RECENT CASE

CHEVRON UP IN SMOKE?: TOBACCO AT THE CROSSROADS OF ADMINISTRATIVE LAW, *Brown & Williamson Tobacco Corp. v. Food & Drug Administration*, 153 F.3d 155 (4th Cir. 1998).

As our nation enters the new millennium, the public health regulatory regime faces a fundamental challenge in the form of tobacco. Tobacco kills more Americans than any other activity or product. It has been estimated that at least 529,000 deaths in the United States—roughly one out of every four deaths each year—are attributable to smoking.[1] This annual death toll is greater than that from automobile accidents, homicides, alcohol, airplane crashes, suicides, fires, illegal drugs, and AIDS combined.[2] To put this health harm in historical perspective, one hundred thousand more Americans die each year from smoking than the total number of our soldiers killed in battle by foreign enemies throughout the nation's history.[3]

Despite this staggering death toll, tobacco products are virtually exempt from the consumer regulations that have improved the public health in other areas, receiving "less government oversight of [their] contents and marketing than ice cream."[4] By contrast, medical products ostensibly designed to improve rather than destroy health, such as pharmaceuticals, are subject to extensive administrative regulation.[5] This bizarre public health asymmetry is dramatized by the fact that the process of manufacturing cigarettes is largely unregulated

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1. *See* Cass R. Sunstein, *Is Tobacco a Drug?: Administrative Agencies as Common Law Courts*, 47 DUKE L.J. 1013, 1020 (1998) (supporting FDA jurisdiction over tobacco products).

2. *See* William B. Schultz, *The FDA's Decision to Regulate Tobacco Products*, 18 PACE L. REV. 27 (1997).

3. The number of tobacco-related deaths each year (529,000) is greater than those incurred in battle in the Revolutionary War (4,435), the War of 1812 (2,260), the Mexican-American War (1,733), the Spanish-American War (385), World War I (53,513), World War II (292,131), the Korean War (33,667), the Vietnam War (47,393), and the Persian Gulf War (148) combined. *See* WORLD ALMANAC AND BOOK OF FACTS 209 (1999).

4. Alix M. Freedman & Suein L. Hwang, *Burning Questions: Tobacco Pact's Limits—and Its Loopholes—Presage Fierce Debate*, WALL ST. J., June 23, 1997, at A1.

5. *See* Jon D. Hanson & Kyle D. Logue, *The Costs of Cigarettes: The Economic Case for Ex Post Incentive-Based Regulation*, 107 YALE L.J. 1163, 1168 (1998).

whereas introduction of the nicotine patch required extensive safety testing and Food and Drug Administration ("FDA") approval.[6]

Recent events threaten the tobacco industry's privileged position of exemption from the modern regulatory state. The disclosure of confidential internal documents demonstrated to the public and policymakers several disturbing truths regarding the industry's behavior. Despite repeated assertions to the contrary, tobacco companies have known and manipulated the addictive qualities of nicotine in cigarettes, publicly denied evidence that they had privately collected regarding the health consequences of smoking, and intentionally and illegally targeted underage consumers to replace those smokers dying of tobacco-related illnesses.[7] These disclosures have coincided with an epidemic in youth smoking. The FDA estimates that 3000 children become regular smokers every day and that the total level of youth smoking has increased by a third since 1991.[8]

Former Federal Trade Commissioner Michael Pertschuk has noted that integrating tobacco into the public health regulatory state "will test the responsiveness of our democratic institutions and is going to be a challenge the nature of which we have never before faced in America."[9] This Note examines the challenge that resolving the tobacco dilemma presents to the legal doctrine of administrative law and to the functioning of the public health regulatory state by assessing the recent Fourth Circuit decision of *Brown & Williamson Tobacco Corp. v. Food & Drug Administration.*[10] The Fourth Circuit's decision denying the FDA jurisdiction over tobacco products has broad implications for the modern doctrine of administrative law established in large part by the Supreme Court's landmark decision in *Chevron U.S.A., Inc. v. National Resources Defense Council.*[11] The Supreme Court, which recently granted certiorari

6. *See Cyanamid Unit, Elan Win FDA Approval To Sell Nicotine Patch,* WALL ST. J., Jan. 29, 1992, at B12.

7. *See* Hanson & Logue, *supra* note 5, at 1319.

8. *See* Factsheets (visited Apr. 26, 1999) <http://www.tobaccofreekids.org/html/factsheets1.cfm>.

9. Freedman & Hwang, *supra* note 4.

10. 153 F.3d 155 (4th Cir. 1998), *cert. granted,* 119 S. Ct. 1495 (1999) (No. 98-1152).

11. 467 U.S. 837 (1984).

to review *Brown & Williamson*,[12] should take this important opportunity to reaffirm the *Chevron* doctrine against the Fourth Circuit's aggrandizement of judicial power.

PROCEDURAL HISTORY

On August 28, 1996, the FDA published a final rule entitled "Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents."[13] This rule set out regulations limiting the advertising and promotion of tobacco products, and restricting the sale and distribution of cigarettes and smokeless tobacco to minors. A group of cigarette and smokeless tobacco manufacturers, convenience store retailers, and advertisers filed suit in federal district court in North Carolina challenging the rule and seeking declaratory and injunctive relief. The suit challenged the FDA's jurisdiction over tobacco, alleging that, as a matter of law, (1) Congress had withheld from the FDA the jurisdiction to regulate tobacco products as marketed by the plaintiff group; and (2) the Federal Food, Drug and Cosmetic Act (FDCA) did not permit the FDA to regulate tobacco products either as drugs or as devices.[14]

On April 25, 1997, the district court concluded that Congress did not intend to withhold from the FDA jurisdiction to regulate tobacco products.[15] The district court held that the FDA possessed the statutory authority under the FDCA to regulate tobacco products, but that this regulatory authority did not extend to its efforts to restrict advertising.[16] The district court stayed implementation of the majority of the FDA's regulations pending appeal.[17] The district court declined to invalidate those regulations which had already gone into effect—the proof of age requirement for tobacco sales and the restrictions on sales to persons under age 18. Both the FDA and the plaintiff group appealed the district court's decision to the

12. *See Brown & Williamson*, 119 S. Ct. 1495 (1999) (No. 98-1152).

