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 AMICUS CURIAE OF PACIFIC LEGAL FOUNDATION IN SUPPORT OF AFFIRMANCE

Filed September 9, 1999

This is a replacement cover page for the above referenced brief filed at the U.S. Supreme Court. Original cover could not be legibly photocopied

QUESTION PRESENTED

Does the Food and Drug Administration have statutory jurisdiction to regulate all tobacco products as drugs or devices under the Federal Food, Drug and Cosmetic Act of 1938?

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INTEREST OF AMICUS CURIAE

Pursuant to Supreme Court Rule 37, consent to file this brief was received from all parties and lodged with the Clerk of this Court.[1]

Pacific Legal Foundation is the largest and most experienced nonprofit public interest law foundation of its kind in America. Founded in 1973, PLF provides a voice in the courts for mainstream Americans who believe in limited government, private property rights, individual freedom, and free enterprise. PLF litigates nationwide in state and federal courts with the support of thousands of citizens from coast to coast. PLF is headquartered in Sacramento, California, and has offices in Miami, Florida; Honolulu, Hawaii; Bellevue, Washington; and a liaison office in Anchorage, Alaska.

PLF has participated in numerous cases concerning the scope of federal agency authority. For example, PLF participated as amicus curiae before this Court in *Babbitt v. Sweet Home Chapter of Communities for a Greater Oregon*, 515 U.S. 687 (1995); and *Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984); and before the United States Courts of Appeals in *National Mining Association v. United States Army Corps of Engineers*, 145 F.3d 1399 (D.C. Cir. 1998).

PLF seeks to augment the arguments of Respondents by elucidating the limitations on federal agency power under administrative law principles. PLF believes its public policy perspective and litigation experience dealing with administrative law issues will provide an additional viewpoint on the legal issues presented.

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[1] Pursuant to Supreme Court Rule 37.6, Amicus Curiae Pacific Legal Foundation affirms that no counsel for any party in this case authored this brief in whole or in part; and, furthermore, that no person or entity has made a monetary contribution specifically for the preparation or submission of this brief.

STATEMENT OF THE CASE

On August 28, 1996, the Food and Drug Administration (FDA) published a final rule in the Federal Register, "Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents," 61 Fed. Reg. 44,395 (1996). Subsequently, the Respondents filed this suit challenging FDA's exercise of jurisdiction over tobacco products. The United States District Court for the Middle District of North Carolina rejected the challenge, finding that Congress did not intend "to withhold from FDA" the authority to regulate tobacco. *Coyne Beahm, Inc. v. United States Food and Drug Administration*, 966 F. Supp. 1374, 1387 (M.D. N.C. 1997). The United States Court of Appeals for the Fourth Circuit reversed. *Brown & Williamson Tobacco Corp. v. Food & Drug Administration*, 153 F.3d 155 (4th Cir. 1998).

The Fourth Circuit's opinion was based on two rationales. First, notwithstanding the provisions of the Food, Drug and Cosmetic Act (Act) defining "drugs" and "devices," FDA's regulation was inconsistent with the Act as a whole. Because FDA did not and could not comply with the statutory mandates of the Act in its treatment of tobacco, Congress could not have intended that Act, or FDA's administration of it, to apply to tobacco products. Second, FDA's assertion of jurisdiction could not be meshed with congressional intent as to the Act, or with the regulatory scheme created by Congress through statutes directed specifically at tobacco products. FDA petitioned for a writ of certiorari to resolve this important question, which this Court granted.

SUMMARY OF ARGUMENT

As FDA and its Amici ably illustrate, the importance of national tobacco policy is difficult to understate. The production, sale, and export of tobacco products has significant impacts on our national economy and on the health of American citizens. But it is the very significance of the issue that

demonstrates that national tobacco policy properly belongs in the open halls of a democratically elected Congress. FDA's interjection of itself into this issue of broad national policy intrudes into an area Congress reserved to itself. FDA's role is limited to the application of congressional policy; it has no power to establish it.

FDA's decision to recast the contours of its own jurisdiction under an existing federal statute is entitled to no deference. FDA's arguments to the contrary not only rely upon a crabbed interpretation of this Court's decision in *Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, but also utterly ignore this Court's repeated pronouncements that an agency's determination of its own jurisdiction is not entitled to deference, particularly where, as here, the agency redrafts its jurisdiction in a way that upsets long-settled agency practice without sufficient reason.

