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Administrative Law—The Fourth Circuit Strikes Down the FDA'S Tobacco Regulations

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ADMINISTRATIVE LAW—THE FOURTH CIRCUIT STRIKES DOWN THE FDA'S TOBACCO REGULATIONS

Brown & Williamson Tobacco Corp. v. FDA,
153 F.3d 155 (4th Cir. 1998)

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I. INTRODUCTION

Tobacco litigation has seized national headlines for the latter half of this decade. Battles over the power to regulate tobacco, however, have waged for the past half century. This Case Note examines the quest for regulatory control over tobacco within the context of *Brown & Williamson Tobacco Corp. v. FDA*. A review of this challenge to the Food and Drug Administration's authority illustrates that interpretations of legislative history and standards of review serve as guideposts in the judicial assignment of this increasingly important power.

A. *The Tobacco Regulations*

On August 28, 1996, as several states prepared lawsuits against the tobacco companies,¹ the Food and Drug Administration ("FDA") made its

* The author would like to thank Professor Neil Hamilton, Trustees Professor of Regulatory Policy, William Mitchell College of Law, for his assistance with this article.

first attempt to regulate tobacco and limit its impact on public health.² The FDA has promulgated a number of regulations concerning the advertising and sale of tobacco products. The regulations restrict sales to minors,³ require certain labeling on packages,⁴ and impose limitations on advertising.⁵ The advertising restrictions—which limit most ads to a black-

1. See, e.g., David Phelps, *Blue Cross Given Green Light*, STAR TRIB. (Minneapolis-St. Paul), July 26, 1996, at 1D; David Phelps, *The Tobacco Fight*, STAR TRIB. (Minneapolis-St. Paul), Oct. 21, 1996, at 1A (explaining that seventeen states had filed suit against the tobacco companies).

2. See Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents, 61 Fed. Reg. 44,396 (1996) (to be codified at 21 C.F.R. pts. 801, 803, 804, 807, 820, and 897). The agency explained:

Tobacco use is the single leading cause of preventable death in the United States. More than 400,000 people die each year from tobacco-related illnesses, such as cancer, respiratory illnesses, and heart disease, often suffering long and painful deaths. Tobacco alone kills more people each year in the United States than acquired immunodeficiency syndrome (AIDS), car accidents, alcohol, homicides, illegal drugs, suicides, and fires, combined.

Id. at 44,398.

3. See 21 C.F.R. § 897.14 (1998). 21 C.F.R. § 897.14 prohibits retailers from selling tobacco products to a person younger than eighteen years of age and requires asking a purchaser twenty-six years old or younger for identification. See *id.* Vending machines are prohibited unless located in an area closed to minors. See 21 C.F.R. § 897.16 (1998). Minnesota state law also prohibits sale to minors. See MINN. STAT. § 609.685 (1998) (making sale of tobacco to minors a gross misdemeanor).

4. See 21 C.F.R. § 897.24–25 (1998). Tobacco packages must include a description of the product—such as “cigarettes”—and the label “Nicotine-Delivery Device for Persons 18 or Older.” *Id.*

5. See 21 C.F.R. § 897.30 (1998). The advertising restrictions are by far the most restrictive. The regulations prohibit tobacco companies from advertising within one thousand feet of a playground or elementary or secondary school. See *id.* Advertising and labeling of tobacco products is limited to black text on a white background, except in areas closed to minors and in adult publications. See 21 C.F.R. § 897.32 (1996). Advertising involving audio (such as radio ads) may not include music or sound effects. See *id.* In addition, tobacco companies may not sell products other than tobacco labeled with the brand name or other identification of a tobacco product, give bonuses for the purchase of tobacco, or advertise at athletic or cultural events using the brand name or identification of a tobacco product. See 21 C.F.R. § 897.34 (1996). Interestingly, Congress has considered bills which would prohibit tobacco companies from using other than black-and-white text format advertisements, advertising within one thousand yards of a school, sponsoring sports activities, or distributing samples. See Angela Turriciano, *The FDA Sends Smoke Signals to Big Tobacco: Will the FDA Suffer Backlash, Will Alcohol Be Regulated Next, and Will the Health of Americans Prevail?*, 25 PEPP. L. REV. 617, 623 (1998). These bills were not enacted. See *id.*

and white format and prohibit sponsorship of any athletic or cultural event using a tobacco brand name—have a serious impact on the industry.⁶ The FDA focused on preventing use by minors, explaining that most smokers begin to use tobacco at this critical age.⁷

When several tobacco companies, convenience store owners, and advertising agencies challenged the FDA's rule, a U.S. district court in North Carolina held that the FDA had the authority to regulate tobacco products under the Federal Food, Drug, and Cosmetics Act ("FDCA")⁸ as combination devices.⁹ On appeal, the Court of Appeals for the Fourth Circuit reversed in *Brown & Williamson Tobacco Corp. v. Food & Drug Administration*.¹⁰

This note addresses whether the FDA has the authority to regulate tobacco products. It discusses the agency's change in position, subsequent legislative history, and the impact of these issues on the scope of review. It concludes that the Fourth Circuit improperly relied on bills that were not enacted and tobacco legislation enacted after the FDCA—subsequent legislative history—as a basis for its decision.

6. See Turriciano, *supra* note 5, at 630-31.

7. See Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents, 61 Fed. Reg. 44,396, 44,397 (1996) (to be codified at 21 C.F.R. pts. 801, 803, 804, 807, 820, and 897). According to studies cited by the FDA, 82% of current and former adult smokers first smoked before age 18. See *id.* at 44,574. Most adults who smoke became regular smokers before age 18. See *id.* The FDA noted:

As long as children and adolescents become addicted to cigarette and smokeless tobacco use in these numbers, there is little chance that society will be able [to] reduce the toll of tobacco-related illnesses. If, however, the number of children and adolescents who begin tobacco use can be substantially diminished, tobacco-related illness can be correspondingly reduced because data suggest that anyone who does not begin smoking in childhood or adolescence is unlikely to ever begin Thus, the appropriate emphasis is on reducing the use of tobacco products by children and adolescents.

Id. at 44,399.

8. Act of 1938, ch. 675, 52 Stat. 140 (1938) (codified as amended at 21 U.S.C. §§ 301-394 (1994)).

9. See *Coyne Beahm, Inc. v. FDA*, 966 F. Supp. 1374, 1397 (M.D.N.C. 1997), *rev'd sub nom. Brown & Williamson Tobacco Corp. v. FDA*, 153 F.3d 155 (4th Cir. 1998), and *petition for cert. filed*, 67 U.S.L.W. 3484 (U.S. Jan. 19, 1999) (No. 98-1152). The case did, however, take most of the sting out of the regulations by striking the advertising restrictions as outside of the FDA's authority. See *id.* at 1399-1400.

10. 153 F.3d 155 (4th Cir. 1998).

B. *The FDA's Analysis of the FDCA*

The FDA made extensive findings in support of tobacco regulations. The agency asserted jurisdiction over tobacco as a combination device.¹¹ The FDCA defines "drug" as:

(A) articles recognized in the official United States Pharmacopoeia . . . ; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals¹²

A "device" under the FDCA is an:

instrument, apparatus, implement, machine . . . which is recognized in the official National Formulary . . .

(2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or

intended to affect the structure or any function of the body of man or other animals, and

which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.¹³

The FDA found cigarettes and smokeless tobacco to be combination drug/device products because they include both nicotine and a delivery system.¹⁴ Further, they are "intended to affect the structure or any function of the body."¹⁵

The Safe Medical Devices Act of 1976 gives the FDA the authority to regulate combination drug/device products.¹⁶ This amendment to the

11. 61 Fed. Reg. at 44,396 (1996).

12. 21 U.S.C. § 321(g)(1) (1994).

13. *Id.* § 321(h).

14. For a detailed explanation of the FDA's regulations, see Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents, 61 Fed. Reg. 44,396, 44,403 (1996) (to be codified at 21 C.F.R. pts. 801, 803, 804, 807, 820, and 897).

15. 21 U.S.C. § 321(h) (1994).

16. *See id.* § 353(g)(1); *see also* 61 Fed. Reg. at 44,400 (1996).

FDCA states that the FDA “shall determine the *primary mode of action* of the combination product” and regulate accordingly.¹⁷ The FDA made its determination based not on how tobacco functions as a combination product but rather on which classification—drug or device—provided it with the most authority over tobacco. The agency explained:

Because of this additional flexibility [of the device provisions], the agency has determined that the device authorities provide the most appropriate basis for regulating cigarettes and smokeless tobacco. Because millions of Americans are addicted to cigarettes and smokeless tobacco, regulation of these products presents unique safety problems that require careful, tailored solutions. The Medical Device Amendments provide the agency with regulatory options that are well suited to the unique problems presented by cigarettes and smokeless tobacco.¹⁸

This determination has significance because, although the FDA found otherwise,¹⁹ the agency may not have been able to regulate tobacco under the drug provisions of the FDCA. The FDCA defines a “new drug” as:

[A]ny drug . . . not generally recognized . . . as safe and effective for use.²⁰

. . . .