13. 61 Fed. Reg. 44,396 (1996) (to be codified at 21 C.F.R. pt. 801, 803-04, 807, 820, and 897).

14. *See Brown & Williamson*, 153 F.3d at 159.

15. *See* Coyne Beahm, Inc. v. FDA, 966 F.Supp. 1374, 1388 (M.D.N.C.1997).

16. *See id.* at 1393-1400.

17. *See id.* at 1400-01.

Fourth Circuit Court of Appeals.[18]

On August 14, 1998, a divided three-judge panel of the Fourth Circuit reversed the district court.[19] The majority opinion, authored by Judge Widener, found that the FDA did not have jurisdiction over tobacco products, invalidating its August 28, 1996 regulations.[20] Judge Widener characterized the FDA's position as "assert[ing] jurisdiction over tobacco products based on its conclusion that tobacco products fit within the literal definitions of drug and device as set forth in the [FDCA]."[21] The majority opinion characterized this plain meaning approach to statutory interpretation as a "limited, mechanistic inquiry . . . insufficient to determine Congress' intent."[22] Citing *Chevron*, the majority opinion characterized its duty to be to apply traditional tools of statutory construction to determine if Congress intended to grant the FDA jurisdiction over tobacco.[23]

Judge Widener's analysis began with the question as to what should be the proper default rule for determining the FDA's jurisdiction. The majority opinion took issue with the district court's position that the issue was "whether Congress has evinced its clear intent to withhold from FDA jurisdiction to regulate tobacco products as 'customarily marketed.'"[24] By contrast, the majority opinion concluded that "the issue is correctly framed as whether Congress intended to delegate such jurisdiction to the FDA."[25] Judge Widener asserted that such a congressional delegation of administrative authority is a prerequisite for any *Chevron* deference to the agency's statutory interpretation.[26] The court further implied that *Chevron* deference was less appropriate in cases such as this when an

18. *See Brown & Williamson*, 153 F.3d at 160.

19. *See id.*

20. *See id.* The majority opinion was joined by Judge Michael, a Senior United States District Judge for the Western District of Virginia sitting on the Fourth Circuit by designation. A dissent was filed by Senior United States Circuit Judge Hall (see discussion *infra*).

21. *Id.* at 161. The Act defines the term "drug" as "articles (other than food) intended to affect the structure or any function of the body of man or other animals." 21 U.S.C. § 321(g)(1)(C).

22. *Brown & Williamson*, 153 F.3d at 161.

23. *See id.*

24. *Id.* (quoting *Coyne Beahm*, 966 F. Supp. at 1380).

25. *Id.* (citing Bowen v. Georgetown Univ. Hosp., 488 U.S. 204, 208 (1988) and INS v. Chadha, 462 U.S. 919, n. 16 (1983)).

26. *See id.* (citing Adams Fruit Co. v. Barrett, 494 U.S. 638, 649 (1990)).

agency is attempting to expand its jurisdiction. The majority opinion also emphasized the "crucial role of context" in statutory interpretation as opposed to simply relying on the text's plain meaning.[27]

The majority opinion's first argument against the FDA's claim of jurisdiction was that tobacco products did not meet the literal definitions of the FDCA because

> the definitions of drug and device require not only that the article "affect the structure or any function of the body," but also that these effects be intended. 21 U.S.C. §§ 321 (g)(1)(c), 321(h)(3). As noted by the district court, "no court has ever found that a product is 'intended for use' or 'intended to affect' within the meaning of the [FDCA] absent manufacturer claims as to that product's use." Coyne Beahm, 966 F.Supp. at 1390. Even the FDA does not contend that tobacco manufacturers make any such claim. Coyne Beahm, 966 F.Supp. at 1389 n.14[28]

The majority opinion rejected as overly "mechanical" the position that the FDA's jurisdiction turned solely on the literal definitions of the terms of the FDCA.[29] The Fourth Circuit instead endorsed a "holistic approach" to statutory construction which purported to examine these literal definitions contextually in view of the language and structure of the FDCA as a whole.[30]

The majority's "holistic" analysis then proceeded to examine whether tobacco products fit into the overall regulatory scheme Congress created with the FDCA.[31] The court noted that the August 28, 1996 regulations modified, rather than banned, the sale of tobacco products. Judge Widener proceeded to discuss at great length why a faithful application of the FDCA's operative provisions could not accommodate merely regulating tobacco products. The court argued that if the FDA had jurisdiction over tobacco products under the FDCA, its only legal option would be to ban cigarettes. The court concluded that "because an absolute ban falls outside the scope of congressional intent," Congress must not have intended to give

27. *Id.* at 162.
28. *Id.* at 163.
29. See *id.*
30. *Id.*
31. *See id.*

the FDA jurisdiction over tobacco.[32]

Judge Widener then presented several examples of "extrinsic evidence" to support his conclusion that Congress intended to withhold jurisdiction over tobacco products from the FDA.[33] The majority opinion stated that these examples were "like pieces of a puzzle in that no single event is outcome determinative. However, when viewed as a whole, it is clear that Congress did not intend to give the FDA jurisdiction over tobacco products."[34] The majority opinion also noted that Congress clearly did not intend to give the FDA jurisdiction over tobacco when it passed the FDCA in 1938.[35]

The Fourth Circuit's first piece of extrinsic evidence refuting FDA jurisdiction over tobacco was the agency's own historical actions. The court observed that from 1914 until the present rulemaking attempt, the FDA had consistently stated that tobacco products were outside the scope of its jurisdiction.[36] The Fourth Circuit considered this history relevant in light of its view that an agency interpretation of a statutory provision that conflicts with an earlier interpretation is entitled to "considerably less deference" than a consistently held position.[37] The court concluded that this historical record precluded the FDA from re-interpreting the FDCA to allow the agency jurisdiction over tobacco products.

