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.

On Writ of Certiorari
to the United States Court of Appeals
for the Fourth Circuit

BRIEF OF WASHINGTON LEGAL FOUNDATION AND U.S. REPS. CASS BALLENGER AND HOWARD COBLE AS *AMICI CURIAE* IN SUPPORT OF RESPONDENTS

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QUESTION PRESENTED

In adopting the Federal Food, Drug, and Cosmetic Act, did Congress intend to authorize the Food and Drug Administration to regulate tobacco products, as they are customarily marketed (i.e., without reference to claims of health benefits), as "drugs" or "devices?"

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STATEMENT OF INTEREST

The Washington Legal Foundation (WLF) is a nonprofit public interest law and policy center with supporters in all 50 states.[1] WLF regularly appears before federal and state

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[1] Pursuant to Supreme Court Rule 37.6, WLF states that no counsel for a party authored this brief in whole or in part and that no person or entity, other than WLF, contributed monetarily to the (continued...)

courts to promote economic liberty, free enterprise principles, and a limited and accountable government. To that end, WLF has appeared before this and other federal courts in cases in which federal administrative agencies have exceeded legal bounds in their regulation of the business community. *See, e.g., American Trucking Association v. U.S. Environmental Protection Agency,* 175 F.3d 1027 (D.C. Cir. 1999)(reh. pending). In *Washington Legal Found. v. Friedman*, 13 F. Supp. 2d 51 (D.D.C. 1998), WLF successfully argued that Food and Drug Administration (FDA) efforts to restrict dissemination of truthful information about off-label uses of FDA-approved drugs and medical devices violate the First Amendment. WLF also participated in this matter as an *amicus curiae* when it was before the district court and the court of appeals.

Congressmen Cass Ballenger and Howard Coble are Members of the U.S. House of Representatives from North Carolina. They believes that it should be left up to Congress to d[illegible] whether, and to what extent, tobacco products should be regulated by FDA.

Amici are not simply concerned that FDA, in reaching out to exercise jurisdiction over tobacco products, has exceeded the bounds of its statutory authority. *Amici* are also concerned that FDA has justified its decision to exercise jurisdiction by interpreting its enabling statute in a manner that gives FDA unfettered discretion to regulate virtually any consumer product. Federal statutes interpreted in so

[1](...continued)
preparation and submission of this brief.

broad a manner raise troubling constitutional issues regarding the delegation of legislative power.

Amici submit this brief in support of Respondents with the written consent of all parties. The written consents are on file with the Clerk of the Court.

STATEMENT OF THE CASE

In the interests of judicial economy, WLF hereby incorporates by reference the Statement contained in the brief of Respondent R.J. Reynolds Tobacco Co.

In brief, in August 1996, the Food and Drug Administration (FDA) issued a final rule that sought to restrict the advertising and promotion of tobacco products as well as their sale and distribution. 61 Fed. Reg. 44,396 (1996). FDA had not previously claimed authority to regulate tobacco products as they are "customarily marketed" (i.e., without reference to claims of health benefits).[2] FDA claimed such authority based on its findings that tobacco products fall within the definitions of "drug[s]" and

[2] FDA has in the past exercised jurisdiction over tobacco products whose manufacturers marketed them on the basis of explicit health claims. *See, United States v. 354 Bulk Cartons Trim Reducing Cigarettes,* 178 F. Supp. 847 (D.N.J. 1959)(cigarettes marketed as effective in combating obesity); *United States v. 40 Cartons, More or Less, Containing Fairfax Cigarettes,* 113 F. Supp. 336 (D.N.J. 1953)(cigarettes advertised as effective in preventing respiratory and other diseases). However, FDA is not now asserting jurisdiction based on any allegations that health claims are being made for tobacco products, and the courts below viewed this case solely as a challenge to FDA's authority to regulate tobacco products as "customarily marketed." *See, e.g.*, Pet. App. 14a, 19a.

"device[s]" under the Federal Food, Drug, and Cosmetics Act (Act), 21 U.S.C. § 301 *et seq.*

The Act defines a "drug" as including "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 defines "device" as including an object:

> [I]ntended 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). FDA concluded that tobacco products qualify as both drugs and devices; FDA said that they are "combination products consisting of nicotine, a drug that can addiction and other significant pharmacological effects on the human body, and device components that deliver nicotine to the body." 61 Fed. Reg. at 44,649-650.