ARGUMENT

I

THE SIGNIFICANT ECONOMIC AND PUBLIC HEALTH IMPACTS OF TOBACCO DEMONSTRATE, BY THEMSELVES, THAT TOBACCO REGULATION IS A MATTER OF NATIONAL POLICY THAT MUST BE ESTABLISHED BY CONGRESS, NOT THROUGH THE UNILATERAL DECISION OF FDA

As comprehensively demonstrated by FDA, national tobacco policy plays a major role in the economic life and physiological welfare of United States citizens. Consequently, the issue in this case is not, as FDA would have it, whether tobacco products are "drugs" or devices" within the meaning of the Food, Drug and Cosmetic Act, 21 U.S.C. 301, *et seq.* The issue in this case is whether national policy on a matter of such obvious public importance ought to be dictated by FDA, or should instead emanate from Congress, "the governmental body

best suited and most obligated to make the choice confronting us in this litigation." *Industrial Union Department, AFL-CIO v. American Petroleum Institute*, 448 U.S. 607, 672 (1980) (Rehnquist, J., concurring in the judgment).

> Congress has the resources and the power to inform itself, and is the appropriate forum where the conflicting pros and cons should have been presented and considered.

United States v. Robel, 389 U.S. 258, 276 (1967) (Brennan, J., concurring in the result). Instead, the pros and cons of national tobacco policy have been weighed here by FDA, an administrative agency that has suddenly decided to redefine its statutory jurisdiction under a federal law in which the jurisdictional provisions have remained more or less fixed since 1938.

FDA admits that it sought to interject itself into national tobacco policy through the implementation of the regulations at issue because the agency believed that the country, as a whole, needed a more forceful anti-tobacco policy:

> The [FDA] is proposing new regulations . . . in order to address the serious public health problems caused by the use of and addiction to [tobacco] products.

60 Fed. Reg. 41,313, 41,314 (1995).

FDA's Proposed Rule repeatedly manifested the agency's perception that existing state and federal regulations were not effective *enough* in curbing tobacco use by youths. For example, it acknowledged that "all States prohibit the sale of tobacco products to persons under the age of 18," *id* at 41,315, consistent with the Alcohol, Drug Abuse and Mental Health Administration Reorganization Act, *id.* at 41,323, but contended that such state laws were not being effectively enforced, *id.* at 41,315. It elsewhere indicated that existing federal laws already addressed tobacco product advertising, and even that its

own regulations encountered preemption issues and potential conflict problems from other federal acts, *id.* at 41,314, 41,319, but the agency proceeded to propose advertising regulations. *Id.* at 41,315. In general, FDA indicated its awareness of other tobacco-specific legislation by asserting that the Proposed Rule was arrived at after FDA "examined many domestic and foreign tobacco control statutes, regulations, and legislation." *Id.* at 41,315. FDA nevertheless concluded:

> The agency has examined many options for reducing tobacco use by children and adolescents, *and believes that an effective program must address* the following two areas: (1) Restrictions on cigarette and smokeless tobacco sales that will make these products less accessible to young people; and (2) restrictions on labeling and advertising to help reduce the appeal of tobacco products to young people along with requirements for a manufacturer-funded national education campaign aimed at those under 18 years of age to help reduce the products' appeal to these young people.

Id.

For example, FDA acknowledged that Congress had specifically enacted the Comprehensive Smokeless Tobacco Health Education Act to discourage young people from using smokeless tobacco. And even though it stated that there were 3 million users under the age of 21 of smokeless tobacco in 1986 when Congress passed that legislation, *id.* at 41,317, and 1 million adolescent males who used smokeless tobacco today, *id.* at 41,314 (use of smokeless tobacco by girls is not extensive, *id.* at 41,341), it concluded that Act was not achieving its goal:

> Despite the Smokeless Act and State laws prohibiting sales to minors, a high percentage of persons under the age of 18 use smokeless tobacco products.

Id. As a result,

> [t]he recent and very large increase in the use of smokeless tobacco products by young people and the addictive nature of these products has persuaded the agency that these products must be included in any regulatory approach that is designed to help prevent future generations of young people from becoming addicted to nicotine-containing tobacco products.

Id. at 41,318. Despite FDA's recognition of the fact that Congress had taken affirmative steps to curb the use of smokeless tobacco by young people, FDA was "persuaded" that Congress' efforts were not having as dramatic an impact as its own regulations would.

Without any prior history of regulating smokeless tobacco or cigarettes, FDA developed what it believed were more effective regulatory means to reduce tobacco use by young people, even though no congressional legislation had delegated any such authority to FDA. FDA's avowed purpose for its rule was to meet the goals announced in a Department of Health and Human Services Report, "Healthy People 2000":

> The objective of the proposed rule is to meet the goal of the report "Healthy People 2000" by reducing roughly by half children's and adolescents' use of tobacco products. If this objective is not met within seven years of the date of publication of the final rule, the agency will take additional measures to help achieve the reduction in the use of tobacco products by young people.