To market a “new drug,” a manufacturer must submit an application to the FDA including full reports of investigations which have been made to show whether or not such drug is safe for use and whether such drug is effective in use.²¹

The FDA’s next bit of creativity involved the classification of tobacco as a type of device. The applicable statute divides devices into three classes. The agency regulates Class I devices using “general controls” under the Act; Class II devices require additional “special controls” such as

17. 21 U.S.C. § 353(g)(1) (emphasis added).

18. 61 Fed. Reg. at 44,404; *see also* *Brown & Williamson Tobacco Corp. v. FDA*, 153 F.3d 155, 165 (4th Cir. 1998) (describing the agency’s determination as “obvious sophistry”).

19. Not directly addressing premarket approval, the FDA stated that the drug provisions allow it to “regulate these combination products.” 61 Fed. Reg. at 44,414.

20. 21 U.S.C. § 321(p)(1) (1994).

21. *Id.* § 355(b).

performance standards; Class III devices require premarket approval.²² A device has Class III status if Class I and II controls would not "provide reasonable assurance of [its] safety and effectiveness" and its use "presents a potential unreasonable risk of illness or injury."²³ Premarket approval requires "reasonable assurance of its safety and effectiveness."²⁴ The FDA avoided a classification dilemma by choosing not to classify tobacco and by regulating it under the general device controls.²⁵

These and other arguments led to the FDA's district court victory.²⁶

C. *The Fourth Circuit's Opinion*

The Fourth Circuit reversed the district court's holding and held that the FDA does not have jurisdiction over tobacco.²⁷ The court did not defer to the agency's interpretation of the Federal Food, Drug, and Cosmetics Act because it found the statute unambiguous²⁸ under the standard of review articulated in the controlling case of *Chevron U.S.A., Inc. v. Natural Resources Defense Counsel, Inc.*²⁹ By promulgating the rule discussed above, the Fourth Circuit determined that the FDA acted outside the "bounds of its congressionally-established authority."³⁰

In reaching this conclusion, the court examined the plain language

22. *See id.* § 360c(a)(1).

23. *Id.*

24. *Id.*

25. *See* 61 Fed. Reg. at 44,396-404; *see also* *Brown & Williamson Tobacco Corp. v. FDA*, 153 F.3d 155, 176 (4th Cir. 1998). The Fourth Circuit noted that the FDA would not be able to approve tobacco products as a drug because the FDA admits they are unsafe. *See id.* at 165. The Fourth Circuit was unimpressed with the FDA's attempt to avoid obvious difficulties with premarket approval by relying upon the device provisions of the Act. *See id.* The Commissioner of the FDA had stated in congressional hearings that "if cigarettes were to be classified as drugs, they would have to be removed from the market because it would be impossible to prove they were safe for their intended [use]." *Id.* at 168. The agency's justification for not completely banning tobacco due to its documented effect on public health illustrates the tension in its position. *See* 61 Fed. Reg. at 44,398. The FDA cited addicted users and the possibility of a black market in sidestepping the basic issue of safety. *See id.*

26. *See* *Coyne Beahm, Inc. v. FDA*, 966 F. Supp. 1374, 1397 (M.D.N.C. 1997), *rev'd sub nom.* *Brown & Williamson Tobacco Corp. v. FDA*, 153 F.3d 155 (4th Cir. 1998), and *petition for cert. filed* 67 U.S.L.W. 3484 (U.S. Jan 19, 1999) (No. 98-1152).

27. *See* *Brown & Williamson*, 153 F.3d at 176.

28. *See id.* at 161.

29. 467 U.S. 837 (1984). *See infra* notes 136-39 and accompanying text. The Fourth Circuit based its decision on the first step of *Chevron's* two-step rule; therefore, it never reached the question of whether the FDA's regulation reflected a "permissible construction." *See* *Brown & Williamson*, 153 F.3d at 161.

30. *Brown & Williamson*, 153 F.3d at 161-62.

of the statute, the statutory scheme, legislative history, and other relevant statutes. Beginning with the statute itself, the court found that tobacco products are not drugs or devices under the Act.³¹ The FDCA requires that a drug or device be “intended to affect the structure or any function of the body.”³² Tobacco certainly affects a structure or function of the body and thus could possibly fit the definition, but tobacco manufacturers do not market their products based on that characteristic. Tobacco’s impact on the body is thus not intended within the meaning of the Act.³³

The court next considered the structure and purpose of the FDCA as a whole.³⁴ Numerous provisions in the Act require the FDA to ensure the safety of products. For example, the device provisions of the Act enable the FDA to prohibit the sale of a device lacking a “reasonable assurance of safety.”³⁵ The drug provisions require new drugs to be approved prior to marketing for their safety.³⁶ Basically, if tobacco products were drugs or devices, the Act would require the FDA to ensure their safety, but the FDA contends the products are far from safe.³⁷ According to the court, “Congress did not equip the FDA with tools appropriate for the regulation of tobacco because it had no intention that the Act apply to tobacco prod-

31. See *id.* at 163-64.

32. See *id.* at 163 (citing 21 U.S.C. § 321(g)(1)(C) (1994)).

33. See *Brown & Williamson*, 153 F.3d at 163. Judge Hall, in his dissent, stated:

It strikes me as patently absurd to contend that cigarettes and smokeless tobacco, products that are (under the assumed facts) actually designed to exert powerful and quintessentially drug-like effects on the users, should escape FDA regulation because the products are marketed as essential accoutrements of a more exciting or more sophisticated lifestyle.

Id. at 178 (Hall, J., dissenting). In addition, the FDCA was deliberately drafted broadly because Congress could not foresee every drug which the FDA would need to regulate. See *id.* at 179 (Hall, J., dissenting). The district court deferred to the agency’s definition of “intended use” which considered foreseeable use, actual consumer use, and knowledge of the manufacturers. See *Coyne Beahm, Inc. v. FDA*, 966 F. Supp. 1374, 1391-92 (M.D.N.C. 1997), *rev’d sub nom. Brown & Williamson Tobacco Corp. v. FDA*, 153 F.3d 155 (4th Cir. 1998), and *petition for cert. filed*, 67 U.S.L.W. 3484 (U.S. Jan. 19, 1999) (No. 98-1152). The district court also upheld the FDA’s finding that tobacco products were combination products under the FDCA and, with some misgivings, allowed the FDA to choose whether to regulate them as drugs or devices. See *id.* at 1392-97.

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

35. See *id.* at 164-66.

36. See *id.* The Fourth Circuit also discussed the labeling and cease-distribution provisions of the Act. See *id.*

37. See *id.* at 164. The Fourth Circuit held that the agency improperly weighed the risks inherent in removing tobacco from the market with tobacco’s negative impact on public health. See *id.* The agency should have weighed the benefits of tobacco with the harm caused by using it. See *id.*

ucts.”³⁸

The court’s examination of legislative history includes the Agency’s prior interpretations of its enabling act. For sixty years, the FDA took the position that “cigarettes marketed without therapeutic claims” were not subject to its jurisdiction.³⁹ Interestingly, the FDA refused to regulate cigarettes even when specifically petitioned to do so.⁴⁰ By its repeated inaction, Congress acquiesced in the FDA’s opinion that it lacked jurisdiction over tobacco; Congress considered and rejected fifteen bills granting the FDA jurisdiction over tobacco.⁴¹

38. *Id.* at 167. A pair of commentators suggested a regulatory approach that treats tobacco as a unique product: “Tobacco products cannot meet the ‘safe and effective’ standard applied to drugs; such products are inherently toxic. Rather, the overall standard should be no more poisonous (or dangerous) than necessary, as is consistent with the recommendations of several major public health reports.” John Slade, M.D. & Jack E. Henningfield, Ph.D., *Tobacco Regulation: Context and Issues*, 53 FOOD & DRUG L.J. Supp. 43, 65 (1998).

39. *Brown & Williamson*, 153 F.3d at 168. The court noted several specific comments to this effect by the FDA between 1930 and 1989. *See id.* at 168-70. The dissent stated that an agency may change its position, especially when new information becomes available. *See id.* at 180 (Hall, J., dissenting). The FDA’s knowledge regarding the effect of tobacco on health has increased substantially since the enactment of its enabling legislation. *See id.*; *see also* FDA’s Petition for Writ of Certiorari, *FDA v. Brown & Williamson Tobacco Corp.*, (No. 98-1152), available in Food & Drug Administration, *Children & Tobacco: Court Opinions and Briefs* (visited Mar. 31, 1999) <<http://www.fda.gov/opacom/campaigns/tobacco/tobcourt.html>>. In its petition, the FDA wrote:

Prior to the present proceeding, FDA simply did not have clear and compelling evidence that nicotine is extremely addictive, that consumers use tobacco products because they are addicted to the products and want to obtain their mood-altering and other effects, that manufacturers know that consumers use tobacco products primarily for those reasons, and that manufacturers have deliberately and carefully engineered tobacco products to deliver pharmacologically active doses of nicotine.