Key to FDA's conclusion was its determination that tobacco products are "intended" to affect the structure or function of the human body. While acknowledging that tobacco manufacturers have not sought to market their products based on any health claims, FDA based its "intent" determination on three assertions. First, FDA asserted that it is foreseeable to manufacturers that consumers will use tobacco products in order to sustain a nicotine addiction and to experience nicotine's mood-altering and appetite suppressant effects. 61 Fed. Reg. at 44,701-739. Second,

FDA asserted that those uses are the predominant reason that people smoke; it asserted that non-pharmacological reasons for smoking are secondary. *Id.* at 44,807-846. Third, FDA asserted that manufacturers "have in mind" that consumers will use their products for their pharmacological effects; FDA based that assertion on evidence that manufacturers were aware of nicotine's effects and took steps to ensure that nicotine levels that exist naturally in tobacco were not reduced significantly during the manufacturing process. *Id.* at 44,847-097.

FDA had on numerous prior occasions concluded that it lacked jurisdiction under the Act to regulate tobacco products as customarily marketed, based primarily on a determination that such products are not "intended" to affect the structure or any function of the body in the absence of health claims directed to consumers. *See, e.g.*, Letter from FDA Commissioner Kennedy to Action on Smoking and Health (ASH) (Dec. 5, 1977), J.A. 44-49 ("The interpretation of the Act by FDA consistently has been that cigarettes are not drugs unless health claims are made by vendors."). FDA stated that it was entitled to change its mind regarding the proper interpretation of the Act's "intent" requirement and, furthermore, that the evidence upon which it based its intent determination was unavailable to FDA until relatively recently.

Having determined that tobacco products qualify as both drugs and devices, FDA asserted the right to regulate them under the device provisions of the Act. Pet. App. 13a. Pursuant to those provisions, it imposed numerous restrictions on sales and advertising of tobacco products. 61 Fed. Reg. at 44,616-618.

FDA summarily dismissed objections that its rationale for regulating tobacco products as drugs and devices applied with equal force to a broad range of consumer products not currently subject to FDA regulation. Without regard to whether such products (including, *e.g.*, guns and other weapons) are intended to affect the structure or any function of the body, FDA distinguished such products on the ground that they do not bring about the same level of pharmacological effects on the body as is produced by tobacco products. *Id.* at 44,682-685.

Respondents filed suit in federal district court, challenging FDA's actions on numerous grounds. On August 14, 1998, the U.S. Court of Appeals for the Fourth Circuit issued a decision striking down the FDA regulations on the ground that FDA lacks jurisdiction to regulate tobacco products -- reversing the district court's decision on that issue. Pet. App. 1a-54a. The appeals court said that tobacco products could be found to fall within the Act's definition of drugs or devices only by applying "[a] mechanical reading of only the definitions provisions" of the Act. *Id.* at 19a. The appeals court held that an examination of the entire FDA regulatory scheme created under the Act, FDA's historical position on tobacco regulation, congressional response to that position, and tobacco-specific legislation adopted by Congress all indicate that Congress never intended to grant jurisdiction to FDA to regulate tobacco products. *Id.* at 20a-53a.

The Court granted FDA's petition for a writ of certiorari on April 26, 1999.

SUMMARY OF ARGUMENT

Amici agree with Respondents that the language and history of the Act, as well as the entire history of congressional regulation of tobacco products, indicate that Congress has never granted FDA authority to regulate tobacco products. *Amici* believe that FDA's interpretation of the Act is untenable for an additional reason: as interpreted by FDA, the Act constitutes an unconstitutional delegation of legislative power. Under FDA's interpretation, FDA would be free to regulate a broad range of heretofore unregulated consumer products, unshackled by any restrictions on its authority other than FDA's views regarding what best promotes public health. Moreover, the Act (as interpreted by FDA) allows the agency standardless discretion to impose whatever level of controls on a product it deems appropriate, without regard to whether those controls render the product safe for human use. Such wholesale delegation of legislative powers to an executive branch agency -- without the provision of any intelligible principle by which FDA is to guide its conduct -- would violate the Constitution's prohibition against such delegations. *J.W. Hampton, Jr., & Co. v. United States,* 276 U.S. 394, 409 (1928). Congress should not be presumed to have legislated in such an unconstitutional manner; accordingly, FDA's newly minted interpretation of the Act should be rejected. *Industrial Union Dep't, AFL-CIO v. American Petroleum Institute,* 448 U.S. 607, 646 (1980) (plurality)("A construction of the statute that avoids [an] open-ended grant [of legislative power to an administrative agency] should certainly be favored.").

