The United States Supreme Court invalidated the Food and Drug Administration’s (FDA) attempt to regulate tobacco under the Food, Drug, and Cosmetic Act (FDCA). The significance of this decision for environmental purposes is in the Court’s altered application of the long-standing two-step Chevron Doctrine. Rather than turn to the plain meaning of the statute, the Court expanded Chevron’s first step to include the “context” of the regulatory scheme. By expanding the interpretive tools under Chevron’s step one, the Court could determine Congressional intent without having to reach the “reasonableness” of the FDA’s decision under step two. Without the deference principle typically afforded under Chevron’s second step, attempts by environmental agencies to assert authority in uncharted areas of regulation may be significantly jeopardized.
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INTRODUCTION

In one of the highest profile administrative law cases of 2000, Food & Drug Administration v. Brown & Williamson Tobacco Corp., the Supreme Court invalidated the federal regulation of tobacco under the Food, Drug, and Cosmetic Act (FDCA). Some administrative law pundits predict that this decision will have broad implications for administrative agencies such as the Environmental Protection Agency (EPA). In future cases, petitioners challenging EPA rules may cite Brown & Williamson to prove that Congressional inaction precludes EPA from asserting regulatory authority. These opponents may allege that Congress' inaction and deadlock over certain environmental issues and laws actually forecloses the EPA from exercising its authority. Such challenges could erode EPA's rulemaking functions.

Ultimately, the Brown & Williamson decision distorts the traditional interpretive approach of considering the "plain meaning" of the statute in isolation. This may intensify a growing trend toward "anti-deference." This approach allows lower courts to take a contextual approach to the analysis of administrative agency rules, resulting in judicial decisions that are arbitrarily based on personal preferences. The blurring of what were once bright-line rules will result in unpredictable outcomes and ambiguity.

The most likely impact of Brown & Williamson, however, will not be inharmonious with Supreme Court's landmark decision in

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4. See, e.g., O'Reilly, supra note 3.
5. See id. (arguing that the Brown & Williamson majority's distortion of the Chevron doctrine resulted in a type of "anti-deference" that restrains an agency's "gap-filling" role).
Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc., which established the Court's long-standing two-prong doctrine of judicial deference to agency implementation of statutory commands. Indeed, recent decisions indicate that lower courts will apply Brown & Williamson alongside a Chevron analysis. For administrative law purposes, Brown & Williamson may simply be viewed as merely an "interesting application of the Chevron doctrine.\" Hence, the dramatic implications of the new rule may only manifest where agencies exercise authority in areas previously foreclosed from their jurisdiction.

I

BACKGROUND

Congress created the Food and Drug Administration (FDA) when it enacted the FDCA in 1938. That Act gave the FDA authority over a number of drugs that had not been covered under the Pure Food and Drugs Act of 1906 (PFDA). Specifically, the FDCA expanded the definition of "drugs" from articles intended for medicinal use to "articles intended to affect the structure or any function of the body." This expansion gave the

6. 467 U.S. 837 (1984). The Chevron decision concerned the EPA's interpretation of the Clean Air Act's (CAA) definition of "stationary source." Id. at 846. The Act required EPA to limit emissions from all stationary sources. EPA interpreted the term to mean the entire plant, rather than an individual building. Through the Court's consideration of EPA's statutory interpretation, it developed a two-prong analysis: first, the court looks to the "plain meaning" of the statute to determine whether ambiguity exists; second, if ambiguity does exist, the court determines whether the interpretation is "reasonable." Id. at 842-43. In Chevron, the Court concluded that the "plain meaning" of "stationary source" was not apparent in the CAA but accepted EPA's interpretation of the term as reasonable. Id. at 865.


8. Funk, supra note 1, at 8.

9. Pure Food and Drugs Act, Pub. L. No. 59-384, 34 Stat. 768 (1906). Because the PFDA specifically regulated drugs used for "medicinal purposes" and tobacco was not labeled for medicinal use, the Bureau of Chemistry determined that tobacco was beyond the confines of the Act. See David A Rienzo, About Face: How FDA Changed Its Mind, Took on the Tobacco Companies in Their Own Back Yard, and Won, 53 FOOD & DRUG L.J. 243, 244 (1998).

10. Compare Pure Food and Drugs Act, Pub. L. No. 59-384, ch. 3915, § 6, 34 Stat. 768, 769 (1906) (defining drugs as "all medicines and preparations . . . and any substance or mixture of substances intended to be used for the cure, mitigation, or prevention of disease, . . . "); with 21 U.S.C. § 321(g)(1)(B), (C) (1994) (defining "drugs" to include "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and . . . articles (other than food) intended to affect the structure or any function of the body of man or other animals . . . ").
FDA considerably more jurisdiction than had previously been afforded under the PFDA.

This broadened authority, however, was not without limitations. The newer statute required that the manufacturer “intend” that the drug affect the “structure or any function of the body” in order for FDA to regulate an article as a “drug.” Thus, with the exception of a brief period in the 1950s, when FDA proved manufacturer intent by identifying advertisements that touted the beneficial health effects of cigarettes, the FDA played a minor role in tobacco regulation. In fact, on several occasions FDA denied its jurisdiction over tobacco. Yet, in 1994, after decades of inaction, FDA Commissioner David Kessler announced that the agency would actively pursue an investigation into whether tobacco products could be regulated under the FDCA.

Following years of Congressional hearings and probing investigations, FDA published its final rule entitled “Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents.” This rule marked FDA’s first attempt to assert jurisdiction over tobacco when used for non-therapeutic purposes.