Id. at 41,314. The Proposed Rule specifically stated that the Rule "would not restrict the use of tobacco products by adults." *Id.* As conceded by FDA, the primary impetus for the rule was not the implementation of the Food, Drug and Cosmetic Act (the purpose of which is to regulate drugs as a whole, and does

not specify that the agency's mandate has any special force with respect to young people), but to meet the "outcome-based" quantitative health goals outlined in an executive agency report. *Id.* at 41,314. Thus, even though Congress created the Substance Abuse and Mental Health Services Administration to carry out a program of state-operated regulatory programs, FDA argued:

> FDA strongly supports the basic *objectives* of this program, but believes that their full *achievement* would demand a broad arsenal of controls; including industry programs to complement and fortify the new State inspectional programs.

Id. at 41,362 (emphasis added). FDA's language indicated that it had concluded that the means chosen by the congressional scheme were inadequate to meet the goals of "Healthy People 2000." Consequently, FDA felt it incumbent upon itself to "complement" Congress' work by embarking upon a more comprehensive regulatory program:

> FDA believes that, if aggressively implemented and supported by both industry and public sector entities, comprehensive programs designed to discourage youthful tobacco consumption could reasonably achieve the "Healthy People 2000" goal.

Id.

In the end, FDA's decision to regulate tobacco products was tantamount to treating "Healthy People 2000" as independent or supplemental authorization to embark upon tobacco regulation. That is, since congressional action would not achieve the goals of that report, FDA decided it would achieve them by agency fiat. But

> [f]ormulation of policy is a *legislature's* primary responsibility, entrusted to it by the electorate . . . . "Without explicit action by law-makers, decisions of

> great constitutional import and effect would be relegated by default to administrators who, under our system of government are not endowed with authority to decide them."

Robel, 389 U.S. at 276 (Brennan, J., concurring in the result) (emphasis added, citation omitted). FDA's decision to regulate tobacco to achieve the goals of "Healthy People 2000" is one that FDA simply did not have the authority to make.

The sheer number of comments received in response to FDA's Proposed Rule,[2] the contentiousness of the current litigation, and the bald fact that tobacco products are manifestly marketable to a profitable proportion of American citizens, attests to the fact that a sizeable segment of the United States population has a stake in national tobacco policy. FDA's perception that our nation's tobacco policy has failed to promote what is best for the American people's health may indicate that direct congressional legislation has been ineffective or inefficient in addressing problems related to the use of tobacco products. But the failure of Congress to establish or implement a forceful national policy is not a legal ground for the extra-democratic exercise of power being flexed here by FDA. Acquiescence to administrative action in this case would amount to sanctioning a system in which our government is made up of one branch--the executive--whose intentions may be unimpeachable, but whose practices are nonetheless unsuited to a democratic republic.

In *Federal Trade Commission v. Ruberoid Co.*, 343 U.S. 470 (1952), Justice Jackson, in dissent, exclaimed:

[2] The comments were so numerous that the Final Rule consumed 922 pages of the Federal Register, and the FDA addressed matters ranging far outside of its expertise, including the nondelegation doctrine, federal preemption doctrine, the First Amendment, and the Fifth Amendment's Takings Clause. 61 Fed. Reg. 44,396-45,318 (1996).

> The rise of administrative bodies probably has been the most significant legal trend of the last century and perhaps more values today are affected by their decisions than by those of all the courts, review of administrative decisions apart. They also have begun to have important consequences on personal rights. They have become a veritable fourth branch of the Government, which has deranged our three-branch legal theories. . . .

Federal Trade Commission, 343 U.S. at 487. While Justice Jackson decried the rise of the administrative state, administrative agencies are a fact of modern life. And what keeps administrative agencies from devolving into Justice Jackson's distrusted "fourth branch" are the checks placed upon agency power by the actions of the three constitutionally sanctioned branches: agency power is limited by legislative delegations, executive discretion, and judicial review. In short, administrative agencies do not upset our three-branch system precisely because they can be maintained within the constitutional system of checks and balances.

But FDA's unprecedented foray into the area of tobacco regulation upsets this balance. FDA's decision amounts to one of *establishing* national tobacco policy, rather than merely applying it through a valid legislative delegation. The task of establishing national policy on a matter as politically and economically charged as tobacco is not one that can be assumed by an executive agency in isolation. Rather it is a task that properly belongs in Congress.

> The principle that authority granted by the legislature must be limited by adequate standards serves two primary functions vital to preserving the separation of powers required by the Constitution. First, it insures that *the fundamental policy decisions in our society*

> *will be made not by an appointed official but by the body immediately responsible to the people.*

Arizona v. California, 373 U.S. 546, 626 (1963) (Harlan, J., dissenting) (emphasis added).