Id.

40. *See Brown & Williamson*, 153 F.3d at 169. In finding that it did not have authority to regulate tobacco, the FDA relied on *FTC v. Liggett & Meyers Tobacco Co.*, 108 F. Supp. 573, 577 (S.D.N.Y. 1952) (holding that tobacco is not a drug under the Federal Trade Commission Act). The *Liggett* court applied a definition similar to that in the federal Food, Drug and Cosmetics Act and distinguished between beneficial and non-adverse effects. *See id.* at 575. A claim of a non-adverse effect, such as less irritation, does not qualify as a therapeutic claim. *See id.* A drug has a therapeutic purpose. *See id.*

41. *See Brown & Williamson*, 153 F.3d at 170. The district court had found the agency’s prior position and these unenacted bills inadequate to suggest legislative acquiescence. *See Coyne Beahm, Inc. v. FDA*, 966 F. Supp. 1374, 1382 (M.D.N.C. 1997), *rev’d sub nom. Brown & Williamson Tobacco Corp. v. FDA*, 153 F.3d 155 (4th Cir. 1998), and *petition for cert. filed* 67 U.S.L.W. 3484 (U.S. Jan 19, 1999) (No.

In addition, Congress enacted other legislation specifically addressing labeling and advertising of tobacco products and access by minors—the Federal Cigarette Labeling and Advertising Act,⁴² the Comprehensive Smokeless Tobacco Act,⁴³ and the Alcohol Drug Abuse and Mental Health Administration Reorganization Act⁴⁴—suggesting that it did not intend to delegate to the FDA authority over tobacco.⁴⁵

According to the Fourth Circuit, the goals of the Federal Cigarette Labeling and Advertising Act (“FCLAA”) are not consistent with FDA jurisdiction over tobacco for three reasons. First, the FCLAA states that a national policy regarding tobacco must consider the impact of any legislation on the economy.⁴⁶ The FDA’s enabling act does not allow it to promulgate rules based on such broad societal concerns. Second, the FCLAA allows the sale of tobacco products with certain labeling despite the dangerousness of the products, but the FDA’s enabling act does not permit the sale of unsafe products.⁴⁷ Third, a House committee considered granting the FDA jurisdiction over tobacco, but the FCLAA, as passed by Congress, did not include this provision.⁴⁸ The committee heard testimony that allowing the FDA to regulate tobacco may lead to a complete ban, a result not desired by Congress.⁴⁹

98-1152). It stressed that these bills were only discussed in committees and never reported to the chambers. *See id.* at 1383. The court also distinguished between acquiescence based on agency action and agency inaction, stating that the precedent only supports acquiescence to action. *See id.* In addition, “[e]ven if Congress acquiesced to FDA’s assertion of lack of jurisdiction, such acquiescence would not necessarily connote Congress’ opposition to FDA’s assertion of jurisdiction.” *Id.* at 1384.

42. Pub. L. No. 89-92, 79 Stat. 283 (1965) (codified as amended at 15 U.S.C. §§ 1331-1341 (1994)).

43. Pub. L. No. 99-952, 100 Stat. 30 (1986) (codified as amended at 15 U.S.C. §§ 4401-4408 (1994)).

44. Pub. L. No. 102-321, 106 Stat. 323 (1992) (codified as amended at 42 U.S.C. §§ 300x-26 (1994)).

45. *See Brown & Williamson*, 153 F.3d at 171-76.

46. *See id.* at 172.

47. *See id.* at 172-73 (explaining that the House Committee on Interstate and Foreign Commerce addressed this issue prior to passage of the FCLAA and that the FCLLA requires warnings on package labels and advertisements).

48. *See id.* at 173. One commentator notes that Congress has given a regulatory role regarding tobacco to several agencies other than the FDA—the Federal Trade Commission, Health and Human Services, Department of Agriculture, Bureau of Alcohol, Tobacco and Firearms, and the Internal Revenue Service. *See John E. Jevicky, FDA’s Regulation of Tobacco Products: A Flagrant Disregard of Congressional Intent*, 24 N. KY. L. REV. 535, 542 (1997).

49. *See Brown & Williamson*, 153 F.3d at 172. Similarly, the goals of the Smokeless Tobacco Act and Alcohol, Drug Abuse, and Mental Health Administration Reorganization Act suggest that the FDA does not have jurisdiction over to-

In summary, the court in *Brown & Williamson* noted, "At its core, this case is about who has the power to make this type of major policy decision [N]either federal agencies nor the courts can substitute their policy judgments for those of Congress."⁵⁰ One might conclude that the court restrained the FDA from expanding its jurisdiction by a liberal interpretation of its enabling act. On the other hand, the court rejected the agency's analysis—based on the agency's decades of experience—for its own. *Brown & Williamson* raises troubling questions about unaccountable power; the public does not elect either agency heads or judges.⁵¹ In particular, the case raises these questions: When should a court defer to an agency's change in position? What weight should courts give to Congress' failure to act?

II. SEARCHING FOR CONGRESSIONAL INTENT: AN AGENCY'S CHANGE IN POSITION

Courts tend to accept an agency's reversal of its policies because agencies have to regulate in light of changing technology and public attitudes.⁵² Courts must defer to an agency's interpretation of its enabling legislation even if it varies. In *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*,⁵³ the U.S. Supreme Court stated:

The fact that the agency has from time to time changed its in-

tacco. *See id.* at 171-76. The Smokeless Tobacco Act provides a "detailed scheme" which "evidences [Congress'] intent to retain authority over regulation of smokeless tobacco." *See id.* at 175. The Alcohol, Drug Abuse, and Mental Health Reorganization Act focuses on state regulation in preventing minors from gaining access to tobacco. *See id.*

50. *Id.* at 176.

51. *See* Kenneth Culp Davis & Richard J. Pierce, Jr., 3 ADMINISTRATIVE LAW TREATISE §§ 17.1, 17.4 (3d ed. 1994 & Supp. 1998) (noting that conferring broad policymaking power on unelected bureaucrats raises serious questions and that courts lack political legitimacy).

52. *See, e.g.,* *Rust v. Sullivan*, 500 U.S. 173, 174 (1991) (noting that agencies are allowed to adapt rules and policies to changes in circumstances); *National Muffler Dealers Ass'n, Inc. v. U.S.*, 440 U.S. 472, 485 (1979) ("We would be reluctant to adopt the rigid view that an agency may not alter its interpretation in light of administrative experience."); *Committee for Effective Cellular Rules v. FCC*, 53 F.3d 1309, 1317 (D.C. Cir. 1995) ("This flexibility is necessary to allow agencies . . . to respond to rapidly changing '[t]echnological, commercial, and societal aspects of the . . . industry' as they fulfill their delegated duties.") (quoting *Rainbow Broad. v. FCC*, 949 F.2d 405, 409 (D.C. Cir. 1991)); *Peoples Fed. Sav. & Loan Ass'n v. Commissioner*, 948 F.2d 289, 302 (6th Cir. 1991) (stating that the IRS "should have the freedom to alter its interpretations in light of its experience and perception of congressional movement").

53. 467 U.S. 837 (1984).

terpretation of the term 'source' does not, as respondents argue, lead us to conclude that no deference should be accorded the agency's interpretation of the statute. An initial agency interpretation is not instantly carved in stone. On the contrary, the agency, to engage in informed rulemaking, must consider varying interpretations and the wisdom of its policy on a continuing basis.⁵⁴

In *Rust v. Sullivan*,⁵⁵ the Supreme Court held that the U.S. Department of Health and Human Services ("HHS") provided a reasoned basis for its change of policy and thus acted within the authority granted by its enabling act.⁵⁶ HHS issued regulations requiring that clinics receiving federal funds may not counsel patients regarding abortion or refer patients to abortion providers; engage in activities, such as lobbying, that promote abortion; or operate a clinic which is not "physically and financially separate" from abortion-related activities.⁵⁷ Prior to the promulgation of these regulations, the agency allowed "nondirective counseling and referral for abortion."⁵⁸ The court held that, because the enabling act was ambiguous⁵⁹ and HHS gave a "reasoned analysis" of the basis for the regulations, the agency acted within the bounds of its enabling statute.⁶⁰ *Rust v. Sullivan* raised the question of when an agency explanation is suffi-

54. *Id.* at 863-64. *But see* Motor Vehicle Mfg. Ass'n v. State Farm Mut. Ins. Co., 463 U.S. 29, 42 (1983) ("[A]n agency changing its course by rescinding a rule is obligated to supply a reasoned analysis for the change beyond that which may be required when an agency does not act in the first instance."). The Court held that the agency had acted arbitrarily and capriciously because it failed to supply the requisite "reasoned analysis" in the case. *See id.*

55. 500 U.S. 173 (1991).