FDA insists that tobacco products are "intended" to affect the structure/function of the body, despite its acknowledgment that manufacturers have never conveyed such an intent to consumers, and that (in the appeals court's words) "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." Pet. App. 19a. Applying its newly enlarged definition of "intent," FDA based its "intent" determination with respect to tobacco products on three findings: (1) the foreseeability of consumer use of tobacco products in a manner designed to affect structure/function; (2) the predominance of such uses over uses in a manner not designed to affect structure/function; and (3) tobacco manufacturers "have in mind" that consumers will engage in such uses. But thousands of consumer products not now regulated by FDA and which FDA has shown no interest in regulating -- e.g., guns, coffee makers -- qualify as "drugs" or "devices" under FDA's new definition of "intent." When it applies that new definition, FDA can articulate no intelligible principle that explains its decision to regulate tobacco products but not the thousands of other products that meet FDA's "intent" threshold. In the absence of such an intelligible principle, FDA has unbridled authority to regulate consumer products as "drugs" or "devices" based solely on its views of public health needs. In contrast, the definition of "intent" employed before 1996 -- that a manufacturer does not "intend" its product to affect the structure/function of the body unless the manufacturer conveys that intent to consumers in some way -- provided clear congressional guidance regarding the limits of FDA jurisdiction.

FDA's decision to restrict tobacco sales and marketing without imposing a total ban is based on a similarly novel interpretation of its legislative authority to regulate drugs and devices. Numerous provisions of the Act indicate that FDA is to prohibit the distribution of drugs/devices unless FDA can assure that the products are safe and effective for their intended uses. *See, e.g.*, 21 U.S.C. §§ 355(c)(1)(A), 360e(d)(1)(A)(I). Yet, FDA now asserts that such provisions should be interpreted as granting it the discretion to regulate tobacco products as drugs and devices without banning them altogether, despite FDA's admission that none of its proposed restrictions on sales and marketing would render them safe or effective for any intended use. Thus freed of that formerly recognized restraint on its regulatory authority, FDA can point to no "intelligible principle" to guide its decision-making with respect to the extent of controls it will impose on the distribution of drugs and devices. Congress should not be assumed to have granted such standardless regulatory authority to FDA, which would amount to an unconstitutional delegation of legislative authority.

ARGUMENT

I. The Nondelegation Doctrine Imposes Constitutional Limits on Congress's Power To Delegate Its Authority to Representatives of the Executive Branch

Article I of the Constitution assigns all legislative powers within the federal government to Congress, and this Court has stood firmly behind the principle that Congress may not assign those powers to others. *See, e.g., Field v. Clark*, 143 U.S. 649, 692 (1892)("That Congress cannot delegate legislative power to the president is a principle

universally recognized as vital to the integrity and maintenance of the system of government ordained by the Constitution."). As John Locke -- whose opinions are credited with shaping the views of many of the Founders -- wrote more than 300 years ago:

> The power of the legislative, being derived from the people by a positive voluntary grant and institution, can be no other, than what the positive grant conveyed, which being only to make laws, and not to make legislators, the legislative can have no power to transfer their authority of making laws, and place it in other hands.

J. Locke, *Second Treatise of Civil Government, in the Tradition of Freedom,* ¶ 141, at 244 (M. Meyer ed. 1957)(quoted in *Industrial Union*, 448 U.S. at 472-73 (Rehnquist, J., concurring in the judgment)).