When Congress enacted the Food, Drug and Cosmetic Act, it made laws, not legislators. *See Industrial Union*, 448 U.S. at 673 (Rehnquist, J., concurring in the judgment). National tobacco policy is of tremendous importance to many American citizens politically, economically, and personally. It cannot be credibly contended that Congress committed this policy to the jurisdiction of FDA in the absence of any language whatsoever specifying that authority. "It is the hard choices, and not the filling in of the blanks, which must be made by the elected representatives of the people." *Id.* at 687 (Rehnquist, J., concurring in the judgment). Because policy matters of this scale must be made by Congress, and may not be made by administrative agencies, this Court should affirm the decision of the Court below that FDA has no authority to regulate tobacco products.

II

IN ADOPTING REGULATIONS GOVERNING TOBACCO PRODUCTS, FDA HAS ACTED *ULTRA VIRES* BY UNREASONABLY EXERCISING AUTHORITY BEYOND THE BOUNDS OF ITS LEGISLATED DELEGATION

FDA's recent change of position leading to its decision to exercise jurisdiction over tobacco products should not be given "controlling weight" under *Chevron*. Brief for the Petitioners at 17. The rationale announced in *Chevron*, though well-suited to the issue in that case, does not carry as much force in other contexts. As explained below, one of those contexts is in the area of determining agency jurisdiction.

The *Chevron* doctrine is not a blanket doctrine of deference to administrative agency determinations. Instead, its holding is rather specific. *Chevron* dealt with a regulation promulgated by the Environmental Protection Agency to implement the Clean Air Act Amendments of 1977. *Chevron*, 467 U.S. at 840-41. EPA was charged with establishing standards for a state permitting program to regulate "new or modified major stationary sources" of air pollution. *Id.* at 840. In implementing the Act, EPA adopted a regulation which defined "stationary source" to mean an entire plant, rather than each emitting device within a plant. *Id.* By defining "stationary source" in this manner, which was dubbed the "bubble" concept, an industrial facility could modify one or another of its emitting devices and, so long as the total plant's emissions remained below requisite levels, it would fall under the same permit. *Id.* The Natural Resources Defense Council challenged the EPA's regulation. *Id.*

In upholding EPA's regulation, this Court announced a test to determine the validity of agency regulations:

> First, always, is the question 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. If, however, the court determines Congress has not directly addressed the precise question at issue, the court does not simply impose its own construction on the statute, as would be necessary in the absence of an administrative interpretation. Rather, 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 842-43. Thus, this Court cast the analysis as one in which a court resolves two questions: (1) has Congress resolved the issue through its statute; and (2) is the agency's construction of the statute permissible. If the answer to the first is no and the second yes, then the Court must defer to the agency's determination.

There are problems with applying this test to FDA's tobacco regulation in the way FDA suggests. First, FDA jumps right to answering question two--that is, they argue that their interpretation is reasonable--without sufficiently resolving the first question: whether Congress has spoken to the question at issue. Second, even if the Food, Drug and Cosmetic Act could be understood to have left this matter to the agency's discretion, the doctrine of deference does not necessarily apply to an agency's interpretation of its own jurisdiction.

A. FDA's Reliance upon *Chevron* Is Misplaced, Because Congress Did Not Delegate the Authority to FDA to Regulate Tobacco Products in the Food, Drug and Cosmetic Act

Of course, Congress did not specifically state in the Food, Drug and Cosmetic Act that FDA did *not* have jurisdiction over tobacco products. However, the record is clear that, until 1996, this *lack* of congressional specificity had been consistently interpreted by FDA to preclude its jurisdiction over tobacco. Accordingly, Congress has consistently regulated tobacco directly, without reference to FDA. Thus, deference to FDA's new interpretation of its jurisdiction is not appropriate.

From 1914 until FDA's tobacco rule in 1996, FDA repeatedly and consistently maintained that it did not have jurisdiction over tobacco products. *Brown & Williamson*, 153 F.3d at 168. And even though the term "drug" has been part of FDA's jurisdictional mandate since 1906, and the term "device" has been part of the jurisdictional mandate since 1938, FDA "repeatedly informed Congress that cigarettes marketed

without therapeutic claims do not fit within the scope of the Act." *Id.* Indeed, FDA refused to exercise jurisdiction over cigarettes in 1977 partly on the basis that

> "Congress, had the matter been considered, would not have intended cigarettes to be included as an article 'intended to affect the functions of the "body of man" or in any other definition of "drug."'"

Id. at 169 (citations omitted). FDA's new position contends these earlier pronouncements are irrelevant: congressional silence amounts to an agency license, rather than a limitation.

But, though Congress may have been silent in the Act, Congress was not silent as a general matter. Congress repeatedly considered delegating authority to FDA to regulate tobacco--and repeatedly rejected it. *See id.* at 170-73. Instead, Congress regulated tobacco products directly--even to the point of specifically addressing some of the same concerns that appear to have motivated FDA in this case. *Id.* at 175. Thus, this is not a case in which "congressional inaction demonstrates 'unawareness, preoccupation, or paralysis.'" *Brown & Williamson*, 153 F.3d at 170-71 (citation omitted).