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12. In <em>United States v. 354 Bulk Cartons</em>, 178 F. Supp. 847 (D.N.J. 1959), the court held that FDA properly asserted jurisdiction under the FDCA when manufacturers promised weight loss as a result of tobacco use. Because the manufacturer presented cigarettes as having therapeutic benefits, the court found that FDA correctly identified cigarettes as drugs under 21 U.S.C. § 321(g)(1)(C). Id. at 851. In <em>United States v. 46 Cartons, More or Less, Containing Fairfax Cigarettes</em>, 113 F. Supp. 336 (D.N.J. 1953), the manufacturer claimed that cigarettes prevented respiratory infections and other ailments. Because the advertisement promised a “prevention of disease,” the court determined that FDA’s jurisdiction was properly asserted under 21 U.S.C. § 321(g)(1)(B). Id. at 339.
13. See infra note 56 and accompanying text.
14. See William B. Schultz, <em>The FDA’s Decision to Regulate Tobacco Products</em>, 18 PACE L. REV. 27, 28 (1997) (discussing the FDA Commissioner’s decision to begin an investigation into the tobacco industry’s dishonest marketing techniques).
15. In response to the Commissioner’s announcement, Congressman Waxman (D-CA) immediately called for hearings to assess the effects of tobacco. These hearings, investigations, patent searches, and FTC evaluations revealed that as early as the 1960s, tobacco companies were researching how to control nicotine levels in cigarettes. Further evidence demonstrated that manufacturers did not use nicotine “solely for taste” as the industry had persistently claimed. Id. at 28-31.
17. During the 1950s, the FDA asserted its regulatory authority when manufacturers marketed cigarettes as providing increased health benefits. See supra note 12 and accompanying text. This is because the FDA considered its jurisdiction
industry objected vigorously to FDA's assertion of regulatory authority, alleging that cigarettes and smokeless tobacco did not fall under the requisite statutory definitions.\textsuperscript{18} FDA, however, justified its expansion of jurisdiction based on substantial new evidence of the tobacco manufacturers' misrepresentations about the addictive nature of tobacco.\textsuperscript{19}

FDA determined that the best way to achieve regulatory control over tobacco was to regulate it as a combination drug and drug delivery device.\textsuperscript{20} FDA's interpretation of both the "drug" and "device" provisions allowed it to solidly assert its authority over tobacco as a combination product. First, FDA determined tobacco to be a drug that affects the "structure or any function of the body"\textsuperscript{21} because nicotine addiction results in "psychoactive, or mood-altering, effects on the brain."\textsuperscript{22} FDA further established that tobacco has the sort of physical and pharmacological effects caused by drugs already under its jurisdiction.\textsuperscript{23} Second, FDA's regulatory scheme satisfied the FDCA's definition of "drug delivery device,"\textsuperscript{24} since cigarettes to only encompass those instances when tobacco products were sold as having therapeutic benefits. See Rienzo, supra note 9, at 245-46 (1998).


19. See Schultz, supra note 14, at 29-30. The investigations revealed that in the early 1960s there was knowledge of manufacturers' intent that nicotine has an addictive effect on the body. A search of industry patents indicated that the stated purpose of various tobacco patents "was to increase the amount of nicotine in a cigarette through the use of high nicotine tobaccos, without creating an unacceptably harsh tasting cigarette." Id. at 29. The Federal Trade Commission also provided significant insight into the tobacco companies' conduct, which suggested that manufacturers wanted to keep nicotine levels from being reduced. Id. at 30. Moreover, the FDA also discovered that Brown & Williamson actually created a new tobacco product "that contained twice the usual amount of nicotine," and U.S. Customs revealed that Brown & Williamson distributed over 500,000 pounds of this high-level nicotine in September 1992 alone. Id. at 30-31.

20. In order to assert its regulatory authority, FDA must show that the article satisfies the "drug" or "device" provisions of the FDCA. 21 U.S.C. § 321(g)(1), (h). If FDA successfully shows that the article satisfies both the drug and device criteria, the agency may choose to regulate the article as a "combination product." See 21 U.S.C. § 353(g)(1) (2000) (giving the FDA the ability to regulate "combination products" that "constitute a combination of a drug, device or biologic product"). Regulating a "combination product" allows FDA to exercise its authority under either the "drug" or "device" mechanisms. Final Tobacco Rule, supra note 16, at 44,400.


23. Similar drugs under FDA jurisdiction include appetite suppressants and stimulants. Id. at 44,632.

24. 21 U.S.C. § 321(h) (2000) (defining "device" as "instrument, apparatus, implement, machine, contrivance ... or other similar or related article, including any
deliver nicotine directly to the body in a manner that is readily absorbed by the user.\textsuperscript{25}

FDA recognized that in order to regulate a drug on the open market, it must show that the drug is "safe and effective."\textsuperscript{26} The agency was unable to prove that tobacco is safe and effective, so the FDA's regulation under the drug provision would have resulted in tobacco's automatic removal from the market. Because neither the FDA nor society was prepared to take cigarettes entirely out of the market,\textsuperscript{27} the agency chose instead to regulate tobacco under the "device" provision.\textsuperscript{28} This provision provided FDA with "the most appropriate and flexible mechanism"\textsuperscript{29} for regulating tobacco; it also allowed the agency to regulate a potentially harmful device by establishing restrictions and conditions on tobacco sales and distribution.

Confident in its authority under the FDCA, FDA issued a proposed rule consisting of several restrictions that prohibited tobacco sales, limited methods of distribution, and restricted advertisements and promotions geared towards minors.\textsuperscript{30} In response, several retailers, advertisers, and tobacco manufacturers filed suit in federal district court in North Carolina to block implementation of the proposed rules.\textsuperscript{31}

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\textsuperscript{26} 21 U.S.C. § 393(b)(2) (2000). Because FDA chose to regulate tobacco as a "drug delivery device," it regulated the sale and distribution of tobacco under 21 U.S.C. § 360j(e). Section 360j(e) states that FDA may "require that a device be restricted to sale, distribution, or use ... upon such other conditions as [FDA] may prescribe such regulation, if, because of its potentiality for harmful effect or the collateral measures necessary to its use, [FDA] determines that there cannot otherwise be reasonable assurance of its safety and effectiveness." Id.

\textsuperscript{27} Proposed Tobacco Rule, supra note 25, at 41,348 (reporting the FDA's conclusion that it did not believe tobacco's "sudden and total withdrawal from the market would provide the best means of protecting the public health.").


\textsuperscript{29} Proposed Tobacco Rule, supra note 25, at 41,314 (basing its decision, in part, on the fact that this provision allows FDA to restrict the sale, distribution, and marketing of tobacco while still allowing it to remain on the market).

\textsuperscript{30} id.