56. *See id.* at 187. Four years earlier, the Court noted in a footnote to *INS v. Cardoza-Fonseca* that "[a]n agency interpretation of a relevant provision which conflicts with the agency's earlier interpretation is 'entitled to considerably less deference' than a consistently held agency view." 480 U.S. 421, 447 n.30 (1987) (citation omitted). Some circuit courts have followed *Cardoza-Fonseca*. *See, e.g.,* Wolpaw v. Commissioner, 47 F.3d 787, 790 (6th Cir. 1995). *Rust* rejected this position. *See Rust*, 500 U.S. at 185-87.

57. *See Rust*, 500 U.S. at 179-181.

58. *See id.* at 186.

59. Title X, Section 1008 of the Public Health Service Act states, "None of the funds appropriated under this subchapter shall be used in programs where abortion is a method of family planning." *Id.* at 184. *See also* Pub. L. No. 57-242, 58 Stat. 682 (1994) (codified as amended at 42 U.S.C. § 300a-6 (1994)).

60. *Id.* at 187. The agency defended its position by stating that the new regulations implement more effectively the intent of the enabling act, reflect client experience with the former policy, and, perhaps most interestingly, are in accord with a shift in public attitude. *See id.* The final rationale appears disturbingly legislative in nature.

cient. How readily do or should courts accept rationalizations not backed by solid evidence? When should an agency have the power to make sweeping policy decisions through reinterpretation of its enabling act?

Following *Rust*, circuit courts have deferred to agency interpretations of ambiguous enabling legislation. The Tenth Circuit, in *Public Lands Council v. Babbitt*,⁶¹ upheld the Secretary of the Interior's reversal of a policy it had enforced for sixty-one years.⁶² The new regulation claimed title for the government to range improvements such as fences, contrary to the agency's prior position.⁶³ The court noted that an agency need only provide a "reasoned analysis" when the enabling act is ambiguous.⁶⁴ If the statutory language is clear and "supports the new regulation," the court can decide the issue without proceeding to step two of the *Chevron* analysis.⁶⁵ The court accepted the agency's rationale based on efficient administration of its enabling acts, unified procedures between the Bureau of Land Management and the Forest Service, and avoiding a confusing provision in the prior rule.⁶⁶ Similarly, the Second Circuit in *Himes v. Shalala*⁶⁷ accepted an agency's change in position due to an amendment of one section of its enabling statute.⁶⁸

Rust v. Sullivan does not directly govern the Fourth Circuit's analysis in *Brown & Williamson*. The dissent cited *Rust* and stated that the agency had a reasoned basis for changing its policy in light of recent information regarding the effect of smoking on public health.⁶⁹ The majority, however, decided the case based on step one of the *Chevron* analysis: Congress unambiguously withheld from the FDA the jurisdiction to regulate to-

61. 154 F.3d 1160 (10th Cir. 1998).

62. *Id.* at 1178-79 n.13.

63. *See id.* at 1165-66. The Secretary of the Interior adopted other regulations related to the management of grazing rights. *See id.* First, it redefined "grazing preference" to include use of the land for purposes other than grazing. *See id.* at 1165. Second, the agency no longer required that the holder of a grazing preference work in the "livestock business." *See id.* Third, the agency authorized conservation use of grazing permit. *See id.* The Secretary implements the Taylor Grazing Act of 1934, the Federal Lands Policy and Management Act of 1976, and the Public Rangelands Improvement Act of 1978. *See id.* at 1163-64.

64. *See id.* at 1180.

65. *See id.* at 1179-80.

66. *See id.* at 1178.

67. 999 F.2d 684 (2d Cir. 1993).

68. *See id.* at 690. The court appeared particularly lenient in this case because the agency's policy did not "represent an inexplicable, sharp break from the past." *Id.*

69. *See Brown & Williamson Tobacco Corp. v. FDA*, 153 F.3d 155, 180 (4th Cir. 1998) (Hall, J., dissenting) ("[I]t is now a scientific certainty that nicotine is extremely addictive.").

bacco.⁷⁰ The Fourth Circuit interpreted *Chevron* and *Rust* consistently with the Tenth Circuit's interpretation in *Public Lands Council*.

If the Fourth Circuit found the enabling legislation ambiguous, it would be compelled to defer to the FDA's change in position as long as the FDA reasonably interpreted the statute.⁷¹ By finding, however, that Congress acquiesced to the FDA's statements regarding its lack of jurisdiction and thus intended that result, the court held the FDA to its initial position.⁷² The district court stated that acquiescence to the prior policy does not suggest that Congress would oppose a change in the policy.⁷³ Congress could hardly logically support both a policy and its opposite, but it could interpret an agency's discretion broadly enough to encompass both possibilities. Congress may, moreover, appreciate the changes that underlie an agency's reversal and thus alter its previous viewpoint. This second possibility, however, should require an amendment of the agency's enabling act.

III. SUBSEQUENT LEGISLATIVE HISTORY: A "POOR BEACON"?⁷⁴

The Fourth Circuit relied on subsequent legislative history in two ways. First, because Congress failed to pass legislation overturning the FDA's long-standing interpretation, the court found that Congress acquiesced to that position.⁷⁵ Second, the court discerned the intent of the Congress which enacted the FDCA through examining tobacco-specific

70. *See id.* at 161-62. The court reasoned:

It is only if the intent of Congress is ambiguous that we defer to a permissible interpretation by the agency. And we note, with emphasis, that the Supreme Court has stated that "[a] precondition to deference under *Chevron* is a congressional delegation of administrative authority." Accordingly, no deference is due the FDA's construction of the Act unless it is acting within the bounds of its congressionally-established authority. If the court can ascertain Congress' intent on a particular question by applying the traditional rules of statutory construction, then it must give effect to that intent. . . . In fact, the Court instructs that the inquiry ends with the statutory language when the language is unambiguous

Id. at 161-62 (citations omitted).

71. *See id.* at 161.

72. *See id.* at 170-71.

73. *See Coyne Beahm, Inc. v. FDA*, 966 F. Supp. 1374, 1383 (M.D.N.C. 1997), *rev'd sub nom. Brown & Williamson Tobacco Corp. v. FDA*, 153 F.3d 155 (4th Cir. 1998), and *petition for cert. filed* 67 U.S.L.W. 3484 (U.S. Jan 19, 1999) (No. 98-1152).

74. *Zuber v. Allen*, 396 U.S. 168, 185 (1969) ("Legislative silence is a poor beacon to follow in discerning the proper statutory route.").

75. *See Brown & Williamson*, 153 F.3d at 171.

legislation passed by later Congresses.⁷⁶ Both of these methods have received substantial criticism.

"Subsequent legislative history" has been described as "an oxymoron."⁷⁷ Discerning the intent of one Congress through the actions of a later Congress lacks reliability. Finding intent in Congress' failure to act raises still more concerns. What is the message in the silence? Nevertheless, courts have found such history difficult to resist. On this issue, Professor Tribe wrote:

Indeed, to decree that we must ignore legal silences altogether is no more plausible than to command that we ignore the uncovered parts of a canvas or the pauses in a sonata. As Susan Sontag reminds us, '[t]o look at something which is "empty" is still to be looking, still to be seeing something—if only the ghosts of one's own expectations . . . [.] Silence remains, inescapably, a form of speech . . . and an element in a dialogue.'⁷⁸

A. *Legislative Acquiescence*

"[W]hen an administrative interpretation of a statute has been called to the legislature's attention, there is reason to regard the failure of the legislature to act as evidence of the correctness of the interpretation."⁷⁹ The Supreme Court has upheld legislative acquiescence in some circumstances. *Bob Jones University v. United States*⁸⁰ addressed an IRS revenue ruling which denied tax-exempt status to private schools that discriminate on the basis of race.⁸¹ Congress rejected thirteen bills in twelve years which would have overturned the ruling, and it amended section 501(c)(3) of the IRS Code—the statutory section at issue—during that time period.⁸²

76. See *id.* at 178.

77. *Strickland v. Commissioner, Me. Dep't of Human Servs.*, 48 F.3d 12, 18 (1st Cir. 1994).

78. LAURENCE H. TRIBE, *CONSTITUTIONAL CHOICES* 35-36 (1985) (citing *The Aesthetics of Silence*, in *STYLES OF RADIANCE WILL*, 810, 811 (1969)).

79. *Lanehart v. Horner*, 818 F.2d 1574, 1579 (Fed. Cir. 1987) (citations omitted).

80. 461 U.S. 574 (1983).