The Fourth Circuit also cited Congress' historical refusal to enact legislation overturning the FDA's consistent disavowal of jurisdiction over tobacco products.[38] The court noted that even though Congress had on several occasions enacted legislation to deal with tobacco-related health harms, it had never addressed the issue of FDA jurisdiction.[39] Congress had also failed to pass any of the fifteen different bills introduced that would have expressly granted the FDA jurisdiction over tobacco products.[40] The majority opinion concluded that this

32. *Id.* at 168.
33. *Id.* at 167.
34. *Id.*
35. *See id.*
36. *See id.* at 170.
37. *Id.* at 170 n.18 (quoting Good Samaritan Hosp. v. Shalala, 508 U.S. 402, 417 (1993)).
38. *See id.* at 170.
39. *See id.*
40. *See id.*

pattern of congressional inaction constituted legislative ratification of the FDA's disavowal of jurisdiction over tobacco. Judge Widener argued that this "acquiescence" proved that Congress did not intend to allow the FDA to claim jurisdiction over tobacco products.[41]

The final piece of extrinsic evidence presented by the majority opinion was a series of tobacco-related statutes that supposedly proved that Congress had created a comprehensive regulatory scheme for tobacco that precluded FDA jurisdiction.[42] The majority first pointed to The Federal Cigarette Labeling and Advertising Act ("FCLAA"), which required manufacturers to place specific health-hazard warnings from the Surgeon General on cigarette packaging, advertising, and billboards.[43] The second congressional action cited by the majority was the Alcohol and Drug Abuse Amendments of 1983.[44] These amendments directed the Secretary of Health & Human Services (the FDA's parent agency) to report to Congress current findings on the "addictive property of tobacco" and to recommend "legislative and administrative action as the Secretary may deem appropriate."[45] The final statute cited was the Alcohol, Drug Abuse, and Mental Health Administration Reorganization Act of 1992.[46] This act provided financial incentives to states that enact and enforce youth access restrictions on tobacco products. The court concluded that this pattern of legislation evinced a clear intent by Congress to reserve for itself, rather than the FDA, the authority to regulate tobacco products.[47]

The Fourth Circuit asserted that its decision to deny the FDA jurisdiction over tobacco products was a separate question from whether further government regulations were necessary to address tobacco-related health harms. The court instead characterized its decision as an affirmation of democratic principles: "[a]t its core, this case is about who has the power to make this type of major policy decision. As the Supreme Court

41. *See id.* at 170-71.
42. *See id.* at 171.
43. *See id.* (citing Pub. L. No. 89-92, 79 Stat. 282 (1965)).
44. *See id.* at 173-74.
45. *Id.* at 174 (citing 42 U.S.C. § 290-aa-2(b)(2)-(3)).
46. *See id.* at 175 (Pub. L. No. 102-321, 106 Stat. 394).
47. *See id.* at 176.

has previously stated about a different agency and its enabling statute, neither federal agencies nor the courts can substitute their policy judgment for those of Congress."[48] The majority opinion ended by saying that the merits of the FDA's proposed regulations were irrelevant because Congress never intended to delegate jurisdiction over tobacco products to the agency.[49]

Judge Hall dissented from the majority opinion.[50] His dissent presented two general propositions to refute the majority's holding that the FDA lacked jurisdiction over tobacco products. Judge Hall argued that FDA regulations aimed at curbing youth tobacco use could not possibly be contrary to the general remedial intent of the FDCA to protect the public health.[51] He also concluded that a judicial examination of the contextual evidence beyond the literal terms of the FDCA "falls far short of demonstrating that Congress intended to deny or withdraw jurisdiction over tobacco from the FDA."[52]

Judge Hall specifically rejected the majority opinion's holistic approach to statutory interpretation. The dissent instead characterized the court's responsibility to be to enforce the terms of a statute according to its plain meaning unless the context clearly commanded a contrary result.[53] The dissent noted that the majority opinion gave relatively short shrift to the FDA's primary claim that the FDCA's definition of a drug as "articles (other than food) intended to affect the structure or function of the body" supported its jurisdiction over tobacco products.[54] Judge Hall stated that the rule-making record gave "voluminous evidence of the pharmacological effects of nicotine . . . ."[55] He rejected the majority's conclusion that these pharmacological effects failed to fall under the statutory term "intended" because the industry had not asserted health benefits from tobacco use.[56] Judge Hall instead cited with

48. *Id.* (citing *MCI*, 512 U.S. at 234 (refusing to allow a judicial preference for a particular policy outcome to guide its interpretation of the federal Communications Act of 1934)).

49. *See id.* at 176.

50. *See id.*

51. *See id.*

52. *Id.*

53. *See id* at 177.

54. *Id.* (citing 21 U.S.C. § 321(g)(1)(C)).

55. *Id.*

56. *See id.* at 178.

approval the FDA's four independent rationales as to why tobacco products are intended to affect the body and are therefore "drugs" under the FDCA.[57]

Having concluded that tobacco products "come squarely within the plain terms of the FDCA,"[58] Judge Hall argued that FDA jurisdiction was appropriate unless such jurisdiction would frustrate a clear contrary congressional intent or yield a patently absurd result.[59] He first dismissed the majority's position that FDA lacked jurisdiction because the operative provisions of the FDCA would require a prohibition on tobacco sales. Judge Hall argued that the substance of the FDA's regulations was a separate issue from that of its jurisdiction: "[h]ow the FDA has chosen to regulate tobacco has no bearing on the question of whether that agency has the authority to regulate it at all . . . ."[60] Judge Hall then made a traditional "greater includes the lesser" argument to support the FDA's choice of regulation as opposed to prohibition: "[i]t is no argument to say that the FDA can do nothing because it could have done more."[61]

Judge Hall presented an alternative characterization of Congress's legislative intent in enacting the FDCA. Hall criticized the majority opinion's emphasis on the fact that Congress in 1938 did not specifically intend tobacco to be under the FDA's jurisdiction.[62] The dissent characterized the FDCA to be a remedial statute intended to protect the public health: "Congress did not 'intend' that any particular product be included . . . 'Rather than itemize each product subject to regulation under the FDCA, Congress defined these categories broadly so that each encompasses a wide range of product.'"[63]

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57. *See id.* at 177. The FDA put forward four arguments supporting its position that tobacco products were "intended" to affect the body:

> 1) a reasonable manufacturer would foresee that consumers would use the product to satisfy addiction; 2) most consumers do in fact use tobacco products to satisfy addiction; 3) the manufacturers have long known that consumers use the products for the pharmacological effects; and 4) the manufacturers design the products to deliver active doses of nicotine.