\textsuperscript{31} See Coyne Beahm, Inc. v. FDA, 966 F. Supp. 1374, 1379 (M.D.N.C. 1997). The agency received more than 700,000 submissions during the notice and comment period, making the tobacco regulation the most commented-on proposed rule in history. See David A. Kessler et al., The Food and Drug Administration's Regulation of Tobacco Products, 335 NEW ENG. J. MED. 988 (1996); Termini, supra note 18, at 64 n.9; see also Final Tobacco Rule, supra note 16, at 44,418 n.24 (noting that the agency received comments that represented the views of nearly one million people.
The plaintiffs argued that because Congress had withheld FDA jurisdiction over tobacco, the agency could not regulate tobacco as a drug or as a device.\textsuperscript{32} Responding to the plaintiffs' concerns, the District Court deciphered the meaning of the "drug" and "device" provisions under the FDCA through its consideration of tobacco's effect on the structure or function of the human body.\textsuperscript{33} The court concluded that Congress' intent was unclear and that the FDA was reasonable in its interpretation of the statute.\textsuperscript{34} Nevertheless, the District Court concluded that even though FDA had the authority to regulate the "sale and distribution" of tobacco under the FDCA, it did not have jurisdiction over tobacco advertising.\textsuperscript{35} Both sides appealed the District Court's decision to the Fourth Circuit Court of Appeals.

A three-judge panel of the Fourth Circuit Court of Appeals reversed the District Court holding.\textsuperscript{36} Employing the "traditional tools of statutory construction," the court found "fundamental conflicts" and "internal inconsistencies" within FDA's regulatory scheme.\textsuperscript{37} Specifically, the court concluded that those conflicts resided in the "device" mechanism of the FDCA. That provision requires FDA to place conditions and restrictions on the sale of drug delivery devices in order to ensure "reasonable safety."\textsuperscript{38} The court concluded that because tobacco is dangerous, it is inherently unsafe. Therefore, FDA could not satisfy the requirements of the "device" provision.\textsuperscript{39}

The court also discovered several inconsistencies in FDA's application of the FDCA's mandatory provisions of ensuring the safety of regulated drugs and devices.\textsuperscript{40} It concluded that a proper application of the provisions would have resulted in the complete ban of tobacco.\textsuperscript{41} Hence, even though the court indicated that the FDCA's definitions of "drug" and "device"

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Many of the comments were the result of letter writing campaigns. One tobacco company initiated a writing campaign that generated over 300,000 submissions opposing FDA's rules and overall jurisdiction).

\textsuperscript{32} Coyne Beahm, 966 F. Supp. at 1379.
\textsuperscript{33} Id. at 1388.
\textsuperscript{34} Id. at 1396-97.
\textsuperscript{35} Id. at 1399-1400.
\textsuperscript{37} Id. at 161, 165-66.
\textsuperscript{38} Id. at 164.
\textsuperscript{39} Id.
\textsuperscript{40} 21 U.S.C. § 393(b)(2) (2000) (the FDA must ensure the "safety and effectiveness of devices intended for human use").
\textsuperscript{41} Brown & Williamson, 153 F.3d at 164-67.
appeared to support FDA’s authority to regulate tobacco, the Fourth Circuit concluded that the “overall regulatory scheme created by Congress” precluded the agency from asserting such jurisdiction. The FDA appealed to the Supreme Court, which granted writ of certiorari on April 26, 1999.

II
THE BROWN & WILLIAMSON DECISION

In a 5-4 decision, the Supreme Court affirmed the Fourth Circuit decision, holding that FDA indeed lacks jurisdiction over tobacco products. Both the Fourth Circuit and the Supreme Court agreed that fundamental conflicts and several inconsistencies in its regulatory framework prohibited FDA from establishing its authority. The Supreme Court focused its analysis, however, on Congressional intent and determined that FDA lacked the requisite authority to assert its jurisdiction over tobacco as a “combination product” under the FDCA.

A. The Majority Opinion

The Court’s analysis fell entirely under “step one” of the prevailing two-step test announced in Chevron. In step one of Chevron, the court considers the “plain meaning” of the statute and “whether Congress ha[s] directly spoken to the precise question at issue” to determine whether ambiguity exists. If Congress has directly addressed the issue, the court must end its inquiry there and “give effect to the unambiguously expressed intent of Congress.” If, however, Congress has not directly and unambiguously addressed the issue, thus leaving ambiguity as to its intent, the court then determines whether the agency’s interpretation is “reasonable.”

In order to determine Congressional intent under step one of Chevron, the Court examined the history of both FDA and the

42. Id. at 163.
43. Id.
45. Id. at 136.
46. Id. at 142-43.
47. Justice O'Connor wrote for the majority, joined by Chief Justice Rehnquist and Justices Scalia, Thomas, and Kennedy.
49. Id. at 842.
50. Id. at 843.
51. Id.
52. Id.
FDCA and determined that the "context" strongly favored the manufacturers' position. The Court concluded that it need not restrict itself to analyzing the question of whether Congress "specifically addressed the question at issue" in isolation but instead could view the perceived ambiguity in context, allowing the court to interpret the statute "as a symmetrical and coherent regulatory scheme." The Court determined that FDA had renounced jurisdiction over tobacco throughout its history. Moreover, the Court found that Congress' past legislation precluded FDA from asserting jurisdiction, and that FDA's regulation of tobacco would contradict the FDCA's provisions.