81. See *id.* at 578. "Based on the 'national policy to discourage racial discrimination in education,' the IRS ruled that 'a private school not having a racially nondiscriminatory policy as to students is not "charitable" within the common law concepts reflected in sections 170 and 501(c)(3) of the Code.'" *Id.* at 579 (quoting Rev. Rul. 71-447, 1971-2 C.B. 230, 231).

82. See *id.* at 599-600. Congress held "exhaustive hearings" beginning a month after the publication of the revenue ruling. See *id.* at 600. This is no "ordinary claim of legislative acquiescence." *Id.*

The Supreme Court explained, "Few issues have been the subject of more vigorous and widespread debate and discussion in and out of Congress than those related to racial segregation in education."⁸³

Two years later, the Supreme Court again found legislative acquiescence in the case *United States v. Riverside Bayview Homes, Inc.*⁸⁴ *Riverside* addressed the Corps of Engineer's interpretation of the Clean Air Act to cover wetlands.⁸⁵ The Court noted that Congress amended the Clean Water Act and debated the scope of wetlands protection under the Act in both houses.⁸⁶ As the Act was finally passed, however, it did not limit the Corps' jurisdiction over wetlands.⁸⁷

Bob Jones and *Riverside* both involve high-profile issues.⁸⁸ Circuit courts have hesitated to extend legislative acquiescence to topics receiving less attention from Congress and the public.⁸⁹ The D.C. Circuit, in fact, has "consistently required *express* congressional approval of an administrative interpretation if it is to be viewed as statutorily mandated."⁹⁰ Legislative acquiescence forms just one of various tools of statutory construction;

83. *Id.* at 599. Compare *Lanehart*, 818 F.2d at 1579. The *Lanehart* court failed to find legislative acquiescence where the issue—overtime pay for firefighters—did not involve "considerable public controversy" and Congress lacked "prolonged and acute awareness." *Id.* "Ordinarily, and quite appropriately, courts are slow to attribute significance to the failure of Congress to act on particular legislation." *Id.*

84. 474 U.S. 121 (1985).

85. See *id.* at 123. The Corps promulgated a rule defining "navigable waters" as including "freshwater wetlands." *Id.* at 123-24. The Corps required a permit to discharge fill into "waters of the United States." *Id.* at 123.

86. See *id.* at 136.

87. See *id.* at 136-37; see also *NLRB v. Bell Aerospace Co.*, 416 U.S. 267, 282-84 (1974) (finding acquiescence where a Senate and House conference committee report explained that Congress did not overturn the agency interpretation in re-enacting legislation).

88. In addition to issues of public controversy, the Supreme Court has also found acquiescence in cases of national security, "where congressional silence is not to be equated with congressional disapproval." *Haig v. Agee*, 453 U.S. 280, 291 (1981).

89. See *Peoples Fed. Savs. & Loan Ass'n v. Commissioner*, 948 F.2d 289, 301 (6th Cir. 1991) (declining to find acquiescence where "the apparent degree of scrutiny [by Congress] . . . is zero"); *Lanehart v. Horner*, 818 F.2d 1574, 1579 (Fed. Cir. 1987) (finding that the re-enactment doctrine does not apply where Congress did not consider the specific issue at hand). Compare *Michigan United Conservation Clubs v. Lujan*, 949 F.2d 202, 210 (6th Cir. 1991) (finding that, where agency delayed implementation of regulation to allow Congress to debate legislation, Congress' failure to pass the legislation suggests ratification of the agency policy).

90. *AFL-CIO v. Brock*, 835 F.2d 912, 915 (D.C. Cir. 1987). "The district court mistakenly relied on the familiar notion that Congress is presumed to be aware of administrative interpretations of a statute or regulation when it adopts such language in a statute." *Id.* at 916, n.6.

its application seems to depend on the strength of the agency's position overall. Courts rely on it in addition to other factors but do not tend to give it considerable weight.⁹¹ Where the regulatory scheme is complex⁹² or the enabling act is clear,⁹³ courts are less likely to find acquiescence.

Circuit courts have criticized the re-enactment doctrine⁹⁴ for two primary reasons: the negative impact on agency decision-making and lack of reliability. One court explains, "The re-enactment doctrine, if rigidly applied, becomes a trap for agencies. . . . [T]he misuse of this doctrine may drastically curtail the scope and materially impair the flexibility of administration actions."⁹⁵ Additionally, congressional inaction "may indicate no more than the press of other business."⁹⁶ Inaction does not con-

91. See *Strickland v. Commissioner, Me. Dept. of Human Servs.*, 48 F.3d 12, 19 (1st Cir. 1995) ("[T]he solitary reference to which appellants cling is too slender a reed to be accorded controlling weight under the totality of the circumstances that obtain here."); *Sweet Home Chapter v. Babbitt*, 17 F.3d 1463, 1471 (D.C. Cir. 1994) ("We conclude that the acquiescence-by-reenactment rule is not applicable to a situation where the regulations violate the original statutory language and where Congress' decision not to amend the relevant statutory provisions evidently stems from a belief that the provisions have been clear all along."), *rev'd*, 515 U.S. 687 (1995); *Michigan United*, 949 F.2d at 210 ("[W]hile post-enactment developments cannot be accorded the weight of contemporary legislative history, and Congress' failure to disapprove a regulation is not dispositive of congressional intent, the district court would be remiss if it ignored evidence that implies congressional intent."); *Massachusetts v. Secretary of Health & Human Servs.*, 899 F.2d 53, 61 (1st Cir. 1990) ("Although appellees have stated a strong case for congressional acquiescence, the ratification of one agency policy by Congress does not preclude a change in that policy."), *vacated by Sullivan v. Massachusetts*, 500 U.S. 949 (1991).

92. See *Bell Fed. Sav. & Loan Ass'n v. Commissioner*, 40 F.3d 224, 230 (7th Cir. 1994) ("The regulations and statutes involved in this area are too complex for us to venture to assume Congress's intent through its silence.").

93. See *Mississippi Poultry Ass'n v. Madigan*, 992 F.2d 1359, 1364-65 (5th Cir. 1993) (finding that Congress "is not required to respond to the Agency's disregard of unequivocally expressed congressional intent by amending a statute that is both clear and unambiguous on its face").

94. The re-enactment doctrine, closely related to legislative acquiescence, provides that, if Congress re-enacts a provision with knowledge of an administrative interpretation, and does not revise or repeal that interpretation, Congress has acquiesced to the agency's position. See *NLRB v. Bell Aerospace Co.*, 416 U.S. 267, 275 (1974) (citing *Peoples Fed. Sav. & Loan Ass'n v. Commissioner*, 948 F.2d 289, 300-01 (6th Cir. 1991)). The Sixth Circuit stated, "[A]n important consideration in the application of the re-enactment doctrine is 'the degree of scrutiny Congress has devoted to the regulation during subsequent re-enactments of the statute.'" *Peoples*, 948 F.2d at 301 (quoting *National Muffler Dealers Ass'n v. United States*, 440 U.S. 472, 477 (1979)).

95. *Peoples*, 948 F.2d at 302.

96. *Sweet Home*, 17 F.3d at 1469; see also *Arnold Tours, Inc. v. Camp*, 472 F.2d 427, 437 (1st Cir. 1972). That court observed:

tain the same guaranties as action—debate in both houses, passage by both houses, signature by the President.⁹⁷ Legislative acquiescence allows Congress to change the law without any political accountability.⁹⁸

Legislative acquiescence, moreover, upholds an agency's policy choice and prevents a court from making that judgment; courts do not generally use it to choose between two agency positions. The U.S. Supreme Court has explained:

We have held that "the construction of a statute by those charged with its execution should be followed unless there are compelling indications that it is wrong, especially when Congress has refused to alter the administrative construction." Such deference "is particularly appropriate where, as here, an agency's interpretation involves issues of considerable public controversy, and Congress has not acted to correct any misperception of its statutory objectives."⁹⁹

We cannot determine whether any committee or subcommittee of Congress rejected, on the merits, the proposal to overturn the Comptroller's ruling that national banks could engage in the travel agency business. It may well have been that this ruling was simply viewed as an inconsequential aberration which would probably involve very few national banks and hence was not deserving of legislative attention.

Id.

97. *Cf.* *Central Bank v. First Interstate Bank*, 511 U.S. 164, 186 (1994) ("Congressional inaction cannot amend a duly enacted statute."); *Strickland v. Commissioner, Me. Dep't of Human Servs.*, 48 F.3d 12, 18 (1st Cir. 1995) (noting that Congress cannot amend a statute merely by inserting a proposed change in a unicameral or bicameral report).

98. Professor Tribe explained:

[R]eading in the "silence of Congress" an indication of *its* "will" represents an attempt by judges to disclaim responsibility for altering the legal landscape by passing the buck to Congress. . . . Worse still, Congress itself may conspire in this buck-passing—for, having said nothing, its members are free in turn to point right back to the courts when called upon to defend what the courts claim that Congress has, by its silence, brought to pass.

