of its own jurisdiction when the agency seeks to regulate in an entirely new and unprecedented area, as the FDA seeks to do in this case. *Id.* at 1012. "The more significant the question and the greater the impact that expansion of the agency's jurisdiction is likely to have, the greater the likelihood that Congress did not intend implicitly to delegate that determination to an agency." *Id.* at 1008; see also *Industrial Union Dep't*, 448 U.S. at 645 (plurality op.) (refusing to infer that Congress intended to delegate to OHSA "unprecedented power over American industry"); *id.* at 669 (Powell, J., concurring) ("It is simply unreasonable to believe that Congress intended OSHA to pursue the desirable goal of risk-free workplaces to the extent that the economic viability

of particular industries — or significant segments thereof — is threatened.").

The case for denying deference is particularly strong where, as here, an agency's jurisdictional claim involves not just the statute it has been authorized to administer, but also statutes granting interpretive and enforcement authority to *other* agencies. The FDA has no special insight in interpreting these other statutes, or in reconciling conflicting policy goals to accomplish those statutes' purposes. See *Adams Fruit*, 494 U.S. at 649-650 (refusing to defer to agency's interpretation of statute that it was not authorized to enforce). Cf. *Bureau of Alcohol, Tobacco & Firearms*, 464 U.S. at 98 n.8. Indeed, judicial deference in these circumstances might lead to conflicting, and irreconcilable, statutory interpretations by different agencies. See *Martin* v. *Occupational Safety & Health Review Comm'n*, 499 U.S. 144, 152 (1991) (resolving "'jurisdictional' dispute" between two agencies with divided responsibility for enforcement of the same statute); see generally Weaver, *Deference to Regulatory Interpretations: Inter-Agency Conflicts*, 43 ALA. L. REV. 35 (1991).

Thus, even if congressional intent were not so clear, the FDA's bold assertion of the jurisdiction to regulate (and even ban) tobacco — which Congress has characterized as an industry whose activities "cut across the whole spectrum of commercial and social life in the United States," and one in which "Congress, if anyone, must make policy" (see H.R REP. NO. 91-289, at 5 (1969)) — should be greeted skeptically. This is hardly a case in which the agency has merely "fill[ed] a gap" or defined a statutory term in a way that comports with "the legislature's revealed design." FDA Br. 17 (quoting *Chevron*, 467 U.S. at 844). Rather, as even FDA Commissioner Kessler acknowledged in 1994, regulation of tobacco products raises "societal issues of great complexity and magnitude." See *Letter from FDA Commissioner Kessler to Scott Ballin* 3 (Feb. 25, 1994), reprinted in *Regulation of Tobacco Products (Part 1), Hearings Before the Subcomm. on*

Health and the Environment of the House Comm. of Energy and Commerce, 103rd Cong. 25 (1994). In these circumstances, it is simply unreasonable to conclude that Congress intended the courts to defer to the FDA's claim of jurisdiction over tobacco.

To be sure, a few members of this Court have suggested that agencies should be given deference on jurisdictional matters because it is difficult to distinguish between jurisdictional and non-jurisdictional claims and because virtually every agency action can be characterized as "jurisdictional." *Mississippi Power & Light Co.* v. *Mississippi*, 487 U.S. 354, 380-383 (1988) (Scalia, J., concurring); *Dole*, 494 U.S. at 53-54 (White, J., dissenting). While this rationale may have merit in some contexts, it is plainly inapplicable here. The FDA's claim of authority to regulate tobacco — a distinct, multi-billion-dollar industry, subject to industry- and product-specific statutes enforced by other agencies, not heretofore considered to be within the FDA's regulatory power — is indisputably jurisdictional. See Sunstein, *Law and Administration After* Chevron, 90 COLUM. L. REV. 2071, 2097, 2100-2101 (1990). The difficulty in identifying purely "jurisdictional" claims is not implicated in this case.

The government erroneously relies on *CFTC* v. *Schor*, 478 U.S. at 844-845, and *NLRB* v. *City Disposal Systems, Inc.*, 456 U.S. 822, 830 n.7 (1984), for the contention that the FDA's jurisdictional claim warrants *Chevron* deference. See FDA Br. 17 n.3. In *Schor*, Congress had expressly delegated authority to the CFTC to determine the scope of its own jurisdiction over counterclaims. See 478 U.S. at 846. Because Congress's intent on the jurisdictional issue was clear, *Chevron* deference was inapplicable. *Id.* at 845-847. *City Disposal* — and the other cases collected in Justice Scalia's concurrence in *Mississippi Power & Light* (FDA Br. 17 n.3) — involved an agency's determination about *how* it would regulate a product or activity over which it undoubtedly possessed regulatory authority.[6] None of these cases involved an agency's attempt to exercise power in an entirely new and unprecedented area based on its interpretation of statutes that it was not delegated authority to enforce. And none of them supports the radical proposition that an agency's assertion of jurisdiction is always entitled to deference — no matter how purely jurisdictional, no matter how extreme the consequences of the power grab, no matter how dependent on interpretation of statutes enforced and administered by other agencies, and no matter how attenuated from the agency's traditional regulatory sphere.