The prohibition against delegation of legislative power does not mean, of course, that only Congress may write rules that govern national affairs. Indeed, if Congress were prohibited from delegating to others the power to fill in the details of general laws adopted by Congress and to respond to contingencies whose precise details could never be fully anticipated, "the exertion of legislative power [would] become a futility." *Sunshine Anthracite Coal Co. v. Adkins,* 310 U.S. 381, 398 (1940). Thus, the Court's nondelegation doctrine "jurisprudence has been driven by a practical understanding that in our increasingly complex society, replete with ever changing and more technical problems, Congress simply cannot do its job absent an ability to delegate power under broad general directives." *Mistretta v. United States,* 488 U.S. 361, 372 (1989).

But while Congress is permitted to seek the assistance of Executive Branch officials by granting them a considerable degree of discretion regarding how laws are to be carried out, there are constitutional limits on the extent of that discretion. A federal law is an unconstitutional delegation of legislative power if it fails "to lay down . . . an intelligible principle to which the person or body authorized to [exercise the delegated authority] is directed to conform." *J.W. Hampton,* 488 U.S. at 409. *J.W. Hampton*'s "intelligible principle" test has been followed by the Court in numerous subsequent cases raising nondelegation doctrine issues, most recently in *Touby v. United States,* 500 U.S. 160, 165 (1991).

On at least two occasions, the Court has struck down federal laws on non-delegation doctrine grounds, in each case citing the "intelligible principle" test. *Panama Refining Co. v. Ryan,* 293 U.S. 388 (1935); *A.L.A. Schechter Poultry Corp. v. United States,* 295 U.S. 495 (1935). In more recent years when the Court has invoked the nondelegation doctrine, it has done so to justify "giving narrow constructions to statutory delegations that might otherwise be thought to be unconstitutional." *Mistretta,* 488 U.S. at 373 n.7. *See, Industrial Union*, 448 U.S. at 646 (plurality)(narrow construction given to provisions of the Occupational Safety and Health Act of 1970, 29 U.S.C. § 651 *et seq.*, in order to avoid a construction giving rise to a potentially unconstitutional delegation of legislative powers); *Cable Television Ass'n v. United States,* 415 U.S. 336, 342 (1974). *See also, American Trucking Associations, Inc. v. United States Environmental Protection Agency,* 175 F.3d 1027, 1034-40 (D.C. Cir. 1999) (EPA's construction of §§ 108-09 of the Clean Air Act, 42 U.S.C. §§ 7408-09, is invalid because those statutory provisions would fail to

provide EPA with any "intelligible principle" to guide its rulemaking and thus would amount to an unconstitutional delegation of legislative powers if construed in the manner proposed by EPA)(reh. pending).

II. FDA's Unprecedented Interpretation of What Constitutes "Intent" To Affect the Structure/ Function of the Body Results in a Regulatory Regime Lacking Any "Intelligible Principle," To Guide FDA's Determination of Which Products It Is Authorized To Regulate

In support of its decision to assert jurisdiction over tobacco products, FDA has proposed a novel interpretation of the Act's definitions of "drug" and "device." The result of that interpretation is that thousands of additional consumer products now fall within those definitions; of those additional products, FDA has disclaimed any desire to assert jurisdiction other than in the case of tobacco products. Yet, FDA has been unable to point to any "intelligible principle" in the Act that would justify differentiating between tobacco products and those other products; under FDA's interpretation of the Act, FDA is left to its unfettered discretion to determine whether such products will be regulated as drugs/devices. Accordingly, under this Court's nondelegation doctrine jurisprudence, FDA's interpretation of the Act must be rejected.

FDA has statutory authority to regulate as "drug[s]" or "device[s]" only those products that are "intended" to affect the structure or any function of the body. 21 U.S.C. §§ 321(g)(1)(C) and 321(h)(3). Prior to 1996, FDA interpreted those statutes as meaning that a product was not a "drug" or a "device" if the manufacturer made no health

claims regarding the product. That bright-line methodology -- limiting FDA jurisdiction to products marketed with medical claims -- ensured that FDA would have a principled basis for determining which products were subject to regulation. It also provided manufacturers with express guidance as to when their products would not be subject to FDA regulation: their products would not be subject to FDA regulation if they neither directly nor indirectly made any claims that their products would promote health by "affect[ing] the structure or any function of the body." Pursuant to that interpretation, FDA informed ASH in its 1977 letter that cigarettes are not "drugs" unless health claims are made by vendors. J.A. 44-49.