TRIBE, *supra* note 78, at 33-34. See generally DAVID SCHOENBROD, *POWER WITHOUT RESPONSIBILITY: HOW CONGRESS ABUSES THE PEOPLE THROUGH DELEGATION* (1993) (criticizing agency power).

99. *CBS, Inc. v. FCC*, 453 U.S. 367, 382 (1981) (citations omitted). In *NLRB v. Bell Aerospace Co.*, the Court also observed:

[A] court may accord great weight to the longstanding interpretation placed on a statute by an agency charged with its administration. This is especially so where Congress has re-enacted the statute without pertinent

In contrast, the Fourth Circuit in *Brown & Williamson* relied on legislative acquiescence to uphold a former FDA policy over a current FDA policy.¹⁰⁰ At least one circuit court has rejected the application of legislative acquiescence to challenge an agency's reversal. Before the U.S. Supreme Court decided *Rust*, the First Circuit addressed the same abortion regulations.¹⁰¹ The First Circuit explained that "ratification of the previous agency interpretation . . . would not indicate that the secretary's new policy exceeds his statutory authority."¹⁰²

B. Did Congress Acquiesce to the FDA's Prior Position on Tobacco?

After discussing *Bob Jones University*, the Fourth Circuit, in *Brown v. Williamson*, stated, "We are of opinion that the matter before us presents an equally strong case of legislative acquiescence."¹⁰³ The district court, however, had pointed out two flaws with that very conclusion. First, though Congress has considered fifteen bills which would have granted the FDA jurisdiction over tobacco, not one was debated on the House or Senate floor.¹⁰⁴ Second, the *Brown & Williamson* case, unlike either *Bob Jones University* or *Riverside Bayview Homes*, involves agency inaction—the FDA's failure to assert jurisdiction during a period of sixty years—rather than agency action.¹⁰⁵

In *Bob Jones University*, the Supreme Court found acquiescence although the thirteen bills seeking to overturn the IRS Revenue Ruling

change. In these circumstances, congressional failure to revise or repeal the agency's interpretation is persuasive evidence that the interpretation is the one intended by Congress.

416 U.S. 267, 274-75 (1974).

100. See *Brown & Williamson Tobacco Corp. v. FDA*, 153 F.3d 155, 170-71 (4th Cir. 1998).

101. See *Massachusetts v. Secretary of Health & Human Servs.*, 899 F.2d 53 (1st Cir. 1990), *vacated by Sullivan v. Massachusetts*, 500 U.S. 949 (1991).

102. *Id.* at 61. See also *Bell Fed. Savs. & Loan Ass'n v. Commissioner*, 40 F.3d 224, 229 (7th Cir. 1994) ("Flexibility, too, is important as it constitutes one of the basic precepts undergirding administrative law; to require an Act of Congress to undo an agency's initial interpretation of a statute would largely eviscerate the usefulness of this organic body of law.").

103. 153 F.3d at 170.

104. See *Coyne Beahm, Inc. v. FDA*, 966 F. Supp. 1374, 1383 (M.D.N.C. 1996), *rev'd sub nom. Brown & Williamson Tobacco Corp. v. FDA*, 153 F.3d 155 (4th Cir. 1998), and *petition for cert. filed*, 67 U.S.L.W. 3484 (U.S. Jan. 19, 1999) (No. 98-1152). In *United States v. Riverside Bayview Homes*, 474 U.S. 121 (1985), the legislation at issue was reported out of committee. See *id.* at 121.

105. See *Coyne*, 966 F. Supp. at 1383.

never left the committee.¹⁰⁶ In that case, however, numerous committee meetings took place discussing that precise issue and Congress re-enacted the relevant statutory section with no changes.¹⁰⁷ *Brown & Williamson* discussed several statements by the FDA to congressional committees between 1963 and 1989 denying its jurisdiction over tobacco.¹⁰⁸ Some of these statements were made during hearings regarding tobacco legislation.¹⁰⁹ The question remains, however, whether “few issues have been the subject of more vigorous and widespread debate” than the FDA’s jurisdiction over tobacco and whether Congress has been “acutely aware” of the issue.¹¹⁰ Congress has passed significant legislation on the issue of tobacco regulation, but those bills reported out of committee do not specifically address the FDA’s jurisdiction.¹¹¹ Moreover, Congress did not amend the FDCA to reflect its position on tobacco regulation.

The district court’s second criticism also raises serious concerns. According to the Fourth Circuit, Congress acquiesced to the FDA’s *failure* to promulgate and enforce tobacco regulations.¹¹² This increases the level of ambiguity as to Congress’ intent. Courts have admitted the difficulties inherent in interpreting congressional silence;¹¹³ here Congress failed to act based on the agency’s failure to act.¹¹⁴

On the other hand, the FDA explained its judgment to Congress. Congress perhaps acquiesced to the FDA’s position as described in congressional committee hearings. The Fourth Circuit does not address, however, whether the doctrine of acquiescence should have equal force with respect to a policy which did not receive any administrative process.¹¹⁵ If Congress had to dig through committee reports to discover the FDA’s position, it seems less likely that Congress has been “acutely aware” of the issue. Moreover, committee reports themselves have been criticized as a

106. See *Bob Jones Univ. v. U.S.*, 461 U.S. 574, 600 (1983).

107. See *id.*

108. See *Brown & Williamson*, 153 F.3d at 168-70.

109. See *id.*

110. *Bob Jones Univ.*, 461 U.S. at 509.

111. See *Brown & Williamson*, 153 F.3d at 170.

112. See *id.* at 168-71.

113. See *Bob Jones Univ.*, 461 U.S. at 600 (“Ordinarily, and quite appropriately, courts are slow to attribute significance to the failure of Congress to act on particular legislation.”).

114. The First Circuit distinguished between relying on acquiescence to show an agency has authority and to prove an agency lacks authority. See *Massachusetts v. Secretary of Health & Human Servs.*, 899 F.2d 53, 61 (1st Cir. 1990).

115. Compare *United States v. Riverside Bayview Homes*, 474 U.S. 121, 138-39 (1985) (holding subsequent amendments to the Clean Water Act indicated that the rules promulgated by the Corps of Engineers implemented congressional policy).

source of subsequent legislative history.¹¹⁶

C. *Subsequent Legislation*

The Fourth Circuit reviewed tobacco-related legislation passed after the FDCA to determine congressional intent regarding the FDCA. The Supreme Court has routinely criticized this use of subsequent legislative history: “[T]he views of a subsequent Congress form a hazardous basis for inferring the intent of an earlier one.”¹¹⁷ The Court takes this position for two reasons. First, “it is the function of the courts and not the Legislature, much less a committee of one House of the Legislature, to say what an enacted statute means.”¹¹⁸ Second, subsequent legislative history does not form a reliable guide to intent. The Supreme Court stated, “Such history does not bear strong indicia of reliability . . . because as time passes memories fade and a person’s perception of his earlier intention may change.”¹¹⁹ This history may also support more than one conclusion.¹²⁰ Unenacted legislation¹²¹ and committee reports¹²² form particularly suspect

116. See *Consumer Prod. Safety Comm’n v. GTE Sylvania*, 447 U.S. 102, 118 (1980).

117. *United States v. Price*, 361 U.S. 304, 313 (1960); see also *Central Bank v. First Interstate Bank*, 511 U.S. 164, 185 (1993) (“We have observed on more than one occasion that the interpretation given by one Congress (or a committee or Member thereof) to an earlier statute is of little assistance in discerning the meaning of that statute.”)

118. *Pierce v. Underwood*, 487 U.S. 552, 566 (1988); see also *In re Conner Home Sales Corp.*, 190 B.R. 255, 260 (E.D.N.C. 1995) (explaining that relying on subsequent legislative history of an amendment would “in essence allow the legislative history to be given retroactive application”).

119. *Consumer Prod. Safety*, 447 U.S. at 118 n.13; see also *Pennsylvania Med. Soc’y v. Snider*, 29 F.3d 886, 898 (3d Cir. 1994) (“Post-enactment legislative history is not a reliable source for guidance.”)

120. See *Pension Benefit Guar. Corp. v. LTV Corp.*, 496 U.S. 633, 650 (1990); see also *Central Bank*, 511 U.S. at 187 (“Several equally tenable inferences may be drawn from [congressional] inaction.”).

121. See *Pension Benefit Guar.*, 496 U.S. at 650. One commentator noted:

[J]ustifying an interpretation of a prior enactment by pointing to what a subsequent Congress did not enact seems incompatible with our constitutional structure. Although silence contemporary with, or antecedent to, the legislative speech one is construing adheres to and delimits that speech—thus furnishing potentially relevant context—a later silence shares no such boundary with that speech.