B. The FDA's Newly-Asserted Jurisdictional Claim Is Not Based On A Reasoned Analysis And Ignores Legitimate Reliance Interests

The FDA's assertion of jurisdiction to regulate tobacco products also is not entitled to judicial deference because it conflicts with views that the agency has long maintained on the identical issue of statutory construction. As this Court recently recognized, an agency interpretation that "conflicts with the agency's earlier interpretation is entitled to consider-

---

[6] In *City Disposal*, for example, the National Labor Relations Board determined that assertion of a collective bargaining right constituted "concerted activity" within the meaning of the National Labor Relations Act, a statute that Congress intended to be interpreted by the Board to protect employees' concerted efforts to enforce collective bargaining rights. *Capital Cities Cable, Inc.* v. *Crisp*, 467 U.S. 691, 700 (1984), involved the Federal Communications Commission's regulation of cable television, over which Congress intended the FCC to have regulatory authority. See *United States* v. *Southwestern Cable Co.*, 392 U.S. 157, 168 (1968). *CBS, Inc.* v. *FCC*, 453 U.S. 367, 382 (1981), and *Red Lion Broadcasting Co.* v. *FCC*, 395 U.S. 367, 379-381 (1969), involved FCC requirements that television stations provide responsive broadcasts or broadcast access. Both the FCC's general jurisdiction over television stations, and its specific authority to regulate broadcasts and mandate access, were beyond doubt. See *CBS*, 453 U.S. at 379-382, 386; *Red Lion*, 395 U.S. at 379-380.

ably less deference than a consistently held agency view." *Good Samaritan Hosp.* v. *Shalala*, 508 U.S. 402, 417 (1993) (internal quotation marks omitted); see also *INS* v. *Cardoza-Fonseca*, 480 U.S. 421, 446 n.30 (1987); *Pauley*, 501 U.S. at 698. Although "an initial agency interpretation is not instantly carved in stone," *Chevron*, 467 U.S. at 863, there are limits on an agency's ability to break sharply with past practices.[7] The agency must justify its changed interpretation with a reasoned analysis, see, *e.g.*, *Rust* v. *Sullivan*, 500 U.S. 173, 186-187 (1991); and the new position must not infringe legitimate reliance interests, see *Smiley* v. *Citibank (South Dakota), N.A.*, 517 U.S. 735 (1996). The government has not satisfied either of these requirements.

The FDA's claim of authority over tobacco products relies on a change in its position on two crucial issues. To begin with, the FDA has rejected its longstanding interpretation of the requirement that a drug or device be "intended to affect the structure or any function of the body of man" in order to fall within the scope of the FDCA. See 21 U.S.C. §§ 321(g)(1)(C), 321(h)(3). Traditionally, the FDA took the position that the "intended use" of a drug or device was *determined by a manufacturer's express or implicit claims*. See Brown & Williamson Br. at 18-27. Now, for the first time, the FDA asserts that a product's "intended use" may be determined by the effects sought by consumers and subjectively intended by manufacturers, even if no express or implied claims are made. This change in position was essential to the FDA's claim of regulatory authority over tobacco, for which neither express nor implicit therapeutic claims have been made.

[7] Here, of course, the FDA's interpretation of the FDCA was not "instantly carved in stone," but instead was etched there over decades, as the agency time and again reiterated that it had no jurisdiction over tobacco products.

The FDA's new interpretation of "intended use" has staggering implications for the manufacture and sale of pharmaceutical products, and in particular for off-label uses of such products. See Brown & Williamson Br. at 27-31. Expanding the definition of "intended use" in this way also renders the pre-market approval process for new drugs and devices and for generic drugs and follow-on devices much more difficult, expensive, and time-consuming. See *id.* at 31-34. And even if the FDA chooses not to ban the off-label use of a drug or device — a choice it appears to lack the discretion to make — its new interpretation of "intended use" would provide a predicate for state law tort suits and challenges to FDA approvals and clearances by competitors, consumer groups, and others. See *id.* at 34-35. Nowhere has the agency addressed the enormous implications of its changed position.