Now that it has decided to assert jurisdiction over tobacco products, FDA has revised its interpretation of "intended." FDA now contends that the requisite "intent" can be established based on other evidence, even if a manufacturer makes no claims regarding its product's effect on structure/function. In this case, FDA based its "intent" determination with respect to tobacco products on three findings: (1) it is foreseeable that consumers will use tobacco products in a manner designed to affect structure/ function; (2) such uses predominate over uses of tobacco products in a manner not designed to affect structure/ function (*e.g.*, smoking because one enjoys the taste); and (3) tobacco manufacturers "have in mind" that consumers will engage in such uses.

The difficulty with FDA's revised interpretation of "intended" is that it engulfs thousands of consumer products that have never previously been thought to be subject to FDA regulation -- because the manufacturers have never included in their marketing any claims that their products are

to be used "to affect the structure or any function of the body." Nonetheless, although consumer products are rarely marketed in that manner, what FDA says about tobacco products -- that manufacturers foresee that consumers will use their products in a manner that "affect[s] the structure or function of the body" -- can be said about a myriad of items.

An insulated glove keeps the wearer's hands warm so that he or she can stay outside longer -- thus "affect[ing]" "function" (raising hand temperature and increasing ability to "function" out of doors). Similarly, shirts, pants, and coats "affect the structure or function" of the body by trapping warmth, and possibly moisture, to much the same effect as insulated gloves. A catcher's mitt protects the "structure" of the wearer's hands from being injured by a fastball; an air conditioner affects body "function" by helping to regulate body temperature, and improving "function[ing]" on a hot summer day; a hammock affects body "function" by affecting blood flow. A ladder elevates the climber, enabling him or her to "function" more effectively. None of these products has been subject to FDA regulation because health claims generally are not made in connection with their marketing.[3] But manufacturers are well aware that consumers routinely use these products in order to affect body structure/function, and they are highly unlikely to take steps to discourage such uses. Accordingly, such products fall squarely within the definition of "device" adopted by FDA in connection with its tobacco proceedings.

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[3] When such products are marketed in the health-care context, they have been subjected to FDA regulation as "device[s]." For example, air conditioners produced for use in hospitals and which are marketed based on their health benefits for hospital patients have been regulated by FDA. FDA Br. 21.

FDA has responded to criticisms that its new definitions of "drug" and "device" will engulf thousands of additional consumer products, by insisting that such products are distinct from tobacco and thus that FDA will not assert jurisdiction over them. Tellingly, FDA has *not* contended that such products are not "drug[s]" or "device[s]" as FDA has defined those terms in connection with its tobacco regulations. Rather, it has merely highlighted distinctions between such products and tobacco products that are not germane to FDA's new definitions.

For example, a number of commenters asserted that guns and ammunition would qualify as "device[s]" under FDA's new scheme, because gun manufacturers are well aware that an overwhelming number of consumers use guns "to affect the structure or any function of the body of man or other animals," 21 U.S.C. § 321(h)(3), and many guns are designed precisely to enhance their ability to have such effects. FDA responded that guns and other weapons are distinguishable from tobacco products because "tobacco products achieve their effects on the structure and function of the body through nicotine's pharmacological effects," while guns have no similar pharmacological effects. 61 Fed. Reg. at 44,684-685. But while that response may serve to explain why guns should not be deemed a "drug," it does nothing to explain why guns should not be deemed a "device"; indeed, most medical devices do *not* have any pharmacological effects. FDA simply failed to respond directly to the charge that tobacco products are indistinguishable from thousands of other consumer products on the key issue of "intent" to affect structure/function.