Specifically, the Court concluded that regulatory jurisdiction over tobacco would be contrary to FDA's mission to protect public health. FDA seeks to ensure "the safety and effectiveness

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54. Id. at 132-33.
55. Id. at 133 (citing Gustafson v. Alloyd Co., 513 U.S. 561, 569 (1995)).
56. The Court pinpointed several occasions where the FDA renounced its jurisdiction. The Court cited testimony by FDA representatives before Congress stating that the FDA lacked jurisdiction under the FDCA to regulate tobacco. Indeed, the Court cited various hearings where the Surgeon General, the Deputy Commissioner, the HEW Secretary, and various other administrators disavowed FDA jurisdiction. In fact, HEW Secretary Celebrezze actually implored Congress not to amend the FDCA to cover tobacco because such an amendment would effectively ban cigarettes. Overall, FDA never asserted its jurisdiction over tobacco when used for non-therapeutic purposes until it promulgated the proposed rules at issue in this case. Id. at 143-48.
57. According to the Court, since 1965, Congress has enacted six separate pieces of legislation addressing the problem of tobacco on human health. The statutes require health warnings, prohibition of advertisement, U.S. Department of Health and Human Services reports on research and findings, as well as the disbursement of federal block grants to states making it unlawful to sell tobacco to underage consumers. The Court found that these statutes not only indicate that Congress had already spoken on the issue of tobacco regulation, but also the statutes themselves "effectively ratified the FDA's long-held position that it lacks jurisdiction under the FDCA to regulate tobacco products." Id. at 144. The Court deemed it "extremely unlikely" that Congress would intend to subject tobacco to FDA regulation considering the economic and political importance of the tobacco industry at the time of the enactment of the FDCA. Id. at 147. Before 1965, there were several attempts to place tobacco under FDA jurisdiction but none of the proposals became law. Id. Hence, in 1965 Congress ultimately decided to place tobacco regulation under a less rigorous regulatory scheme of the Federal Cigarette Labeling and Advertising Act, Pub. L. No. 89-92 § 5, 79 Stat. 283 (1965) (FCLAA); Pub. L. No. 91-222 § 2, 84 Stat. 88 (1970). Id. at 148. The FCLAA created a program to regulate cigarette labeling and advertising. The program required that a warning appear on all cigarette packaging for the purpose of informing the public of the dangers of cigarettes. See FCLAA, supra.
58. Brown & Williamson, 529 U.S. at 142-43. During the FDA's research and rulemaking proceedings, it exhaustively documented that tobacco products cannot be deemed safe and effective. Id. at 134-35.
of devices intended for human use." The regulation of unsafe drugs, however, would constitute "misbranding" under Section 331(a) of the FDCA. A drug is misbranded if it fails to include adequate directions for use or fails to provide warnings where the drug is "dangerous to health." The Court determined that because there was no mechanism for making tobacco safe for its intended use, and because tobacco was ultimately dangerous to public health, FDA would be required to prohibit the drug under the FDCA. The Court disregarded FDA's belief that a complete ban on tobacco would actually be unsafe due to significant consumer addiction. Instead, the Court concluded that a ban on tobacco products would "plainly contradict Congressional policy."

Furthermore, the Court determined that FDA's justification for regulation contradicted the FDCA. Under the FDCA, in order for a product to be "safe," the likely therapeutic benefits of a product must outweigh the risk of harm. Because FDA determined that tobacco is unsafe, yet discouraged banning it, the Court concluded that FDA's regulatory scheme would clearly contravene Congressional intent. For this reason, the Court found the agency's interpretation of the statute, which established its own jurisdiction to act, flawed because it was inconsistent with the distinct statutory scheme created by Congress to address that precise question at issue.

B. The Dissent

Justice Breyer, joined by Justices Stevens, Souter, and Ginsburg, dissented. Remarkably, the dissent did not question the majority's application of Chevron, but instead the dissent contended that FDA's assessment of its own authority under the

59. Id. at 133-34 (citing 21 U.S.C. § 393(b)(2)).

60. See 21 U.S.C. § 331(a) (1994); see also 21 U.S.C. § 331(j) (a product is misbranded if "it is dangerous to health when used in the dosage or manner, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof"); 21 U.S.C. § 352(f)(1) (stating that a product is misbranded "unless its labeling bears . . . adequate directions for use . . . in such manner and form, as are necessary . . . for the protection of the public health").

61. Id. § 352(j).


63. Id. at 139.

64. Id. (indicating that Congress stopped short of banning tobacco because of its policy of protecting commerce and the national economy. For this reason, entirely banning tobacco would contravene its express policy).

65. Id. at 140-41.

66. Id. at 139.

67. Id. at 126.
FDCA was reasonable. First, the dissent determined that tobacco products fell squarely within the Act's definitions of "drugs" and "devices."\(^{68}\) Second, the dissent demonstrated that the regulation of tobacco is consistent with the overall objectives of FDA.

The dissent first argued that tobacco products fall clearly within the scope of the FDCA's statutory definitions. It determined that FDCA's legislative history, coupled with its language and purpose, sufficiently established FDA's authority to regulate tobacco.\(^{69}\) In fact, the dissent illustrated various instances where FDA established its authority under the FDCA by satisfying the manufacturer intent requirement.\(^{70}\) As early as the 1920s, the dissent emphasized, the tobacco industry made express claims that tobacco had mood-altering effects as well as weight-altering results.\(^{71}\) Furthermore, the dissent pointed out that FDA accumulated significant evidence that cigarette manufacturers have long known that tobacco has physiological effects on the body.\(^{72}\) Finally, the dissent concluded that the FDCA does not command a total ban on tobacco,\(^{73}\) but instead permits FDA to regulate combination products as either a "device" or a "drug" because the "device" provision of the FDCA grants FDA wide remedial discretion.\(^{74}\)

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\(^{68}\) Id. at 162 (Breyer, J., dissenting).

\(^{69}\) The dissent relied on experts who had studied the FDCA's history and found that the statute "is a purposefully broad delegation of discretionary powers by Congress." Id. at 165 (citing James T. O'Reilly, 1 FOOD AND DRUG ADMINISTRATION § 6.01 (2d ed. 1995)). The dissent discussed legislative history and Congress' intent at the time of enacting the FDCA to give administrative agencies broad authority. The dissent stated, "Nor is it surprising that such a statutory delegation of power could lead after many years to an assertion of jurisdiction that the 1938 legislature might not have expected. Such a possibility is inherent in the very nature of a broad delegation." Id. at 166. In response to the majority's assertion that the laws enacted since 1965 require the Court to deny jurisdiction, the dissent asserted that there were no laws enacted at this time that limited FDA jurisdiction. Id. at 165-66. Indeed, whenever Congress attempted to pass a bill limiting or eradicating FDA jurisdiction, these bills failed: "The history shows only that Congress could not muster the votes necessary either to grant or to deny the FDA the relevant authority. It neither favors nor disfavors the majority's position." Id. at 183.

\(^{70}\) Id. at 170 ("[T]he FDA long ago issued regulations that say the relevant 'intent' can be shown not only by a manufacturer's 'expressions,' but also 'by the circumstances surrounding the distribution of the article.'").