TRIBE, *supra* note 78, at 41 (footnote omitted). Compare these observations with the earlier discussion of legislative acquiescence. See *supra* Part III.A. and accompanying notes.

122. See *Consumer Prod. Safety*, 447 U.S. at 118 (refusing to give weight to a statement of the conference committee). Compare *Archer-Daniels-Midland Co. v.*

subsequent legislative history.

The Court has, however, considered subsequent legislation in some circumstances. In particular, where subsequent legislation makes clear the intent of prior legislation, the Court has given it "great weight."¹²³ In *Red Lion Broadcasting Co. v. FCC*,¹²⁴ the Court reviewed an FCC regulation involving the "fairness doctrine"—the requirement that broadcasters cover both sides of an issue.¹²⁵ In particular, the regulation required that individuals have an opportunity to respond to negative publicity.¹²⁶ Congress had amended the FCC's enabling statute, noting the "obligation imposed upon [broadcasters] under this Act . . . to afford reasonable opportunity for the discussion of conflicting views on issues of public importance."¹²⁷

The broad policies which the Fourth Circuit in *Brown & Williamson* discerns from the Federal Cigarette Labeling and Advertising Act differ significantly from the clear message sent in *Red Lion*.¹²⁸ The tobacco legislation does not mention the FDA's jurisdiction. Rather, the Fourth Circuit found that its purposes—regulation based on economic policy and continued legality of tobacco—precluded regulation by the FDA.¹²⁹ Moreover, *Red Lion*, unlike *Brown & Williamson*, addressed the amendment of the agency's enabling act.¹³⁰ Congress makes a stronger statement when it amends the legislation which empowers the agency.

The Fourth Circuit also noted that a congressional committee considered a role for the FDA in tobacco regulation.¹³¹ As enacted, the FCLAA did not contain this provision.¹³² The court stated that this committee report shed light on Congress's intent in enacting the FDCA.¹³³

U.S., 37 F.3d 321, 324 (7th Cir. 1994) (finding that "the slogan that Congress votes on the bill and not on the report strikes us as pretty empty").

123. *Red Lion Broad. Co. v. FCC*, 395 U.S. 367, 380-81 (1969).

124. 395 U.S. 367 (1969).

125. *See id.* at 369.

126. *See id.* at 369-70.

127. *Id.* at 380.

128. *See* FDA's Petition for Writ of Certiorari, *FDA v. Brown & Williamson Tobacco Corp.*, (No. 98-1152), available in Food & Drug Administration, *Children & Tobacco: Court Opinions and Briefs* (visited Mar. 31, 1999) <<http://www.fda.gov/opacom/campaigns/tobacco/tobcourt.html>> (explaining that the statutes discussed by the Fourth Circuit "address narrow issues" and do not exclude the FDA from regulating tobacco).

129. *Brown & Williamson Tobacco Corp. v. FDA*, 153 F.3d 155, 172-73 (4th Cir. 1998).

130. *See Red Lion*, 395 U.S. at 380-81.

131. *See Brown & Williamson*, 153 F.3d at 172-73.

132. *See id.*

133. *See id.*

The Supreme Court, however, has criticized the reliability of post-enactment committee reports.¹³⁴

IV. SCOPE OF REVIEW: "HOW CLEAR IS CLEAR?"¹³⁵

*Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc.*¹³⁶ set forth the standard of review for an agency's interpretation of its enabling act:

When a court reviews an agency's construction of the statute which it administers, it is confronted with two questions. First, always, is the question whether Congress has directly spoken to the precise question at issue. If the intent of Congress is clear, that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress. If, however, the court determines Congress has not directly addressed the precise question at issue, the court does not simply impose its own construction on the statute, as would be necessary in the absence of an administrative interpretation. Rather, if the statute is silent or ambiguous with respect to the specific issue, the question for the court is whether the agency's answer is based on a permissible construction of the statute.¹³⁷

134. See *Consumer Prod. Safety Comm'n v. GTE Sylvania*, 447 U.S. 102, 118 (1980). The FDA's enabling act, the FDCA, was passed in 1938. See Act of 1938, ch. 675, 52 Stat. 140 (1938) (codified as amended at U.S.C. §§ 301-394 (1994)). The Federal Cigarette Labeling and Advertising Act was enacted in 1965. See Pub. L. No. 89-92, 79 Stat. 283 (1965) (codified as amended at 15 U.S.C. §§ 1331-1341 (1994)). The FDA cited the 1976 Medical Device Act, an amendment to the FDCA, in asserting jurisdiction. See *Coyne Beahm, Inc. v. FDA*, 966 F. Supp. 1374, 1396 & 1396 n.18 (M.D.N.C. 1997), *rev'd sub nom. Brown & Williamson Tobacco Corp. v. FDA*, 153 F.3d 155 (4th Cir. 1998), *and petition for cert. filed*, 67 U.S.L.W. 3484 (U.S. Jan. 19, 1999) (No. 98-1152). This pattern could be construed as addressing former legislative history. This would seem, however, to raise similar issues. Looking to one Congress for the intent of another is always problematic. See *Western Fuels-Utah, Inc. v. Lujan*, 895 F.2d 780, 786-87 n.10 (D.C. Cir. 1990).

135. Antonin Scalia, *Judicial Deference To Administrative Interpretations of Law*, 1989 DUKE L.J. 511, 520. Justice Scalia wrote:

Here, of course, is the chink in Chevron's armor—the ambiguity that prevents it from being an absolutely clear guide to future judicial decisions (though still a better one than what it supplanted). How clear is clear? It is here, if Chevron is not abandoned, that the future battles over acceptance of agency interpretations of law will be fought.

Id. at 520-21.

136. 467 U.S. 837 (1984).

137. *Id.* at 842-43 (footnotes omitted).

This has been described as the “*Chevron* two-step” analysis.¹³⁸ *Chevron* defers to the agency interpretation of an ambiguous issue because the agency, not the court, should make policy judgments.¹³⁹ Two administrative law experts explain, “When Congress enacts a statute to be administered by an agency, it has delegated to the agency resolution of all policy disputes that arise under that statute that Congress did not itself resolve.”¹⁴⁰

Commentators have questioned whether *Chevron* deference should apply when an agency interprets the scope of its own power:

Where the agency is to make policy itself, its power must be dominant. But where the agency derives the policy from some other source, it must do so correctly. It is the courts’ job to assure that it does so and hence courts are given dominance of interpretations of law, or derived policy. In the absence of such judicial power, the bureaucracy would be free to act in the derogation of the power properly exercised by these other institutions, particularly the legislatures.¹⁴¹

138. DAVIS & PIERCE, *supra* note 51, § 3.2.

139. The Court wrote:

Judges are not experts in the field, and are not part of either political branch of the Government. Courts must, in some cases, reconcile competing political interests, but not on the basis of the judges’ personal policy preferences. In contrast, an agency to which Congress has delegated policy-making responsibilities may, within the limits of that delegation, properly rely upon the incumbent administration’s views of wise policy to inform its judgments. While agencies are not directly accountable to the people, the Chief Executive is, and it is entirely appropriate for this political branch of the Government to make such policy choices—resolving the competing interests which Congress itself either inadvertently did not resolve, or intentionally left to be resolved by the agency charged with the administration of the statute in light of everyday realities.

When a challenge to an agency construction of a statutory provision, fairly conceptualized, really centers on the wisdom of the agency’s policy, rather than whether it is a reasonable choice within a gap left open by Congress, the challenge must fail. In such a case, federal judges—who have no constituency—have a duty to respect legitimate policy choices made by those who do. The responsibilities for assessing the wisdom of such policy choices and resolving the struggle between competing views of the public interest are not judicial ones: “Our constitution vests such responsibilities in the political branches.”

Chevron, 467 U.S. at 865-66.

140. DAVIS & PIERCE, *supra* note 51, § 3.3, at 114.

141. CHARLES H. KOCH, JR., ADMINISTRATIVE LAW AND PRACTICE § 12.32, at 251

The Supreme Court has provided some support for this approach. In *Adams Fruit Co. v. Barrett*,¹⁴² the Court noted, "Although agency determinations within the scope of delegated authority are entitled to deference, it is fundamental 'that an agency may not bootstrap itself into an area in which it has no jurisdiction.'"¹⁴³ Separating policy-making decisions from non-policy-making decisions does not, however, seem intuitive. In the facts of *Brown & Williamson*, for example, the FDA had broadened its jurisdiction through interpretation of its enabling legislation, but it also made a policy judgment based on its expertise and empirical data regarding the effect of tobacco on public health.

Chevron states that courts need only defer to agencies acting "within the limits of [their] delegation,"¹⁴⁴ which seems to suggest that a court consider the limits of agency power as a part of step one. If, however, those limits are not clear, the court must defer to an agency's reasonable interpretation. This marks a difference between the *Chevron* approach and the more independent review of *Adams Fruit*, as described above.