A number of other commentators suggested that caffeine-containing and caffeine-related products -- such as

coffee and coffee makers -- should be regulated as drugs or devices under FDA's new definition of "intent." FDA responded that those products are distinguishable because "food" is explicitly excepted from the definition of "drug" (21 U.S.C. § 321(g)(1)(C)), and because "the effects of these caffeine-containing products on the structure and function of the body are significantly less than those for nicotine. . . . For instance, unlike nicotine, caffeine is not recognized at this time as an addictive drug." 61 Fed. Reg. at 44,683-684. But the Act's definition of "device" does not contain a similar exemption for food, so there is no reason that coffee makers and coffee mugs (as "instrument[s]" that deliver caffeine to the body) could not be deemed "device[s]." Moreover, the relative effects of caffeine and nicotine on structure/function of the body have no bearing on whether coffee is "intended" to have such effects, as that word is now defined by FDA. There is little doubt that most consumers drink coffee to experience the pharmacological effects of the caffeine contained therein, and that manufacturers of coffee makers and mugs are well aware of that motivation. Thus, coffee makers and mugs meet FDA's new definition of "device[s]" just as assuredly as do tobacco products; the only difference is that FDA has chosen to regulate only the latter.

To be sure, FDA has provided numerous explanations regarding why it deems tobacco products to fall within its new definition of drugs and devices and why it deems numerous other, seemingly-similar products not to be covered. For example, other products may not be "associated with harms to health" (61 Fed. Reg. at 44,681), or may not achieve their effects "through pharmacological means." *Id.* at 44,678. But these are distinctions that derive solely from FDA itself; FDA can point to no language in the Act that

sets forth an "intelligible principle" from which FDA derived these distinctions. If tobacco products are "devic[e]s" under FDA's newly adopted definition of that term, then so are thousands of other products that also meet that definition.

The only possible construction of the Act that could save FDA's decision to regulate tobacco products but not to regulate those other products is a construction that grants FDA unfettered discretion in deciding whether to regulate a product deemed to be a "drug" or "device." But, as noted above, the nondelegation doctrine prohibits Congress from granting such unfettered discretion to executive branch agencies. Accordingly, FDA's interpretation of the "intent" component of the Act's drug/device definitions must be rejected because it would raise serious concerns regarding the constitutionality of the Act as so construed. *Industrial Union,* 448 U.S. at 646.

In the debate over unconstitutional delegations of legislative power, it is well established that "no statute can be entirely precise, and that some judgments, even some judgments involving policy considerations, must be left to the officers executing the law." *Mistretta,* 488 U.S. at 415 (Scalia, J., dissenting). Chief Justice John Marshall explained that while wholesale delegation of legislative powers is impermissible, the necessities of administration require that administrators be permitted to "fill up the details" with respect to matters "of less interest" so long as they are acting pursuant to "general provisions" of law set forth by Congress. *Wayman v. Southard,* 10 Wheat. (23 U.S.) 1, 41 (1825). Because Congress cannot possibly anticipate all events that may unfold following its adoption of legislation, it has no practical choice but to authorize an

administrator carrying out the legislation to make some policy decisions in order to deal with contingencies as they arise. *Field v. Clark*, 143 U.S. at 691.

But the practicality-based arguments in favor of permitting policy judgments to be made by members of the Executive Branch are at their weakest when, as here, the policy consequences are of such national importance and have been the subject of intense public focus. When Congress adopted the Act in 1938, it was well aware of tobacco products, and claims that those products had adverse health consequences. As the record in this case attests, Congress and the nation have focused repeatedly on whether and to what extent to regulate the sale and advertising of tobacco products. This is not a case in which "'the inherent necessities'" of running a government require that decisions regarding regulation of tobacco products be made by administrators. *Mistretta,* 488 U.S. at 372 (quoting *J.W. Hampton,* 276 U.S. at 406). Congress is quite capable of making the decision regarding whether tobacco products should be regulated by FDA.

Moreover, that decision in large measure boils down to a trade-off between, on the one hand, promoting public health and, on the other hand, preserving personal autonomy and avoiding disruption of the national economy. Decisions of that type are quintessentially legislative in nature and may not be delegated by Congress to others. *Industrial Union,* 448 U.S. at 685 (Rehnquist, J., concurring in the judgment) (the nondelegation doctrine "ensures to the extent consistent with orderly governmental administration that important choices of social policy are made by Congress, the branch of the government most responsive to the popular will."). FDA's interpretation of the Act is tenable only if the Act is

construed as a grant to FDA to decide in its unfettered discretion whether tobacco products should be regulated as drugs/devices. Because such a construction raises serious constitutional concerns under the nondelegation doctrine, FDA's interpretation of the Act must be rejected.