\(^{71}\) Id. at 171-72 (explaining that the tobacco industry produced various advertisements touting the "stimulating quality" of cigarettes as well as tobacco's medical benefits).

\(^{72}\) Id. at 173 (quoting a draft report by Phillip Morris which indicated that nicotine contains substances similar to quinine, cocaine, and morphine).

\(^{73}\) Id. at 175-76.

\(^{74}\) Id.
For these reasons, the dissent asserted, FDA's regulation was entirely consistent with the FDCA's basic purpose, to protect public health. Thus, FDA was not required to ban tobacco if a ban posed more harm than other remedies. Rather, the misbranding and device classification provisions gave FDA leeway to consider the safety of the product before providing a remedy. Specifically, FDA can find the comparative safety of a product by determining that it would be less dangerous to make the product available than to completely and suddenly withdraw it from consumption. The FDCA's flexible construction allows FDA to consider all factors in its determination of whether the remedies are consistent with the statute's basic purpose of protecting public health. Most significantly, the dissent argued that a court-mandated ban on tobacco would affect FDA's choice of remedies rather than its jurisdiction.

Finally, the dissent offered justification for the FDA's past silence in the area of tobacco regulation. Before the various inquiries and hearings on tobacco, FDA was unable to prove the "intent" requirement of the FDCA. After receiving damaging evidence regarding manufacturers' knowledge about the harmful effects of tobacco, however, FDA found it much easier to prove that manufacturers intended tobacco to "affect the structure or any function of the body" under FDCA. Hence, even though FDA previously disclaimed its role in regulating tobacco, the dissent found the agency's reasons for changing course to be entirely justified.

75. 21 U.S.C. § 260h(e)(3).
76. Brown & Williamson, 529 U.S. at 176-78.
77. See 21 U.S.C. § 360hh(e)(2)(B)(i)(II) (stating that an agency should not recall or withdraw a device from the market if the "risk of recall") presents "a greater risk" than not recalling the product).
79. Id. at 191.
80. Id. at 186-87.
81. Id. at 162.
82. The dissent explained that even though the FDA maintained that the 1938 statute did not give it the authority it now seeks to regulate tobacco until the 1990s, this late change in position "does not make a significant legal difference." Id. at 186. Indeed, they argued, each time that the FDA denied jurisdiction, it consistently stated its reasons. The most significant hurdle for the FDA until 1990 was that it lacked sufficient evidence of the manufacturers' "intent" to market addictive drugs. Once the FDA acquired the requisite evidence that the tobacco companies knew that nicotine achieved addictive effects through chemical means, it felt comfortable asserting its jurisdiction. For this reason, according to the dissent, "[n]othing in the law prevents the FDA from changing its policy for such reasons." Id. at 188.
For environmental and administrative law scholars, the Supreme Court’s decision in Brown & Williamson is significant because of the majority's altered application of the Chevron doctrine. The Court introduced a subtle change into what had previously been considered a bright-line framework. The Court effectively collapsed both of Chevron's steps into one by employing a contextual interpretative approach in the first step of Chevron. Since the Court did not reach step two, it never had to follow the established principle of agency deference. This subtle modification of the Chevron doctrine results in a form of “anti-deference” that could dramatically alter agencies' ability to regulate outside their traditional areas of influence. 83

A. The Modified Chevron Rule: A Contextual Approach

The Court's importation of the interpretative tools from the second step of the Chevron doctrine into the first inevitably breaks down the deference principle inherent in the Chevron analysis. Without the deference typically afforded under Chevron's second step, agency interpretation and rulemaking are particularly vulnerable.

1. The Traditional Chevron Application

Under the traditional two-step Chevron analysis, at the first step a court determines Congress "clear intent" by looking at the "plain meaning of the statute." 84 If the statute is clear, the court must end its inquiry there and give "effect to the unambiguously expressed intent of Congress." 85 If the court concludes, however, that Congress has not directly spoken on the issue, the court must consider whether the agency interpretation of the statute is "reasonable." 86 It is not until this second step that the court traditionally considers legislative history. If, in light of the statutory scheme and legislative history, the court determines

83. See O'Reilly, supra note 3 (explaining that the Chevron interpretation model afforded considerable deference to agency decisionmaking, however, the Brown & Williamson decision threatens to replace traditional deference with a strict analysis construed against the agency's previous gap-filling role, thus resulting in an "anti-deference" approach to agency interpretation).
85. Id. at 843.
86. Id. at 842-43.
that the agency's interpretation is compatible with Congressional intent, then the court must defer to the agency's interpretation.\textsuperscript{87}

Under the \textit{Chevron} analysis, as understood before the \textit{Brown \& Williamson} decision, the Court would have first considered whether the FDCA is ambiguous. Since the FDCA did not include or exclude tobacco when it was implemented in 1938, its ambiguous nature would require the Court to assess the reasonableness of the agency's interpretation under \textit{Chevron}'s second step. Typically, this analysis would not examine whether the FDA properly asserted its jurisdiction; rather, the Court would consider whether FDA properly interpreted the statutory terms at issue. Thus, if the Court employed the traditional \textit{Chevron} analysis, it would first determine whether Congress delegated authority to FDA to regulate tobacco under the "drugs" provision of the FDCA. Then, applying the second step, the Court would consider the FDCA's legislative history to determine whether FDA's interpretation of "drug" and "device" was consistent with Congressional intent.

2. \textit{The Changed Rule: The Court's Merging of Chevron's Steps One and Two}

In \textit{Brown \& Williamson}, by contrast, the majority did not perform a traditional \textit{Chevron} analysis. Rather, the Court looked past the plain meaning of the FDCA and used interpretative methods traditionally employed under \textit{Chevron}'s second step, incorporating those methods into its plain meaning analysis. The Court rejected FDA's arguments that nicotine is a drug and that tobacco is a drug delivery device under the FDCA and concluded that the statute did not provide clear FDA jurisdiction.\textsuperscript{88} Then, rather than recognizing the ambiguity of the statute and moving on to step two, the majority appropriated the interpretative tools of step two and incorporated them into step one, justifying this shift as a consideration of the "context" of the ambiguous terms.\textsuperscript{89}

Specifically, the Court assessed the "context" of the terms "drug" and "device" by reviewing the FDCA's statutory construction and legislative history, as well as the legislative history of other tobacco statutes. The alleged purpose of this

\textsuperscript{87} Id. at 843.