Buried in a footnote in *Chevron* is this instruction: "If a court, employing *traditional tools of statutory construction*, ascertains that Congress had an intention on the precise question at issue, that intention is the law and must be given effect."¹⁴⁵ *Chevron* does not include a definition of these traditional tools, and the Supreme Court has not made a definitive statement on this issue. And yet, how the Supreme Court and circuit courts define the traditional tools impacts administrative power,¹⁴⁶ because courts

(1997). Agencies are far better equipped than courts to make policy decisions due to their expertise and procedural possibilities. See *id.* § 12.31[3], at 241. Cf. Scalia, *supra* note 135, at 516-17. Scalia concludes that *Chevron*, even if not a "100% accurate estimation of modern congressional intent," clarifies the law by imposing a consistent rule of deference to agency decision-making. *Id.* "Congress now knows that the ambiguity it creates, whether intentionally or unintentionally, will be resolved, within the bounds of permissible interpretation, not by the courts but by a particular agency, whose policy biases will ordinarily be known." *Id.*

142. 494 U.S. 638 (1990).

143. *Id.* at 650 (citation omitted); see also *Hi-craft Clothing Co. v. NLRB*, 660 F.2d 910, 916 (3d Cir. 1981) ("The more intense scrutiny that is appropriate when the agency interprets its own authority may be grounded in the unspoken premise that government agencies have a tendency to swell, not shrink, and are likely to have an expansive view of their mission.").

144. *Chevron*, 467 U.S. at 865.

145. *Id.* at 843 n.9 (emphasis added).

146. DAVIS & PIERCE, *supra* note 51, § 3.6. The authors noted:

If reviewing courts are free to use any combination of the "traditional tools of statutory construction" they choose in the process of applying *Chevron* step one, few if any cases will reach *Chevron* step two. It is the

sift administrative interpretations through step one of *Chevron*. Interpretations which survive this first step will generally prevail on review. Interpretations remaining in the strainer of step one review will be discarded.

Justice Scalia has attempted to restrict the scope of *Chevron* step one. In a dissenting opinion to *INS v. Cardoza-Fonseca*,¹⁴⁷ he stated:

The Court first implies that courts may substitute their interpretation of a statute for that of an agency whenever, "[e]mploying traditional tools of statutory construction," they are able to reach a conclusion as to the proper interpretation of the statute. But this approach would make deference a doctrine of desperation, authorizing courts to defer only if they would otherwise be unable to construe the enactment at issue.¹⁴⁸

Justice Scalia also explained, "If *Chevron* is to have any meaning, then, congressional intent must be regarded as 'ambiguous' not just when no interpretation is even marginally better than any other, but rather when two or more reasonable, though not necessarily equally valid, interpretations exist."¹⁴⁹

The Supreme Court has not reached agreement as to the scope of the "traditional tools."¹⁵⁰ Advocates of the plain meaning rule would limit step one review to the language of the statute.¹⁵¹ On the other hand, some justices favor a broader review, including legislative history.¹⁵² Circuit courts, though they tend to defer more to agency interpretations,¹⁵³ have split on this issue.¹⁵⁴

very indeterminacy of the "traditional tools" that gives judges the discretion to make policy decisions through the process of statutory construction.

Id. at 129-30.

147. 480 U.S. 421 (1987).

148. *Id.* at 454.

149. Scalia, *supra* note 135, at 520.

150. DAVIS & PIERCE, *supra* note 51, § 3.6, at 126-27.

151. See *Public Citizen v. U.S. Dep't of Justice*, 491 U.S. 440, 469 (1989) (Kennedy, J., concurring) ("There is a ready starting point, which ought to serve also as a sufficient stopping point, for this kind of analysis: the plain language of the statute.").

152. See *Atkins v. Rivera*, 477 U.S. 154, 166 n.10 (1986) (Blackmun, J.) (considering subsequent legislative history as a part of step one review).

153. DAVIS & PIERCE, *supra* note 51, § 3.6, at 88 (Supp. 1998).

154. See, e.g., *Kofa v. INS*, 60 F.3d 1084, 1088 (4th Cir. 1995) ("If the statute is silent or ambiguous on the question, we next turn to the agency's interpretation."); *Arkansas AFL-CIO v. FCC*, 11 F.3d 1430, 1439 (8th Cir. 1993) (considering legislative history as a part of step one); *Security Bank Minn. v. Commissioner*, 994

V. CONCLUSION

The court in *Brown & Williamson* engaged in a detailed discussion of subsequent legislative history as a part of *Chevron* step one review. As discussed above, another circuit may have interpreted step one more narrowly and perhaps reached a different result. The case demonstrates the uncertainty inherent in the *Chevron* test.

Leaving "traditional tools" undefined poses two dangers. First, various circuit courts take differing views leading to inconsistent results. Second, the distinction between review and policy-making becomes less clear. In the gray area of step one, courts may impose their own policy through overly-thorough or overly-creative interpretations of statutory language.¹⁵⁵ Thus, the premise underlying *Chevron*—that agencies, not courts, should make policy—loses force. On the other hand, allowing judges to choose among a variety of possible tools gives them the flexibility to consider the strength of the particular evidence in the case. Judges may then tailor their use of traditional tools to each case.

The Supreme Court should address this issue. In considering the various traditional tools, the Court may want to evaluate the reliability of each tool as a method of discerning congressional intent. As discussed in Part III above, subsequent legislative history has received substantial criticism related to reliability.¹⁵⁶ Its place in the *Chevron* test seems dubious.

Despite the Fourth Circuit's reliance on subsequent legislative history in *Brown & Williamson*, it is unclear to what extent that history influenced its ultimate decision. The opinion includes a compelling discussion of why the FDA's assertion of jurisdiction over tobacco violates the structure and purpose of the FDCA. The crux of the problem is that the FDCA re-

F.2d 432, 436, 441 (8th Cir. 1993) (including legislative history but not subsequent legislative history in step one); *Western Fuels-Utah, Inc. v. Lujan*, 895 F.2d 780, 784, 786 (D.C. Cir. 1990) (employing traditional tools including legislative history but finding subsequent legislative history unreliable); *Massachusetts v. Secretary of Health & Human Servs.*, 899 F.2d 53, 58 (1st Cir. 1990) (stating factors in step one include subsequent legislative history), *rev'd*, *Rust v. Sullivan*, 500 U.S. 173 (1991); *Bridgestone/Firestone, Inc. v. Pension Benefit Guar. Corp.*, 892 F.2d 105, 110 n.5 (D.C. Cir. 1989) ("[T]he pronouncements of a subsequent Congress, here 13 years after the passage of ERISA, are notoriously unreliable indicators of the intent of Congress at the time of passage, and we give very little weight to such revisionist legislative history."); *ACLU v. FCC*, 823 F.2d 1554, 1568 (D.C. Cir. 1987) (holding legislative history may be considered where necessary but not to contradict "plain meaning" of statute); *Almendarez v. Barrett-Fisher Co.*, 762 F.2d 1275, 1278 (5th Cir. 1985) (finding legislative history useful in some circumstances to determine congressional intent).

155. See *DAVIS & PIERCE*, *supra* note 51, § 3.6 (Supp. 1998).

156. See *supra* Part II and accompanying notes.

quires an assurance of safety which the FDA, bound by jurisdictional limitations, cannot provide in the case of tobacco. In other words, the Fourth Circuit may not have required the discussion of subsequent tobacco legislation to tip the balance of evidence against the FDA.

Though *Brown & Williamson* raises troubling issues of judicial interference with agency policy-making, it also addresses agency interference with legislative policy-making. The FDA gathered an impressive set of statistics demonstrating that tobacco is killing Americans.¹⁵⁷ Perhaps its regulations are the solution, but Congress must first grant the FDA the authority to implement them. The FDA appears to have modeled its regulations on a bill in Congress which failed to pass.¹⁵⁸ Thus, not only did the agency arguably exceed the scope of its enabling legislation, it promulgated a policy rejected by Congress. When federal agencies like the FDA choose their own role outside of the authority delegated to them by Congress, our government becomes less representative and its branches less distinct.

On January 19, 1999, the Justice Department filed a petition for certiorari with the U.S. Supreme Court.¹⁵⁹ The FDA still has a hard fight ahead of it, and the tobacco industry may win this round.

Jill Schlick

157. See *supra* note 2 and accompanying text.

158. See *supra* note 5 and accompanying text.

159. See *Brown & Williamson Tobacco Corp. v. FDA*, 153 F.3d 155 (4th Cir. 1998), and *petition for cert. filed*, 67 U.S.L.W. 3484 (U.S. Jan. 19, 1999) (No. 98-1152). The petition has stayed the Fourth Circuit's decision, so the tobacco regulations, meanwhile, remain in effect. See *id.*