Id. (citations omitted).

58. *Id.* at 178.

59. *See id.*

60. *Id.* at 179.

61. *Id.*

62. *See id.* at 179.

63. *Id.* (citing Coyne Beahm v. FDA, 966 F. Supp. at 1380).

Hall stated that the majority opinion erred by not giving this remedial statute the liberal construction necessary to accomplish its public health purpose.[64]

The dissent also found unpersuasive the three pieces of "extrinsic" evidence which the majority relied upon to deny the FDA jurisdiction over tobacco products. Judge Hall noted that the importance the majority opinion attributed to the FDA's historical disavowal of jurisdiction over tobacco ran contrary to the "familiar canon of administrative law that an agency can change its view of what action is possible or necessary, particularly when new facts come to light."[65] He concluded that the evidence the FDA recently discovered regarding the tobacco industry's behavior, in particular their efforts to design tobacco products to sustain nicotine addiction among their users, represented "a perfect illustration of why an agency's opportunity to adopt a new position should remain open."[66]

The dissent proceeded to refute the majority opinion's final piece of extrinsic evidence—that Congress had enacted a comprehensive regulatory scheme to regulate tobacco while also acquiescing in the FDA's disavowal of jurisdiction. Judge Hall criticized Judge Widener's argument as inadequate because it "ignore[d] the fundamental source of intent, the words of the statute itself."[67] Judge Hall also disagreed with the majority opinion's conclusion that a comprehensive regulatory scheme existed reflecting a clear congressional intent to displace FDA jurisdiction. The dissent countered that Congress had instead delegated to an expert agency (the FDA) the legal authority to regulate drugs under the FDCA.[68] The dissent argued that because drugs clearly fit within the literal terms of the FDCA, the majority should have upheld FDA jurisdiction.[69] Judge Hall argued that to uphold such jurisdiction would have been neither absurd nor contrary to congressional intent.[70]

The dissent concluded by addressing an issue not discussed by the majority opinion. Judge Hall disagreed with the district

64. *See id.*
65. *Id.* at 180.
66. *Id.*
67. *Id.*
68. *See id.* at 182.
69. *See id.*
70. *See id.*

court's conclusion that the FDA's advertising regulations exceeded its statutory authority under the FDCA. He concluded that the FDA's promulgation of advertising restrictions should survive the low level of judicial scrutiny required under *Chevron*: "the question is whether the agency's answer is based on a permissible construction of the statute . . . . we need only find that the agency construction is a reasonable one, not the best one."[71]

Following the three judge panel's divided decision in *Brown & Williamson*, the FDA filed a petition to the Fourth Circuit for a rehearing en banc. On November 10, 1998, the Fourth Circuit denied the petition by a vote of six to four, with four judges recusing themselves.[72] The FDA subsequently appealed the Fourth Circuit's decision to the Supreme Court.[73] In the appeal to the High Court, Solicitor General Seth Waxman described the tobacco regulations as "the most important public health and safety rule-making that FDA has conducted in the past 50 years."[74] On April 26, 1999, the Supreme Court granted the government's petition for a writ of certiorari.[75]

ANALYSIS

The Fourth Circuit's decision in *Brown & Williamson* has broad implications for both the doctrine of administrative law and the field of public health. *Brown & Williamson* presents a fundamental challenge to the *Chevron* doctrine, arguably the single most important principle in administrative law. *Chevron* requires judges to defer to an agency's reasonable interpretation of a statute absent a clearly contrary congressional intent.[76] Despite its professions of fealty to *Chevron*, the Fourth Circuit's holistic model of statutory interpretation would represent a dramatic shift of law-

71. *Id.* at 183.

72. *See Brown & Williamson*, 161 F.3d at 764. Voting in favor of a rehearing en banc were Judges Murnaghan, M. Blane Michael and Motz. Voting against the rehearing en banc were Judges Widener, Ervin, Niemeyer, Luttig, Williams, and Traxler. With the concurrence of Judge James H. Michael, Judge Hall dissented. Judge Hall would have granted the petition for rehearing for the reasons expressed in a separate opinion he filed with the opinion of the panel. Chief Judge Wilkinson, and Judges Wilkins, Hamilton, and King, being disqualified, did not participate in the decision.

73. *See* Certiorari Petition No. 98-1152.

74. *Id.*

75. *Brown & Williamson*, 119 S. Ct. 1495 (1999)..

76. *See Chevron*, 467 U.S. 837.

interpreting power from agencies to judges. This shift is contrary both to established precedent and to the relative institutional strengths and weaknesses of judges and agencies. On a more practical note, the Fourth Circuit's crabbed view of the FDA's jurisdiction prevents an agency with significant technical expertise from attempting to ameliorate our nation's most preventable cause of death. Because of these fundamental flaws, the Supreme Court should reverse the Fourth Circuit.

The Fourth Circuit's decision to deny the FDA jurisdiction over tobacco products stems from a misapplication of the *Chevron* doctrine and a misreading of the FDCA. The Fourth Circuit imported three limitations on the application of *Chevron* deference that are not supported by the decision. The majority opinion first argued that a precondition of *Chevron* deference is a congressional delegation of administrative authority to an agency. The court, therefore, misstated the key issue in the case to be whether Congress intended to delegate to the FDA jurisdiction over tobacco products.[77] Because it found that they did not, the Fourth Circuit granted FDA no *Chevron* deference for its interpretation of the statutory term "drug."

The Fourth Circuit's formulation of *Chevron* would require a court to make an initial determination that Congress has delegated the authority to regulate tobacco to the FDA before deferring to that agency's interpretation that it can regulate tobacco as a drug. This level of specificity drains *Chevron* of any meaning. There is no need for *Chevron* deference if Congress has clearly delegated administrative authority to an agency. Conversely, the Fourth Circuit's standard would bar *Chevron* deference in the only context where it has practical significance—when the underlying statute is ambiguous. The more appropriate standard would be to ask whether Congress has delegated to the FDA the authority to enforce provisions of the FDCA that turn on the meaning of the term "drug." Because the answer is yes, the FDA undoubtedly should have been granted *Chevron* deference as to the scope and meaning of those statutory terms.