The FDA's only explanation for embracing its new interpretation of "intended use" is that it has new evidence that nicotine is addictive; that most users of tobacco products seek to satisfy a nicotine addiction and to obtain nicotine's physiological effects; and that manufacturers know that their products are used in this way and "deliberately engineer[] their products to deliver active doses of nicotine." FDA Br. 38-39. But as the respondents have demonstrated, the FDA was aware of evidence of each of these factors for years or even decades, and yet continued to disclaim authority to regulate tobacco. See Philip Morris Br. at 12-15, 24-27. In short, the FDA's claim of "changed circumstances" both is demonstrably false as a historical matter and falls woefully short of the "reasoned analysis" required for such a sharp break with a prior position — particularly when its new position would have such extraordinary practical consequences and would lead to such a quantum expansion of agency jurisdiction. See, *e.g.*, *Smiley*, 517 U.S. at 742; see also *Georgetown Univ. Hosp.*, 488 U.S. at 212-213; *Robertson* v. *Methow Valley Citizens Council*, 490 U.S. 332, 355-

356 (1989); *Motor Vehicles Mfrs. Ass'n of United States, Inc.* v. *State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 50 (1983).

The FDA's new position also represents a sharp break with its considered views on a second issue. The FDA has long explained that it lacked jurisdiction to regulate tobacco because, if the FDCA were applicable, it would be required to ban tobacco from the market. See *Cigarette Labeling and Advertising Hearings Before the House Comm. on Interstate and Foreign Commerce,* 88th Cong. 13, 18 (1964) (letter from Secretary of Health, Education and Welfare); *Hearings Before the Consumer Subcomm. of the Senate Comm. on Commerce on S. 1454*, 92d Cong. 239, 242 (1972) (testimony of FDA Commissioner); *id.* at 245 (testimony of FDA Asst. General Counsel for Foods, Drugs & Product Safety Division). According to the FDA, this result was untenable because banning tobacco "would be inconsistent with the clear congressional intent." *Hearings Before the Consumer Subcomm. of the Senate Comm. on Commerce on S. 1454*, 92d Cong. 242; accord *id.* at 245.

The FDA now claims, however, for the first time, that its assertion of jurisdiction over tobacco is *not* dependent on whether it would be required by the FDCA to ban tobacco. In the FDA's own words, a conclusion "that the Act, as presently written, requires tobacco products to be banned * * * would in no way undermine FDA's conclusion that tobacco products * * * [are] subject to regulation under the Act." FDA Br. 14; accord *id.* at 34 ("Even assuming the regulatory provisions of the Act would require tobacco products to be banned, however, that would not affect the reasonableness of FDA's conclusion that tobacco products are drugs and devices within the meaning of the Act.").

Because the FDA cannot act in conflict with Congress's intent, see *Chevron*, 467 U.S. at 842-843, the agency's current position must be premised on its belief that Congress did not in fact intend tobacco products to remain legal. Yet

the FDA has offered *no* explanation whatsoever for its total about-face on the critical question whether Congress was willing to countenance a ban on cigarettes. Indeed, the government's brief barely mentions the issue — and does so only to assert that Congress's intent about whether tobacco sales should be prohibited is not "dispositive" and that, if unhappy with a ban, Congress could overturn the result by passing *new* legislation. See FDA Br. at 35-36 & n.7. Accordingly, the FDA's new jurisdictional argument, which is premised on this unexplained shift, warrants no deference. See *Smiley*, 517 U.S. at 742; *NLRB* v. *United Food & Commercial Workers Union*, 484 U.S. 112, 124 (1987); *Cardoza-Fonseca*, 480 U.S. at 446.

Finally, the agency's new claim of jurisdiction over tobacco must fail because its prior disclaimer of authority has given rise to substantial reliance interests. See, *e.g.*, *Smiley*, 517 U.S. at 742; *Zenith Radio Corp.*, 437 U.S. at 457-458. Both federal and state legislators have enacted laws premised on the FDA's lack of regulatory authority in this area. See R.J. Reynolds Br. at 36-47 (discussing federal and state tobacco-related laws). That legislation was the result of a political compromise: the labeling, advertising and sale of tobacco products would be subject to stringent federal and state regulation; in return, tobacco would remain on the market. And the political compromise was based on the fundamental premise that the FDA lacked regulatory authority over tobacco. Cf. Scalia, *Judicial Deference*, 1989 DUKE L.J. at 517 (purpose of *Chevron* deference is to give Congress a background presumption against which to legislate). The FDA cannot suddenly change its mind and thereby make nonsense of the congressionally chosen enforcement scheme. See, *e.g.*, *International B'hd of Teamsters* v. *Daniel*, 439 U.S. 551, 568-570 (1979); *Morton* v. *Ruiz*, 415 U.S. 199, 236-237 (1974).

CONCLUSION

The FDA's claim of jurisdiction to regulate tobacco products under the FDCA should not be given deference under *Chevron*, and the judgment of the court of appeals should be affirmed.

Respectfully submitted.

HUGH F. YOUNG, JR.
Product Liability Advisory Council, Inc.
1850 Centennial Park Dr.
Suite 510
Reston, VA 20191
(703) 264-5300

KENNETH S. GELLER
Counsel of Record
SHARON SWINGLE
Mayer, Brown & Platt
1909 K Street, N.W.
Washington, D.C. 20006
(202) 263-3000

Counsel for Amicus Curiae

SEPTEMBER 1999