\textsuperscript{89} Id. at 132 ("The meaning— or ambiguity— of certain words or phrases may only become evident when placed in context.").
review was not to consider whether FDA was *reasonable* in its interpretation of the ambiguous terms in step two but to determine Congressional intent in step one. The Court's use of the contextual interpretative approach under step one, rather than step two, precluded FDA from the benefit of *Chevron* deference that would otherwise have been accorded.

This modification may be best characterized as another phase of the *Chevron* doctrine's unstable continuum. Court decisions post-*Chevron* demonstrate their dissatisfaction with the doctrine through their frequent attempts to reformulate the step one analysis. Indeed, as lower courts have struggled to apply the doctrine adequately, several empirical studies indicate that even the Supreme Court wrestles with its own application of *Chevron*. As an illustration of the Court's uneasiness with the doctrine, one prominent scholar, Thomas Merrill, conducted an

90. Soon after the *Chevron* decision, the Court clarified the first step of *Chevron* in *National R.R. Passenger Corp. v. Boston & Maine Corp.*, 503 U.S. 407 (1992). The Court explained that in determining whether the agency's interpretation is a permissible construction of the language, a court must look to the structure and language of the statute as a whole. *Id.* at 416. According to Thomas Merrill, "[t]his reformulation is obviously designed to make step one of the *Chevron* doctrine a purely textualist inquiry . . . . 'Plain language,' 'structure and language,' and 'the text' are all that count." Thomas W. Merrill, *Textualism and the Future of the *Chevron* Doctrine*, 72 WASH. U. L.Q. 351, 358 (1994). *Brown & Williamson* is the next attempt at reformulating *Chevron*'s step one analysis. Here, however, the Court moves away from a "plain meaning" approach to a "contextual" interpretation.

91. Instead of specifically addressing whether Congress had spoken clearly on the issue at hand, courts began asking simply whether the statute was ambiguous. *See, e.g.*, Mobil Oil Exploration & Producing Southeast, Inc. *v.* United Distribution Cos., 498 U.S. 211 (1991); Pittston Coal Group *v.* Sebben, 488 U.S. 105 (1988); *Honig v. Doe*, 484 U.S. 305 (1988). Other step-one changes involved the initial inquiry of whether the statute had a "plain meaning," which signified the courts' continual movement away from a determination of whether Congress has spoken to the precise question. "The trend . . . has been strongly away from the original *Chevron* formulation of step one." Thomas W. Merrill, *Judicial Deference to Executive Precedent*, 101 YALE L.J. 969, 990-91 (1992).

92. *See, e.g.*, Peter H. Schuck & E. Donald Elliot, *To the *Chevron* Station: An Empirical Study of Federal Administrative Law*, 1990 DUKES. L.J. 984 (1990) (undertaking a comprehensive review of circuit court opinions in conjunction with the *Chevron* test); Merrill, *supra* note 90 (analyzing the acceptance and rejection of agency interpretations by the Supreme Court for the periods prior to and following the *Chevron* decision); Richard L. Revesz, *Environmental Regulation, Ideology, and the D.C. Circuit*, 83 VA. L. REV. 1717 (1997) (finding that D.C. Circuit judges are mostly influenced by political ideology when making administrative law decisions); Linda R. Cohen & Matthew L. Spitzer, *Judicial Deference to Agency Action: A Rational Choice Theory and an Empirical Test*, 69 S. CAL. L. REV. 431 (1996) (concluding through empirical analysis that the Court does not uniformly endorse judicial deference; rather, it favors the doctrine only when it yields policy outcomes more to the Court's liking).
empirical study the year following *Chevron*. His research revealed that the Supreme Court decided nineteen cases involving deference, but applied *Chevron* only once. At the same time, various empirical studies and the case law following *Chevron* all reflect the lower courts' and the Supreme Court's mission to redesign the *Chevron* framework. The holding in *Brown & Williamson* is simply further evidence of this effort.

What is particularly unique about the Court's decision in *Brown & Williamson* are the circumstances surrounding the modification of *Chevron's* step one. The fact that FDA had previously disavowed its ability to regulate tobacco in the past inspired the Court to tweak its first prong analysis rather than assess the reasonableness of the agency's decision. Hence, the Court replaced the "plain meaning" inquiry with the requirement that Congress specifically grant authority to the agency as a precondition to agency deference. Had the Court moved to this second step, it would have committed itself to the deference principle of *Chevron*. In order to circumvent this inevitable

93. Merrill, supra note 91.

94. Id. at 980. Merrill's empirical analysis went beyond the study of *Chevron's* immediate application. He considered the fact that decisions often take time to implement. For this reason, he conducted a seven-year study of *Chevron's* impact. Merrill's methodology involved an assessment of Supreme Court cases where at least one justice acknowledged that the case involved a deference issue. The factors included in this determination were whether the Court deferred to the agency's interpretation, whether the Court actually employed the *Chevron* framework, and if the framework was employed, whether the Court made its decision under the first or second prong of the test. Id. at 981-85. In his analysis, Merrill found "no discernible relationship between the application of the *Chevron* framework and greater acceptance of the executive review." Id. at 984. Indeed, his findings indicate that the Court gave less deference to administrative agencies after *Chevron*. The Supreme Court's overall acceptance rate of agency interpretations went from 75% pre-*Chevron* to only 70% after the decision. Id. In fact, even when the Court actually applied the *Chevron* test from 1984-1990, it only deferred to agency interpretations in 59% of its decisions: "Paradoxically, it appears that adoption of the *Chevron* framework has meant, if anything, a decline in deference to agency views." Id.