III. FDA Lacks Any "Intelligible Principle" To Guide Its Imposition of Regulations That Amount to a Less-Than-Total Ban on the Sale of Tobacco Products

Having determined that tobacco products are "drug[s]" and "device[s]" within the meaning of the Act, FDA has stopped short of imposing a total ban on the sale and distribution of such products -- even though FDA readily concedes that it is unaware of any use for which tobacco products are both safe and effective. Rather, FDA has chosen to impose restrictions on distribution and advertising that stop well short of a total ban. FDA's brief fails to cite any statutory provision that allows it to impose the limited restrictions that it has proposed; rather, FDA justifies its restrictions as necessary to maximize public health. FDA Br. 33. But in the absence of any "intelligible principle" in the Act to guide FDA restrictions on drugs/devices it has not deemed safe, any interpretation of the Act that would permit FDA to impose such restrictions would amount to an unconstitutional delegation of legislative powers to FDA. Accordingly, under the nondelegation doctrine, FDA's interpretation of the Act must be rejected.

As the court of appeals pointed out, numerous provisions of the Act require FDA to focus on whether drugs/devices are safe and effective for their intended uses. Pet. App. 20a-30a. For example, the device provision upon which FDA relies in order to regulate tobacco products, 21

U.S.C. § 360j(e), permits FDA to restrict the sale, distribution, or use of a medical device "if, because of its potentiality for harmful effect or the collateral measures necessary for its use, the Secretary determines that *there cannot otherwise be reasonable assurance for its safety and effectiveness*." (Emphasis added.) In other words, the sole basis for FDA imposition of restrictions under § 360j(e) is to provide "reasonable assurance" that the device is safe and effective. Accordingly, § 360j(e) provides no statutory support for the specific restrictions FDA has imposed on tobacco products because FDA does not claim that its restrictions would provide any kind of assurances that tobacco products would be safe and effective for some intended use.

FDA justifies its decision to impose restrictions that amount to less than a total ban, on its conclusion that harmful health consequences that would arise from a total ban would be worse than the health consequences of permitting tobacco sales to continue. FDA Br. 33-34. But nothing in the Act provides any "intelligible principle" to FDA suggesting how to engage in such balancing processes, or even that it is permitted to do so at all.[4] FDA is left to assert that its balancing process "best comports with the public health purposes of the Act" (FDA Br. 33) -- which is tantamount to a claim that FDA has been given a roving

[4] FDA's half-hearted citation to 21 U.S.C. § 360c(a)(2)(C) (FDA Br. 33) is misplaced. That provision requires FDA to make safety and effectiveness determinations based on "weighing any probable benefit to health from the use of the device against any probable risk of injury or illness from such use." That provision cannot be read as permitting the adverse consequences of a ban to be counted as a "probable benefit to health" that would arise from the continued legal use of tobacco products.

commission to protect "public health" as it sees fit. Because FDA's interpretation of the Act as an open-ended delegation to FDA to take whatever steps it views as necessary to promote public health raises serious constitutional concerns under the nondelegation doctrine, that interpretation must be rejected.

FDA now appears ready to accept the possibility that its proposed restrictions are impermissible. In that event, FDA argues, it is prepared to go ahead and impose a total ban on sales on the ground that no level of restrictions can assure that tobacco products are safe and effective for an intended use. *Id.* at 34-37. FDA argues that invalidation of its proposed restrictions "would not affect the reasonableness of FDA's conclusion that tobacco products are drugs and devices within the meaning of the Act." *Id.* at 34. *Amici* strongly disagree. FDA concedes that its decision to impose only limited restrictions on tobacco sales was prompted by a recognition that a total ban would have a negative impact on public health. Yet, assuming that the Act requires FDA to ban all sales of drugs and devices not shown to be safe and effective, FDA's assertion of jurisdiction over tobacco products will require it to takes steps that all agree will harm public health. That is a strong indication that Congress never intended to give FDA jurisdiction over tobacco products. *See,* Pet. App. 52a.

CONCLUSION

Amici curiae Washington Legal Foundation, *et al.*, respectfully request that the judgment of the Court of Appeals be affirmed.

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