The majority opinion also claims *Chevron* deference to the FDA's interpretation of the term "drug" is inappropriate

77. *Brown & Williamson*, 153 F.3d at 161 (citing Bowen v. Georgetown Univ. Hosp., 488 U.S. 204, 208 (1988) and INS v. Chadha, 462 U.S. 919, n. 16 (1983)).

because the agency is attempting to expand its jurisdiction.[78] This argument contradicts established precedent that *Chevron* deference applies if an agency is reasonably interpreting a provision of a statute it enforces.[79] These precedents reflect the principle underlying *Chevron* that agencies are superior to courts in interpreting ambiguous statutes on both democratic and technocratic grounds.

Agencies enjoy a distinct democratic advantage over courts in statutory interpretation because they are responsive to political pressures from the executive branch. The *Chevron* doctrine recognizes that the interpretation of ambiguous statutes should take into account changing political values as well as the traditional tools of statutory construction. As Cass Sunstein notes,

> *Chevron* appears in this way to accept the suggestion that deciding how to read ambiguities in a law involves no brooding omnipresence in the sky but an emphatically human judgment about policy or principle. This suggestion . . . obviously bears on the question of whether and how the FDA can interpret the word 'drug.'[80]

The FDA's decision to assert jurisdiction over tobacco products reflected the democratic pressures on agency action discussed in *Chevron*. President Clinton has emphasized the regulation of tobacco and it played a public role in the presidential election of 1996.[81]

Agencies also enjoy a technical advantage over courts in interpreting ambiguous statutes. Agencies generally possess a greater institutional familiarity and flexibility in applying statutes than do judges. Resolving the meaning of ambiguous terms such as "drug" often depends on an understanding of the facts underlying a particular situation. In comparison to courts, agencies have superior expertise and capacity to discover and apply these facts to questions of statutory interpretation. *Chevron* deference also facilitates uniformity in the law by centralizing statutory interpretation in the hands of a single

78. *See id.* at 162.

79. *See* Commodity Futures Trading Comm'n v. Schor, 478 U.S. 833, 845-846 (1986); Mississippi Power & Light Co. v. Mississippi ex rel. Moore, 487 U.S. 354, 380-382 (Scalia, J., concurring).

80. *See* Sunstein, *supra* note 1, at 1057 (citations omitted).

81. *See id.*

agency. These factors provide practical support for the deference courts grant agency constructions of ambiguous statutes under *Chevron*.

Both the democratic and technical advantages of *Chevron* deference are present when an agency attempts to expand its jurisdiction. The Fourth Circuit's standard would limit *Chevron* to non-jurisdictional questions. This doctrinal shift would also have two undesirable practical consequences. First, a prime argument for *Chevron* deference is its relatively straightforward application by courts.[82] The Fourth Circuit's standard would force courts to apply a threshold test distinguishing between jurisdictional and non-jurisdictional questions prior to granting an agency *Chevron* deference. At best, this threshold test would reduce the simplicity in application that is one of *Chevron*'s greatest virtues. At worst, the fungible nature of jurisdictional questions would give skeptical lower courts an opportunity to invalidate agency actions with which they disapproved on policy grounds. The Fourth Circuit's decision in *Brown & Williamson* demonstrates how a threshold jurisdictional determination prior to *Chevron* deference empowers courts to the detriment of agencies.

Furthermore, denying an agency *Chevron* deference when it is attempting to expand its jurisdiction would excessively hamper agency actions in an era of rapidly expanding technology. The Fourth Circuit's standard would deprive the FDA of *Chevron* deference whenever it attempted to regulate any of the thousands of new products entering the marketplace. This limitation risks judicial second-guessing of agency actions in extremely technical contexts such as the pharmacological effects of nicotine presented in *Brown & Williamson*. Courts should grant agencies *Chevron* deference in jurisdictional matters to prevent this undesirable outcome and to maximize the public benefits of agency expertise.

The Fourth Circuit also argued that *Chevron* deference to the FDA's position was less warranted in *Brown & Williamson* because the agency was reversing a long-standing interpretation of the FDCA. This conclusion is somewhat odd given that *Chevron* itself featured an agency reversing a clear,

82. *See id* at 1063.

previously held position.[83] The Fourth Circuit erred when it elevated stare decisis in the context of agency action while abrogating it in the judicial context. A judicial reliance on prior precedents advances the rule of law by reinforcing the positive norms of consistency, neutrality, and reasoned elaboration.[84] Stare decisis allows cases to be decided by an objective standard rather than individual facts or the political passions of the day. The Fourth Circuit failed to recognize that individual facts and political considerations are assets, rather than liabilities, to agency decison-making. To this extent, the analogy to stare decisis breaks down. The democratic and technocratic justifications for the *Chevron* doctrine discussed above apply in equal force when an agency is reversing its position. Accordingly, *Chevron* deference should apply in this situation.

Even if the Supreme Court generally were to decide not to extend *Chevron* deference in the event of an agency reversal, it should still apply in cases such as this when the agency's prior position may have been a function of the regulated industry's fraud. As discussed above, the stare decisis argument for limiting *Chevron* deference ignores the doctrine's democratic and technocratic benefits. A potential argument for a "reversal" limitation on *Chevron* would be that an agency suddenly reversing long-held interpretations of statutes could undermine valid reliance interests among regulated parties. Recent evidence of widespread fraud by the tobacco industry precludes any claim of detrimental reliance or loss of justified expectations.[85] The overwhelming historical evidence of industry misbehavior and deception supports the dissent's contention that this case presents "a perfect illustration of why an agency's opportunity to adopt a new position should remain open."[86] To conclude otherwise would be contrary to public policy because it would create a moral hazard by providing an

83. *See Chevron*, 467 U.S. at 838 ("The fact that the EPA has from time to time changed its interpretation of the term 'source' does not lead to the conclusion that no deference should be accorded the EPA's interpretation of the [Clean Air Act]. An agency, to engage in informed rulemaking, must consider varying interpretations and the wisdom of its policy on a continuing basis. . . .").

84. *See* Christopher F. Edley, Jr., ADMINISTRATIVE LAW: RETHINKING JUDICIAL CONTROL OF BUREAUCRACY 21 (1990).