95. Indeed, several holdings post-*Chevron* and pre-*Brown & Williamson* illustrate the Supreme Court's cavalier application of the deference doctrine. The biggest hurdle in the road to *Brown & Williamson* was the Court's decision in *INS v. Cardoza-Fonseca*, 480 U.S. 421 (1987). That case dealt with the interpretation of immigration law, an area where the Court typically has shown considerable deference to administrative interpretation. Indeed, Justice Stevens, the author of *Chevron*, found that the deference principle of *Chevron* did not apply in *Cardoza-Fonseca* because the issue was a "pure question of statutory construction." Id. at 446. Although the importance of the *Cardoza-Fonseca* decision has faded from administrative law, "the episode nevertheless suggests that the Court's commitment to *Chevron*—at least in its unvarnished original form—was at best fragile." Merrill, supra note 91, at 986-87. Indeed, the Court's willingness to ignore the *Chevron* test so soon after its adoption indicates the Court's uneasiness with the doctrine as a whole.

96. See O'Reilly, supra note 3.
determination, the Court deemed the tobacco question an "extraordinary case," giving the Court "reason to hesitate before concluding that Congress has intended such an implicit delegation."97 Indeed, the only way for the Court to manage the extraordinary nature of the case and come to the desired conclusion was to expand the interpretative tools within the *Chevron* framework. This expansion ultimately allows the Court to make arbitrary determinations based on selective interpretation.

**B. Does the Brown & Williamson Decision Portend Any Significant Changes in Agency Authority?**

The facts and circumstances surrounding *Brown & Williamson* confine the holding to exceptional cases where Congress stalemates on important legislation and agencies reverse long-standing interpretations of a statute. Hence, the significance of *Brown & Williamson* will manifest itself only where administrative agencies attempt to regulate in areas that they had previously avoided or were precluded from regulating. Indeed, recent case law indicates that courts are reluctant to find that administrative circumstances are sufficiently "extraordinary" to warrant the invocation of the *Brown & Williamson* analysis.

In *Pronsolino v. Marcus*,98 for example, the District Court of the Northern District of California upheld EPA's authority to determine total maximum daily loads (TMDLs) by distinguishing the facts in *Brown & Williamson*. In *Pronsolino*, landowners brought an action challenging EPA's authority to determine the TMDLs for a river polluted by logging runoff and other non-point sources of pollution.99 The plaintiffs cited *Brown & Williamson* in support of its argument that EPA had foreclosed itself from asserting regulatory authority over TMDLs.100 The court concluded, however, that EPA had never made express statements to Congress indicating its lack of authority to issue TMDLs for polluted water. In addition, even though EPA was slow to implement TMDL requirements, that was not

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98. 91 F. Supp. 2d 1337 (N.D. Cal. 2000); see also Coutts v. United States, 47 Fed. Cl. 118, 126-27 (2000) (recognizing that the Supreme Court's "analysis in *Brown & Williamson* is in accordance with *Chevron* and holding that "the agency's interpretation of its discretion is ratified by language in the statute itself").
100. Id. at 1354 n.17.
inconsistent with its original position. In its consideration of the Chevron doctrine, the court employed Brown & Williamson's contextual modifications and made the same decision as it would have under the traditional Chevron analysis.

Pronsolino reveals that administrative agencies such as EPA must be deliberate in establishing the parameters of their own authority. Other than warning the EPA of the Brown & Williamson decision's potential threat to uncharted or uncertain areas of legislation and authority, the decision simply gives courts more discretion in assessing the legislative history surrounding an agency's interpretation of a statute.

C. The Impact of Brown & Williamson on Agencies That Regulate in New Areas

The implications of Brown & Williamson may manifest in cases where an agency asserts its jurisdiction in new areas of regulation. For example, if Congress adopts certain laws that skirt a major environmental issue and EPA, based on its statutory authority, issues rules to directly resolve the particular environmental question, challengers to these new rules may cite the first step of the Brown & Williamson-modified Chevron doctrine to show that Congress has directly spoken on the issue. If, based on its contextual analysis, the court finds that Congress has spoken at some point in the statute's legislative history, EPA will lose the benefit of the deference principle under the second prong of Chevron. Hence, once the Court opens the door of "contextual interpretation," the entire legislative history of the statute is at its fingertips.

Liberal use of this modified interpretative approach by challengers to EPA rules could open the floodgates to arbitrary judicial decisionmaking. If the modified Chevron doctrine is applied in this manner, not only would it result in a form of "anti-deference," but it would also produce deep-seated problems for untapped areas of agency regulation. This distorted doctrine would effectively prohibit EPA from ever asserting its authority in new areas where it receives additional information and can

101. Id.
102. See generally O'Reilly, supra note 3.
103. Evidence of the ease by which challengers may manipulate legislative history is seen in Brown & Williamson. Petitioners invoked instances as far back as the early 1960s, when FDA disavowed its authority over tobacco regulation, to show that FDA was foreclosed from asserting regulatory jurisdiction. See Food & Drug Admin. v. Brown & Williamson Tobacco Co., 529 U.S. 120, 144-48 (2000); see also supra note 57 and accompanying text.
justify its regulatory interference. Hence, "anti-deference" could transcend controversial topics, such as the regulation of tobacco, and reach other areas of the administrative legal system.

Environmental regulation presents controversial administrative law issues similar to those presented in the regulation of tobacco. One example is EPA's regulation of "indoor air pollution" under the Clean Air Act (CAA). All residences and commercial facilities contain certain levels of indoor air pollutants, which derive from fuels, household cleaning products, and cooling systems. Pesticides and automobile emissions are a tremendous source of these pollutants. Indoor air pollution causes severe health effects and is deemed more dangerous than "outside" air since people spend most of their time indoors. The EPA consistently ranks indoor air quality as one of the top environmental risks to public health.

Even though administrative agencies recognize the severity of the indoor air pollutant problem, EPA allocates minimal resources to its prevention and has not set indoor air pollution as an agency priority. EPA has remained silent for several reasons, including a lack of definitive or explicit authority under the CAA. The parameters of EPA's authority under the CAA are

104. Distortion of the Chevron doctrine may also erode an agency's decision not to exercise its authority in a controversial area. It is well-established that agencies have discretion not to enforce a statutory term. If an agency determines, from the "plain meaning" of a statute, that it does not have authority to enforce a statutory provision, petitioners may cite Brown & Williamson to compel enforcement through anti-deference. See Heckler v. Chaney, 470 U.S. 821, 827, 837-38 (1984) (involving an action brought by prison inmates to compel the FDA to regulate lethal injections as drugs under the FDCA. The court held that "there is a presumption that agency decisions not to institute proceedings are unreviewable." The Court continued that "[t]his general presumption is based on the view that, in the normal course of events, Congress intends to allow broad discretion for its administrative agencies to make particular enforcement decisions, and there often may not exist readily discernible 'law to apply' for courts to conduct judicial review of nonenforcement decisions.").