Congress specifically addressed tobacco regulation in the Cigarette Labeling and Advertising Act, 15 U.S.C. § 1331, stating:

> 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.

15 U.S.C. § 1331. Congress also enacted the Comprehensive Smokeless Tobacco Health Education Act, 15 U.S.C. § 4401, *et seq.*, to address health effects and labeling requirements for smokeless tobacco. These congressional actions specifically regulating tobacco products are relevant to the question of

FDA's authority to regulate tobacco products under its general authority over drugs and devices.

> A basic rule of statutory construction to be applied to resolve a conflict between two different enactments each of whose literal terms cover a specific subject is that "where there is no clear intention otherwise, a specific statute will not be controlled or nullified by a general one . . . ."

Brown-Forman Distillers Corp. v. Mathews, 435 F. Supp. 5, 13 (W.D. Ky. 1976) (citing *Morton v. Mancari*, 417 U.S. 535, 550-51 (1974)) ("Where there is no clear intention otherwise, a specific statute will not be controlled or nullified by a general one, regardless of the priority of enactment.") Thus, even if FDA correctly concluded that tobacco products are drugs or devices within the general terms of the Food, Drug and Cosmetic Act, they could not be understood to override the terms of Congress' more specific tobacco legislation.

In *Brown-Forman Distillers*, a federal district court rejected the FDA's assertion of jurisdiction under circumstances remarkably similar to those presented here. In that case, FDA, for the first time in its history, promulgated regulations in 1975 governing alcoholic beverage labeling. *Brown-Forman Distillers*, 435 F. Supp. at 7. However, FDA's regulations conflicted with regulations promulgated by the Bureau of Alcohol, Tobacco and Firearms, which consistently had been exercising its authority over alcohol labeling according to specific legislation enacted in 1935. *Id.* at 7-8. Brown-Forman Distillers brought suit for declaratory and injunctive relief, asking the Court to determine whose regulations governed. *Id.* at 9. The Court found against FDA, despite its conclusion that the "plain language" of the Food, Drug and Cosmetic Act's definition of "food" gave FDA jurisdiction over alcoholic beverages. *Id.* at 12. The Court's reasoning as it applies to

alcoholic beverage labeling is equally well-suited to FDA's regulation of tobacco:

> In so holding we specifically refuse to accept the defendants' contention that Congress' failure to exclude specifically the labeling of alcoholic beverages from the provisions of the 1938 Act . . . was a dispositive indication of Congress' intention to include labeling authority over alcoholic beverages within the jurisdiction of the FDA. Although such an explicit statement would have been simple for Congress to include within the Act, its failure to do so is not dispositive given the fact that (1) legislative history . . . demonstrates that Congress did not believe the 1938 legislation included labeling authority over alcoholic beverages; and, (2) three years prior to the 1938 Act Congress had previously passed legislation related directly to alcoholic beverages which included a specific and comprehensive section on labeling of such beverages . . . . To accept the defendants' argument we would have to believe that Congress intended to inflict upon the alcoholic beverage industry conflicting labeling requirements. We refuse to make such an assumption.

Id. at 16.

In the present case, the history of FDA's position and federal tobacco policy in general, demonstrate that the Food, Drug and Cosmetic Act's failure to *exclude* tobacco from FDA jurisdiction is not a significant indicator of congressional intent. In the face of FDA's consistent and repeated claims that it had no jurisdiction over tobacco, it would have been rather remarkable for Congress to go to the trouble of stating the fact explicitly, particularly when Congress had manifestly chosen to regulate tobacco directly. Congressional silence in the Food,

Drug and Cosmetic Act, under these circumstances, means that Congress did not recognize a need to exclude tobacco products from FDA's jurisdiction because it was generally understood that the Act did not give FDA jurisdiction over them.

B. Even If the Terms "Drug" or "Device" Within Food, Drug and Cosmetic Act Were Ambiguous, the *Chevron* Doctrine Does Not Necessarily Entitle FDA to Define the Limits of Its Own Jurisdiction

1. *Chevron* Does not Apply to Every Agency Determination

As explained above, *Chevron* dealt with a relatively narrow agency determination, specifically, whether the statutory term "stationary source" could reasonably be interpreted by EPA to include an entire plant for the purposes of establishing regulatory permit standards. But not all agency interpretations of statutes they are charged with administering have the same narrow policy implications that were at stake in *Chevron*. There, several factors militated in favor of a policy of deference. First, the best means by which to regulate emissions sources was a matter that EPA, given its experience and expertise, could resolve better than Congress, particularly for the purpose of establishing a workable and enforceable regulatory scheme. Deference is owed particularly where

> "the statutory policy in the given situation has depended upon more than ordinary knowledge respecting the matters subjected to the agency regulations."