85. *See* Hanson & Logue, *supra* note 5, at 1319.

86. *See Brown & Williamson*, 153 F.3d at 180.

incentive for regulated industry fraud.

The plain meaning of the FDCA clearly supports the FDA's characterization of tobacco products as "drugs." The FDCA defines the term "drug" as "articles (other than food) intended to affect the structure or any function of the body. . . ."[87] The FDA's rule-making evidence provided overwhelming information to support the common-sense notion that tobacco affects the body.[88] The only possible argument that tobacco is not a "drug" within the plain meaning of the FDCA is the majority opinion's position that it does not qualify as a "drug" under the FDCA because these pharmacological effects were not intended.[89] The majority pointed to the historical fact that the FDA had always judged the presence of intent according to whether a manufacturer has put forward public claims of health benefits.[90]

The majority opinion's reliance on this prior FDA practice in determining the plain meaning of the FDCA term "intended" is misplaced for several reasons. As a general matter, the plain meaning of a statute should be distinct from an agency's historical standards for enforcing its regulations. In any event, the FDA should be able to change its mind as to how to interpret the term "intended." As discussed above in the context of *Chevron* deference, an agency may change its mind regarding the appropriate construction of a statutory term without deleterious consequences. The Fourth Circuit's standard would enable a manufacturer to veto FDA jurisdiction over its products by simply not presenting public health claims. This presumes good faith on the part of regulated parties, which is noticeably (almost historically) lacking in the case of the tobacco industry.

The fact that the Fourth Circuit adopted the wrong standard for interpreting the FDCA's statutory term "intended" still should not have led to its conclusion that tobacco was not a drug. The FDA's rule-making procedures presented ample evidence to support its conclusion that the tobacco industry intended for its products to have pharmacological effects on the

87. *Supra* note 21.
88. *See Brown & Williamson*, 153 F.3d at 178.
89. *See id* at 163.
90. *See id.*

human body.[91] Internal tobacco industry documents reveal that cigarette manufacturers were aware of the addictive power of nicotine and designed their product to maximize these effects upon the human body. For example, in 1963 the general counsel of Brown & Williamson observed that his company was "in the business of selling nicotine, an addictive drug."[92] In 1972, an R.J. Reynolds executive characterized the tobacco industry to be "a specialized, highly ritualized and stylized segment of the pharmaceutical industry."[93] Furthermore, cigarette manufacturers artificially increased the level of nicotine in tobacco products in order to maintain addiction in the wake of a consumer preference for lower-tar cigarettes.[94]

The Fourth Circuit's requirement that for tobacco to be a "drug" under the FDCA, its manufacturers must make public therapeutic claims as to its pharmacological effects did not need to focus exclusively on the issue of addiction. The Fourth Circuit could have instead reached a more limited holding: that cigarette manufacturers make public claims in advertising that tobacco products cause the pharmacological effects of stress reduction and weight loss.[95] The fact that consumers purchase tobacco products with an intent to achieve these pharmacological goals would have provided sufficient support for such a conclusion.[96]

The Fourth Circuit's argument that the plain meaning of the FDCA's operative provisions preclude FDA jurisdiction over tobacco is unconvincing. Judge Widener argued that the FDA could not have jurisdiction under the FDCA because the agency would be required to prohibit the sale of tobacco products. This is a red herring argument that assumes its underlying premise—that Congress did not intend to give the FDA the discretionary authority to prohibit tobacco products were it to determine that they were "drugs" under the FDCA. Because Judge Widener fails to prove this premise, his argument has no persuasive force.

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91. *See id* at 177.

92. William B. Schultz, *The FDA's Decision to Regulate Tobacco Products*, 18 PACE L. REV. 27, 32 (1997).

93. *Id.*

94. *See id* at 29-31.

95. *See* Sunstein, *supra* note 1, at 1054-1055.

96. *See id.*

The Fourth Circuit's assessment of the FDCA's operative provisions would force the FDA into a Hobson's Choice regarding tobacco products: prohibit them or leave them unregulated. This false choice echoes the specious argument made by other pro-tobacco forces that because cigarettes are legal they should therefore occupy their place of complete exemption from public health regulation and products tort liability. That the Fourth Circuit constructs this Hobson's Choice is somewhat ironic given the legislative history of the FDCA. The majority opinion argues that the FDA's regulatory jurisdiction under the FDCA's operative provisions is impossible because tobacco is so dangerous. But when the FDCA was first enacted, many legislators did not even consider tobacco to pose any risk to the public health.[97] In any event, prohibition is not the alpha and omega of regulatory options available to health authorities to address harmful drugs such as tobacco. The majority opinion's analysis of the FDCA's operative provisions should be rejected because it is clearly contrary to the traditional canon of statutory interpretation that the greater regulatory power includes the lesser.

The FDA made a reasonable regulatory judgment when it chose to regulate, rather than prohibit, the sale of tobacco products. The experience of Prohibition in the 1920s and 1930s and the possibility of widespread nicotine withdrawal by forty million Americans supported the FDA's decision not to ban cigarettes.[98] The Fourth Circuit refused to recognize the importance the FDA placed on avoiding the harms from a potential black market in contraband tobacco products. This refusal was odd given that the threat of black market cigarettes was judged so seriously in the global tobacco settlement negotiations as to require draconian limits on FDA authority.[99] The tobacco industry itself lent support to the FDA's decision not to prohibit tobacco products when it stated in the context of

97. The essential link between tobacco and illness was not proven to the satisfaction of most until much later in the Twentieth Century. The dissent noted that during debate over the FCLAA in 1969, United States Representative Perkins stated that "not one of the tobacco farmers in my district would knowingly produce any commodity which, when consumed, would cause the dread diseases which have claimed to be associated with tobacco. But the claims . . . are not proved. Tobacco has been impeached in passion but it ha[s] not been convicted in fact. Facts, cold hard facts are the basis upon which congress should legislate." *Brown & Williamson*, 153 F.3d at 180.

98. *See id.* at 164.