107. See id. at 249 n.2 ("A growing body of scientific evidence has indicated that air within homes and other buildings can be more seriously polluted than the outdoor air in even the largest and most industrialized cities.").


110. The EPA is given the authority to regulate pollutants that enter the ambient air. See 42 U.S.C. § 7602 (g). EPA's National Ambient Air Quality Standards (NAAQS)
set by the regulation of "ambient air." However, just as the terms "drug" and "device" left many unfilled gaps in the FDCA, the CAA does not define "ambient air." When Congress enacted the CAA in 1970, it did not consider whether ambient air included the regulation of indoor air pollutants. Just as it did not foresee the need for tobacco regulation in 1938, in 1970 Congress may not have predicted the need to regulate indoor air pollutants. EPA consistently limits its interpretation of "ambient air" to the regulation of outdoor air. Indeed, in various reports and Congressional testimony EPA renounced its authority to regulate indoor air. The CAA amendments of 1990 did nothing to alter this restricted reading of "ambient air."

The parameters of EPA's authority to regulate pollution are limited to six criteria pollutants: carbon monoxide, sulfur dioxide, nitrogen dioxide, particulate matter, oxidants, and lead. These standards promulgated by the EPA, called National Ambient Air Quality Standards (NAAQS), specify the maximum allowable concentrations of these criteria pollutants; however, NAAQS have little direct effect on indoor air quality. Yet, indoor air quality is improved indirectly through emissions standards, asbestos programs, and similar outdoor air quality solutions. For example, EPA has used its authority under Section 112 of the CAA to ban the spraying of asbestos insulation inside

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112. See id. Section 7409 sets the national primary and secondary ambient air quality standards, yet fails to define ambient air.
114. Id. (arguing that since the purpose of the Act is to protect air quality and promote health and welfare, it could be read to cover all air pollution, including indoor).
115. Id. at 359 n.202 (referencing EPA Administrator Anne Gorsuch's statement that the EPA does not have the authority to regulate indoor air since the CAA's ambient air provision "has universally been construed to mean the 'outdoor air'.")
116. Id. at 358-60 (citing A. Gorsuch, Administrator, U.S. Env'tl. Prot. Agency, Transcript of Testimony Before the Subcomm. on Natural Res., Agric., Research, and Env't, House Comm. on Sci. and Tech., Oct. 22, 1981: "There is no construct under the current law for regulation of indoor air pollutants by EPA.").
119. Id.
buildings. EPA used its authority under the National Emission Standards for Hazardous Air Pollutants (NESHAPS) in its reasoning that banning asbestos insulation in effect minimizes asbestos “emissions into the atmosphere.”

EPA may continue to regulate indoor air pollutants under the NESHAPS regulatory mechanism, as it did with the indoor spraying of asbestos. The strict requirements under Section 112 in the classification of “hazardous” pollutants, however, hinder EPA from further developing its authority under this provision. In light of more evidence and research, EPA may satisfy these requirements and thus expand its regulation of indoor air pollutants. Similarly, if EPA had further evidence of the health effects of indoor air pollution, it could expand its definition of ambient air to include indoor air.

An expansive reading of “ambient air” or the NESHAPS provisions under the CAA will face practical complications in light of the recent Brown & Williamson decision. The circumstances surrounding a decision by EPA to regulate indoor air pollution would be distinctly similar to the facts in Brown & Williamson. If a court were to analyze EPA’s regulations under the CAA, it would most likely apply the Chevron framework as amended by Brown & Williamson’s “contextual” modification. EPA’s disavowal of its authority to regulate indoor air under the CAA, and Congress’ decision to not expressly delegate such authority to the EPA in subsequent statutes would face considerable scrutiny under the first prong of Chevron as applied by Brown & Williamson. Application of this new rule would result in a narrow reading of EPA’s authority under the CAA. Hence, even with new scientific proof of the harm caused by indoor air pollutants, like the new evidence of the harmful health effects of smoking and manufacturer intent in Brown & Williamson, the EPA would likely encounter a restricted reading of its statutory authority.

120. Id. pt. 61.
122. See Kirsch, supra note 113, at 358.
123. The D.C. Circuit’s decision in American Trucking Ass’ns v. EPA, 175 F.3d 1027 (D.C. Cir. 1999), aff’d in part and rev’d in part sub nom., Whitman v. American Trucking Associations, 121 S. Ct. 903 (2001), further illustrates the potential for a restricted reading of EPA’s authority under the CAA. In American Trucking, the court held that EPA’s interpretation of certain provisions in the CAA, which gave EPA the authority to issue NAAQS, were an unconstitutional delegation of power. Id. at 1033. The court effectively resurrected the nearly deceased non-delegation doctrine to justify its limited reading of EPA’s authority. Most importantly, the court’s holding
Environmental issues have not seen the dramatic lobbying efforts and the remarkable sums of money drained into the tobacco litigation. The political nature of tobacco litigation may provide justification for the Supreme Court's ideological divide in *Brown & Williamson*. Thus, the uniqueness of the tobacco industry, coupled with inconsistent Congressional decisions, may abate the impact of *Brown & Williamson* in less controversial areas of regulation.

So long as the EPA avoids surrendering its potential authority, it will protect itself from the implications of the *Brown & Williamson* decision. The significance of this solution is illustrated by the court's decision in *Pronsolino*,¹²⁴ where the court differentiated the case from the facts in *Brown & Williamson*. In light of the modified *Chevron* doctrine, the court still deferred to the EPA even though the agency was exceedingly slow in its implementation of TMDL requirements.¹²⁵ Hence, even though recent court decisions indicate a trend towards a form of "anti-deference," the impact is tempered not only by the unique circumstances surrounding *Brown & Williamson*, but also by the uniqueness of the tobacco industry itself.

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¹²⁵. *Id.* at 1354 n.17.