Chevron, 467 U.S. at 844 (citation omitted). Second, requiring judicial deference to the agency's determination in that context, rather than allowing the various state and federal courts to interpret statutory language anew, advanced the overall federal goal of establishing consistent national standards upon which individuals and states could justifiably rely. *See*, Kenneth Culp

Davis and Richard J. Pierce, Jr., *Administrative Law Treatise*, Vol. 1 § 3.4, at 116-18 (3rd ed. 1994). As the Court in *Chevron* explained,

> In these cases, the Administrator's interpretation represents a reasonable accommodation of manifestly competing interests and is entitled to deference: the regulatory scheme is technical and complex, the agency considered the matter in a detailed and reasoned fashion, and the decision involves reconciling conflicting policies.

Chevron, 467 U.S. at 865. Here, these factors which made *Chevron*'s doctrine of deference compelling are absent. The question of whether tobacco is a "drug" or "device" is not a question on which FDA can bring some special knowledge not within the sphere of Congress' own expertise. Further, FDA has not reached its conclusion in a detailed or reasoned fashion, nor has its policy decision dispelled policy conflicts. Instead, FDA's decision has served to exacerbate such conflicts. *See, e.g., Brown-Forman Distillers*, 435 F. Supp. at 14.

Despite the cautionary language in *Chevron*, it is not always obvious under what circumstances *Chevron*'s deferential standard should apply. *See, e.g., INS v. Cardoza-Fonseca*, 480 U.S. 421 (1987); *Dole v. United Steelworkers of America*, 494 U.S. 26 (1990) (In both cases, justices disagreed as to the applicability of *Chevron* deference to an administrative agency determination.). Deference is most suited to those situations in which the agency's determinations relate to matters that fall within an agency's particular expertise or where statutory ambiguities unmistakably manifest Congress' intent that the agency resolve policy questions within a narrow set of parameters. It is inappropriate where deference would result in an inconsistent and unworkable federal regulatory scheme. Here, if substantial deference were given to FDA's determinations of its own jurisdiction, the result would be "delegation

running riot,"--Congress abdicating its responsibility to resolve an important question of national policy and the judiciary sanctioning a "roving commission." *A.L.A. Schechter Poultry Corporation v. United States*, 295 U.S. 495, 551, 553 (1935) (Cardozo, J., concurring).

> [W]here, as here, the review is not of a question of fact, but of a judgment as to the proper balance to be struck between conflicting interests, "(t)he deference owed to an expert tribunal cannot be allowed to slip into a judicial inertia which results in the unauthorized assumption by an agency of major policy decisions properly made by Congress."

National Labor Relations Board v. Brown, 380 U.S. 278, 292 (1965) (citation omitted). "It is axiomatic that an administrative agency's power to promulgate legislative regulations is limited to the authority delegated by Congress." *Bowen v. Georgetown University Hospital*, 488 U.S. 204, 208 (1988). This Court has emphasized that "[a]n agency may not finally decide the limits of its statutory power. That is a judicial function." *Social Security Board v. Nierotko*, 327 U.S. 358, 369 (1946). Thus,

> [t]he determination of the extent of authority given to a delegated agency by Congress *is not left for the decision of him in whom authority is vested.*

Addison v. Holly Hill Fruit Products, 322 U.S. 607, 616 (1944) (emphasis added).

The judicial policy of not deferring to agency determinations of their own jurisdiction is sound. Administrative agencies must operate "canalized within banks that keep it from overflowing," *A.L.A. Schechter Poultry*, 295 U.S. at 551 (Cardozo, J., concurring), and those "canals" are constructed by Congress, not the agency itself. If an agency were capable of reconfiguring the contours of its jurisdictional canals at will, the enabling legislation would be rendered meaningless--

congressional enactments would serve as nothing more than midwives to independent governing bodies. Thus, while it is appropriate to defer to agency determinations of matters which Congress has unequivocally placed into the hands of an administrative agency (as was the case in *Chevron*), the determination of an agency's jurisdictional limits must remain a judicial question, lest the agency "bootstrap itself into an area in which it has no jurisdiction by repeatedly violating its statutory mandate." *Federal Maritime Commission v. Seatrain Lines, Inc.*, 411 U.S. 726, 745 (1973).[3]

> [T]he scope of the FDA's authority does not rest on its assertion of authority but on the actual jurisdiction conferred upon it by Congress through legislative enactment, as construed by the Courts.