99. *See* Freedman & Hwang, *supra* note 4.

the global tobacco settlement that "[t]he risk of creating a substantial black market in tobacco products should be a legitimate concern to all Americans for a variety of reasons . . . ."[100] At a very minimum, the FDA's construction of the FDCA to allow regulations short of prohibition was a reasonable one that should have survived judicial scrutiny under *Chevron.*

The above analysis demonstrates that the FDA had clear textual authority under the FDCA to regulate tobacco products as drugs. The combination of this statutory plain meaning and *Chevron* deference should have led the Fourth Circuit to affirm the FDA's jurisdiction over tobacco products. As mentioned above, the majority opinion erroneously concluded that *Chevron* deference was inappropriate. Nevertheless, the Fourth Circuit's analysis even fails on its own terms. Even assuming the FDA deserved no deference under *Chevron,* the Fourth Circuit still should have upheld the agency's jurisdiction over tobacco products under the FDCA.

The majority eschewed what it called a "mechanical" reliance on the text in favor of a "holistic" model of statutory interpretation.[101] This holistic model gave short shrift to the text and plain meaning of the FDCA, instead focusing almost exclusively on extrinsic contextual evidence.[102] The Fourth Circuit's rejection of a textualist approach to statutory interpretation is undesirable. A judicial focus on a statute's literal terms and its plain meaning provides a strong incentive for enacting legislatures to draft clear statutory language which accurately reflects the democratic resolution of the issue at hand. By contrast, the contextual model places high demands on judges to read the tea leaves (in this case tobacco leaves) of legislative intent in order to determine what a clear statute "really means." This judicial search for the "genuine" legislative intent, an activity that Justice Antonin Scalia has described as "a wild-goose chase,"[103] is usually fruitless and counterproductive.

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100. Hilary Stout & Laurie McGinley, *Clinton Sees Cut in U.S. Smoking Due to Accord--President to Urge Changes In Tobacco Settlement But Still Backs a Deal,* WALL ST. J., July 10, 1997, A16.

101. *See Brown & Williamson,* 153 F.3d at 163.

102. The majority opinion virtually ignored the literal terms of the FDCA. In fact, the dissent noted that it devoted merely three paragraphs to the statutory terms that were the heart of the FDA's jurisdictional claim. *See id* at 177.

103. *See* Antonin Scalia, *Judicial Deference to Administrative Interpretations of Law,* 1989 DUKE L.J. 511, 517.

The unenacted understanding of particular members of Congress should be less important than the actual words of the statute that the body as a whole enacted into law. Furthermore, allowing unelected judges the opportunity to peer behind the curtain of the legislative process creates a risk that they will rewrite democratically enacted statutes to match their own policy preferences.

The Fourth Circuit's holistic analysis in *Brown & Williamson* demonstrates why the debate on statutory interpretation should be resolved in favor of a textualist approach. The majority's lack of emphasis on the FDCA's literal terms made it crucial that the court correctly examine the contextual evidence of legislative intent. However, the contextual evidence the majority relies upon to deprive the FDA of jurisdiction over tobacco is quite unpersuasive. The majority opinion's first piece of contextual evidence is that Congress in 1938 did not intend for tobacco to be included as a drug under the FDCA. This is very likely true but is largely beside the point of whether the FDA should be allowed to regulate tobacco products in 1998. Congress enacted the FDCA in 1938 in order to improve the public health. As Judge Hall noted in dissent,[104] the Supreme Court has characterized the FDCA as a remedial statute that should be "interpreted broadly" and that "Congress fully intended that the Act's coverage be as broad as its literal language indicates."[105] Because the FDCA's literal text easily supports FDA jurisdiction over tobacco, this Supreme Court precedent should have precluded the Fourth Circuit from delving into the subjective intent of Congress in 1938.

It is the Fourth Circuit's focus on congressional intent, rather than the FDA's reliance on the FDCA's plain meaning, that is the overly "mechanical" approach to statutory interpretation. Congress in 1938 did not enact its subjective intent of whether tobacco products were "drugs" under the FDCA. They instead drafted a series of broad terms that would accommodate flexible regulation in the future as facts and values changed.[106]

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104. *Brown & Williamson*, 153 F.3d at 179.

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

106. Cass Sunstein demonstrates the inflexible nature of the Fourth Circuit's "holistic" analysis by applying it to a variety of other contexts. *See* Sunstein, *supra* note 1, at 1029-1030. For example, the Fourth Circuit's approach would deprive the EPA of jurisdiction over DDT under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) since the enacting Congress did not consider DDT to raise "a substantial

The Fourth Circuit's standard would entail an absurd result: limiting the FDA's jurisdiction only to those drugs whose pharmacological effects were known to Congress in 1938. This inflexible approach to statutory interpretation would force the FDA to ignore over half a century of scientific developments. In placing undue importance on the subjective intent of the enacting Congress, the Fourth Circuit disregards a unanimous Supreme Court statement last year that "statutory prohibitions often go beyond the principal evil to cover reasonably comparable evils, and it is ultimately the provisions of our laws rather than the principal concerns of our legislatures by which we are governed."[107]

The Fourth Circuit also argued that the FDA cannot claim jurisdiction now over tobacco products after disavowing it for so many years. Taken to its logical conclusion, this argument would result in a statute of limitations on the agency's ability to remedy issues of public health. As discussed above in the context of *Chevron*, an agency should be able to change its mind in light of changing facts and values. This ability to adapt is one of the greatest institutional assets of regulatory agencies. For the Fourth Circuit to hold otherwise improperly empowers the dead hand of history with an unfortunate side-effect of regulatory ossification.

The Fourth Circuit asserted that Congress' historical failure to overturn the FDA's consistent disavowal of jurisdiction should trump the FDCA's plain language. The majority opinion, therefore, presents a default rule that Congress must affirmatively overcome an agency's denial of jurisdiction. This would allow congressional inaction to have the force of law, a position the Supreme Court addressed and decisively rejected in *INS v. Chadha*.[108] It is unclear from the majority opinion by what standard a reviewing court could ever discern a legally consistent pattern in congressional inaction. The Fourth Circuit's focus on legislative inaction thus limits agency authority by creating an interpretive vacuum leading to increased judicial power. Even if congressional inaction were

question." Sunstein also discusses the restrictive impact the Fourth Circuit's "holistic" analysis would have on sexual harassment law. *See infra* note 107.