Brown-Forman Distillers Corp., 435 F. Supp. at 17. Because, ultimately, the question is one of judicial, rather than agency, interpretation of statutes, *Chevron* deference does not apply. Instead, this Court's role is to examine whether *Congress* conferred authority on FDA to regulate tobacco, regardless of FDA's assertions. Given the history of FDA's administration of the Act and Congress' enactment of laws specifically regulating tobacco products, the implications of reading a power to regulate tobacco into FDA's relatively vague statutory mandate

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[3] *United States v. Riverside Bayview Homes, Inc.*, 474 U.S. 121, 123 (1985), is not contrary authority. That case was a challenge to an as-applied assertion of jurisdiction over wetlands adjacent to navigable waters. This Court found that whether the particular waters in question were "inseparably bound up with 'waters' of the United States" was a matter within the agencies' "technical expertise." *Riverside Bayview*, 474 U.S. at 134. But the Court specifically stated that its holding did *not* address *all* of the agencies' assertions of jurisdiction under the Act. *Id.* at 131 n.8. *See United States v. Wilson*, 133 F.3d 251 (4th Cir. 1997), and *National Mining Association v. United States Army Corps of Engineers*, 145 F.3d 1399 (cases holding that jurisdictional rules adopted by EPA and Corps under Clean Water Act were *ultra vires*).

to regulate "drugs" or "devices" would result in an unmanageable and inconsistent federal regulatory system in which congressional policies established under its tobacco-specific legislation could be undermined or contradicted by FDA policy. This is a result that the *Chevron* doctrine was specifically designed to discourage. This Court's "clear duty in such a situation is to reject the administrative interpretation of the statute." *Securities and Exchange Commission v. Sloan*, 436 U.S. 103, 119 (1978).

2. Even If the *Chevron* Doctrine Required This Court to Defer to an Agency's Determination of Its Own Jurisdiction, Deference Is Not Owed to an Agency's Change of Position Where the Change Is Unreasonable

> One factor to be considered in giving weight to an administrative ruling is "the thoroughness evident in its consideration, the validity of its reasoning, its consistency with earlier and later pronouncements, and all those factors which give it power to persuade, if lacking power to control."

S.E.C. v. Sloan, 436 U.S. at 117-18 (citations omitted). FDA's current rule governing the sale and advertising of tobacco products lacks these factors which suggest judicial deference. In fact, administrative law principles favor FDA's prior position. In particular, the recent vintage of FDA's new jurisdictional determination renders its current arguments regarding interpretation of its statutory delegation unpersuasive.

As mentioned above, Congress gave FDA jurisdiction over "drugs" and "devices" in the Pure Food and Drugs Act of 1906 and the Food, Drug and Cosmetic Act of 1938. From 1914 until 1996, the FDA affirmatively denied jurisdiction over tobacco products. *Brown & Williamson*, 153 F.3d at 168. The Act's definition of "drug," which has remained relatively unchanged through the years, includes "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). The Act's definition of "device" includes a "contrivance . . . intended to affect the structure of any function of the body." 21 U.S.C. § 321(h)(3). As noted by the Court below, FDA derived its former stance partly from the belief that these terms, particularly given the phrase "intended to affect," did not include articles such as cigarettes so long as they were "marketed without health claims." *Brown & Williamson*, 153 F.3d at 169 (citation omitted). In addition, the agency concluded that jurisdiction over tobacco was inconsistent with congressional intent. *Id.* Now, however, FDA has changed its position. It claims that, in order for an article to be classified as a "drug" or "device" it is not necessary that the marketer make any specific health-related claims for the article. Brief for the Petitioners at 19. Instead, it is enough that the marketer "knows" that its product will have a particular effect: tobacco

> manufacturers market their products with claims that they will provide "satisfaction," a "code-word" for the pharmacological effects of nicotine.

Id.

This startlingly recent change in the agency's position should not be countenanced by this Court. Legislative delegations are not unlimited grants of power that can be stretched and compressed at the whim of an agency or as the winds of political sensibilities shift. If any delegation was made by Congress to FDA to regulate tobacco products, that delegation had to have occurred in 1906 or 1938. It is rather a late date for FDA to suddenly discover that those earlier Congresses granted it extraordinarily broad powers that it has heretofore overlooked.

This is not to say that an agency is always obliged to adhere to one interpretation of a statute. This Court has acknowledged that

> "[a]n administrative agency is not disqualified from changing its mind." . . . [But] "[a]n agency interpretation of a relevant provision which conflicts with the agency's earlier interpretation is 'entitled to considerably less deference' than a consistently held agency view."

Good Samaritan Hospital v. Shalala, 508 U.S. 402, 417 (1993) (citations omitted). An agency's change in position opens the door to a more expanded and skeptical inquiry by this Court and, in particular, this Court should *disfavor* changes which result in upsetting long-settled expectations:

> It is a settled doctrine of this court that in case of ambiguity the judicial department will lean in favor of a construction given to a statute by the department charged with the execution of such statute, and, if such construction be acted upon for a number of years, will look with disfavor upon any sudden change.