107. *See* Oncale v. Sundowner Offshore Servs., 118 S.Ct. 998, 1002-1003 (1998) (holding that Title VII of the Civil Rights Act of 1964 allowed for a cause of action for same-sex harassment clearly not contemplated by the enacting Congress).

108. *See Chadha*, 462 U.S. 919.

somewhat relevant to the scope of agency jurisdiction, it would not necessarily be dispositive in this context of FDA jurisdiction over tobacco products. The majority fails to answer the dissent's argument that Congress acquiesced in the FDA's assertion of jurisdiction from 1996 to 1998. The Fourth Circuit's argument regarding congressional inaction is also unpersuasive because it does not take into account that previous congressional and agency actions reflected an incorrect assessment of the facts regarding tobacco products due to industry fraud.

The Fourth Circuit's conclusion that Congress created a comprehensive regulatory scheme over tobacco products that was intended to displace FDA jurisdiction is also quite unconvincing. The statutes on which the Fourth Circuit relies are limited in scope and hardly provide clear evidence for the proposition that Congress intended the FDA to be powerless to address the public health harms from tobacco products. Furthermore, the statutes at issue do nothing to alter the plain textual meaning of the FDCA. This plain meaning grants the FDA jurisdiction over tobacco irrespective of the substance of these other statutes. The fact that the Fourth Circuit perceives in this broad pattern of congressional action a clear legislative intent to divest the FDA of jurisdiction makes the court appear to be merely reasoning backwards from a preordained policy conclusion. This apparent ends-based judicial reasoning in the guise of a holistic analysis lends unintentional support to the textual method of statutory interpretation.

The Fourth Circuit cloaks its decision in the rhetoric of democratic principles, stating that the case turns on the issue of who "has the power to make this type of major policy decision. . . . neither federal agencies nor the courts can substitute their policy judgments for those of Congress."[109] The court fails to heed its own admonition by succumbing to the siren song of judicial activism. The FDA's decision to regulate tobacco products could hardly be considered anti-democratic. The agency's actions were in response to shifting political winds from the executive branch. This is exactly the type of

109. *Brown & Williamson*, 153 F.3d at 176 (citing *MCI*, 512 U.S. at 234 (refusing to allow a judicial preference for a particular policy outcome to guide interpretation of the federal Communications Act of 1934)).

democratic responsiveness that underlies the *Chevron* doctrine.

The Fourth Circuit's decision is fundamentally anti-democratic in part because it poses a fundamental challenge to the *Chevron* doctrine. *Chevron* stands for the proposition that judges cannot substitute their statutory interpretation for agencies unless the text is both unclear and the agency's actions are unreasonable. Neither case presents itself in this situation. The Fourth Circuit essentially concludes that, despite the plain meaning of the FDCA, "we do not think that the Congress meant what they actually said." This activist approach to judging might be permissible if reviewing courts were allowed to approach this issue as one of first impression. This is not the law under *Chevron*. The Fourth Circuit's approach would allow judicial second-guessing of almost every agency action under the pretext of divining legislative intent. This increase in judicial power is anti-democratic and undesirable.

The Fourth Circuit's implicit response to critics of their judicial activism is that they should go to Congress to overturn it. This argument ignores the reality of the modern administrative state. Congress made a policy judgment in 1938 to enact a broad remedial statute whose enforcement would be at the discretion of the FDA. The Fourth Circuit's crabbed view of FDA jurisdiction undercuts the delegation doctrine, which is designed to make full use of agency expertise in administering laws. The Supreme Court should take this opportunity to recognize the right of an agency to change its mind as times and values change.

The Fourth Circuit's decision is not only incorrect as a matter of law, but it has several undesirable practical consequences. The majority opinion's attack on *Chevron* undercuts one of that doctrine's most beneficial side-effects: the developments of agencies as the regulatory version of common-law courts.[110] Furthermore, the Fourth Circuit's decision prevents the FDA from doing anything to address the public health crisis presented by tobacco products. It is by no means certain that FDA regulations alone will effectively address these public health harms. Nevertheless, the Fourth Circuit was correct in one area—these substantive policy questions are not the issue presented by *Brown & Williamson*. The plain meaning of the

110. *See* Sunstein, *supra* note 1, at 1019.

FDCA grants the FDA the authority to regulate tobacco, whether or not those regulations would necessarily be successful. At the very least, reaffirming FDA jurisdiction over cigarettes would correct the bizarre situation now existing where ice cream and nicotine patches are regulated for safety but cigarettes are not. Courts should not preserve this anachronistic exception to the public health regulatory state which is inconsistent with a rational administrative law regime.

The Fourth Circuit's limiting of agency authority in *Brown & Williamson* appears designed to advance the broader judicial trend toward reversing the power and scope of the federal government. Recent judicial decisions foreshadow a potential reinvigoration of the Commerce Clause and the delegation doctrine as constitutional barriers to federal power.[111] The reexamination of these constitutional doctrines could presage a fundamental reassessment of the appropriate role of the federal government in contemporary American society. The reduction of federal government power, particularly the authority of executive branch agencies, entailed by this constitutional development would certainly not be objectionable as a general matter. Nevertheless, the ends of reduced federal powers that the Fourth Circuit seeks do not justify the particular means it embraces in *Brown & Williamson*—ignoring the plain meaning of a democratically enacted statute.

The Fourth Circuit's decision in *Brown & Williamson* forces the Supreme Court to choose one of two starkly contrasting models of statutory interpretation. The *Chevron* doctrine allows expert agency personnel who are responsive to executive branch political pressures to balance complicated mixed questions of fact and law. The Fourth Circuit's decision allows unelected judges to disregard the text of a statute in favor of a strained reading of the tobacco leaves of legislative intent. The Supreme Court should take this high profile opportunity to reverse the Fourth Circuit and restore the appropriate allocation of power between agencies and courts it established in *Chevron*.

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111. *See, e.g.*, United States v. Lopez, 514 U.S. 549 (1995); American Trucking Assoc., Inc. v. U.S. EPA 1999 WL 300618 (D.C. Cir. May 14, 1999) (finding that construction of the Clean Air Act relied upon by the EPA in promulgating air quality standards for particulate matter and ozone was an unconstitutional delegation of legislative power.