United States v. Alabama G.S.R. Co., 142 U.S. 615, 621 (1892). Thus, what is entitled to deference here is not the agency's current interpretation of "drugs" and "devices," but FDA's *prior* construction of the Act, acted upon for a number of years, maintaining that these terms exclude tobacco products. The agency's former interpretation not only reflects the agency's contemporaneous construction of its enabling statute, it is a construction that the agency adhered to for 82 years. *See Alabama G.S.R. Co.*, 142 U.S. at 621; *Davis v. United States*, 495 U.S. 472, 484 (1990) ("[W]e give an agency's interpretations and practices considerable weight where they involve the contemporaneous construction of a statute and where they have been in long use.") *See also General Electric Co. v. Gilbert*, 429 U.S. 125, 142 (1976) (Court rejected agency interpretation where "[i]t is not a contemporaneous interpretation of Title VII, since it was first promulgated eight years after the enactment of that Title.")

Further, the agency's prior interpretation was not simply a by-product of agency inaction or silence. On the contrary, the FDA repeatedly and specifically asserted that it lacked jurisdiction over tobacco products. *Brown & Williamson*, 153 F.3d at 168-70. What is more, this agency position was conveyed to Congress, *id.* at 170. As this Court has stated:

> Although we are chary of attributing significance to Congress' failure to act, a refusal by Congress to overrule an agency's construction of legislation is at least some evidence of the reasonableness of that construction, particularly where the administrative construction has been brought to Congress' attention through legislation specifically designed to supplant it.

Riverside Bayview Homes, 474 U.S. at 137 (citations omitted). *See also Zuber v. Allen*, 396 U.S. 168, 192 (1969) (Agency interpretation "carries most weight when the administrators . . . directly made known their views to Congress in Committee hearings."). Congressional silence in the face of FDA's long-held and vocal position that it lacked authority over tobacco can be cited, with considerable justification, for the proposition that Congress acquiesced in FDA's prior assertions that it lacked authority to regulate tobacco.

Principles of administrative law do not grant FDA the freedom to interpret afresh the Food, Drug and Cosmetic Act as though Congress had enacted the law yesterday. Whatever may have been the merits of interpreting "drug" or "device" to include tobacco products in 1906 or 1938, the day is long past when the agency could have justified its current rule under ordinary principles of deference. As this Court recognized in *Flood v. Kuhn*, 407 U.S. 258 (1972), when it refused to apply anti-trust law to professional baseball despite its express holding

that professional baseball constituted interstate commerce, in circumstances such as this, the reasonable course is to adhere to precedent:

> We continue to be loath, 50 years after *Federal Baseball* and almost two decades after *Toolson*, to overturn those cases judicially when Congress, *by its positive inaction, has allowed those decisions to stand for so long and, far beyond mere inference and implication, has clearly evinced a desire not to disapprove them legislatively*.
>
> Accordingly, we adhere once again to *Federal Baseball* and *Toolson* and to their application to professional baseball. . . . If there is any inconsistency or illogic in all this, it is an inconsistency and illogic of long standing that is to be remedied by the Congress and not by this Court.

Flood, 407 U.S. at 283-84 (emphasis added). If the judiciary is so bound by precedent as to require it to refer the revision of longstanding policy to Congress, an executive agency such as FDA is no less so.

The modern administrative state could not long survive if agencies could upset long-settled constructions of law, merely because a problem appeared in need of a solution. FDA was not created to be a "roving commission to inquire into evils and upon discovery correct them." *A.L.A. Schechter Poultry*, 295 U.S. at 551 (Cardozo, J., concurring). Rather, its mandate is more limited and, at this time, it is confined to the jurisdictional "canals" that have long guided its statutory mission. *Id.* This Court should affirm the decision of the court below and hold that FDA lacks the authority to regulate tobacco products.

CONCLUSION

FDA's assertion of authority to regulate tobacco products on the bare claim that such products may be shoehorned into FDA's delegated authority to regulate "drugs" and "devices" is dubious. The agency's determination is diametrically opposed to the position it took in 1914, and adhered to until 1996, that these terms did not include tobacco products. Not only did FDA make its views on this point known to the public, it made them known to Congress. And Congress relied upon these assertions in formulating national tobacco policy. It implemented this policy through the enactment of tobacco-specific legislation--without delegating further authority to FDA to implement that legislation.

Under these circumstances, FDA's attempt to expand dramatically its power to dictate national social policy is not entitled to judicial deference. FDA is not free to expand its mandate in the absence of congressional action.

For the foregoing reasons, Amicus respectfully requests this Court to affirm the decision of the court below.

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Respectfully submitted,

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