

## IS TOBACCO A DRUG? ADMINISTRATIVE AGENCIES AS COMMON LAW COURTS

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*Professor Cass Sunstein argues that the FDA has the authority to regulate tobacco products. He considers the text of the Federal Food, Drug, and Cosmetic Act, which supports the FDA assertion, and the context of its enactment, which argues against the FDA. He resolves the tension between text and context in favor of FDA jurisdiction by turning to the emerging role of administrative agencies. In modern government, he contends, administrative agencies have become America's common law courts, with the power to adapt statutory regimes to new facts and new values when the underlying statute is ambiguous.*

*Professor Sunstein's Article, like the other pieces in this volume, was written after the United States District Court for the Middle District of North Carolina decided *Coyne Beahm v. FDA*,<sup>1</sup> but before a three judge panel of the United States Court of Appeals for the Fourth Circuit reversed that decision in *Brown & Williamson Tobacco Corp. v. FDA*.<sup>2</sup> In *Coyne Beahm*, the District Court held that the Federal Food, Drug, and Cosmetic Act authorized the FDA to regulate tobacco products, but not tobacco advertising. The Fourth Circuit rejected the District Court's jurisdictional ruling and invalidated the FDA's regulations in their entirety. The Clinton Administration has since requested an en banc rehearing before the Fourth Circuit.<sup>3</sup>*

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1. *Coyne Beahm, Inc. v. FDA*, 966 F. Supp. 1374 (M.D.N.C. 1997).
2. *Brown & Williamson Tobacco Corp. v. FDA*, Nos. 97-1604, 97-1581, 97-1606, 97-1614, 97-1605, 1998 WL 473320, at \*1 (4th Cir. Aug. 14, 1998).
3. See Appellees' Petition for Rehearing, *Brown & Williamson* (No. 97-1604).

## INTRODUCTION

*A. The Problem*

Does the Food and Drug Administration (FDA) have the authority to regulate tobacco and tobacco products? For a long time the FDA said that it did not. In 1996, the FDA changed its mind.<sup>4</sup> The principal issue raised by this assertion of authority is whether tobacco qualifies as a “drug.”

The issue is exceptionally important for both policy and law. It is important for policy because FDA authority over tobacco products is significant in itself, and also because a resolution of the case will provide the backdrop for statutory developments and for any continuing settlement negotiations between the tobacco industry and government.<sup>5</sup> Obviously new initiatives will be much affected by the existing power of the FDA. The question is important for law because it raises large issues not only about the Food, Drug, and Cosmetic Act (FDCA)<sup>6</sup> but also about the nature of statutory interpretation in the administrative state. Above all, these questions involve the respective roles of courts and administrative agencies in settling the meaning of federal law.

The statutory definition of “drug” reads as follows:

The term ‘drug’ means (A) articles recognized in the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; 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 animals; and (D)

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4. See Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents, 61 Fed. Reg. 44,396, 44,396 (1996) (codified at 21 C.F.R. pts. 801, 803, 804, 807, 820, 897 (1997)) [hereinafter FDA Regulations] (announcing regulation of the sale and promotion of cigarettes and smokeless tobacco to individuals under the age of eighteen).

5. These issues have received a great deal of attention in 1997 and 1998. See, e.g., *Excerpts From Agreement Between States and Tobacco Industry*, N.Y. TIMES, June 25, 1997, at B8 [hereinafter *Tobacco Settlement Excerpts*]; see also Barry Meier, *Talks Stall in Effort to Reach Tobacco Accord*, N.Y. TIMES, Aug. 5, 1998, at A14 (reporting that recent settlement negotiations have been abandoned).

6. Pub. L. No. 75-717, 52 Stat. 1040 (1938) (codified as amended at 21 U.S.C. §§ 301-397 (1994 & Supp. II 1997)). The FDCA replaced the Pure Food and Drug Act of June 30, 1906, Pub. L. No. 59-384, 34 Stat. 768 (codified as amended at 21 U.S.C. §§ 1-15 (1934)). See FDCA, § 902(a), 52 Stat. at 1059 (codified at 21 U.S.C. § 301 (1994)).

articles intended for use as a component of any article specified in clause (A), (B), or (C) of this paragraph.<sup>7</sup>

For purposes of the FDA's assertion of jurisdiction over tobacco, the key provision is clause (C), defining a drug as an "article[ ] . . . intended to affect the structure or any function of the body." Is tobacco such an article? I will be urging here that the FDA has the legal authority to answer this question either no or yes, and that its yes in 1996 is therefore lawful.<sup>8</sup>

### *B. Several Puzzles, and a Particular Dispute*

The dispute over the authority of the FDA<sup>9</sup> to regulate tobacco raises a number of questions—indeed, a remarkably high percentage

7. 21 U.S.C. § 321(g)(1) (1994). This subsection goes on to explain that a "food or dietary supplement . . . is not a drug solely because the label or the labeling contains such a claim." *Id.*

8. Ultimately, the FDA concluded that tobacco products are "combination products" involving drugs and devices. *See* FDA Regulations, *supra* note 4, at 44,403. I deal principally here with the issue of whether tobacco products qualify as "drugs." An affirmative answer is the basic predicate for FDA authority under the FDA's conclusion that cigarettes are "devices" because "the primary purpose of parts of the cigarette . . . is to effectuate the delivery of a carefully controlled amount of the nicotine to a site in the human body where it can be absorbed." Analysis Regarding the Food and Drug Administration's Jurisdiction Over Nicotine-Containing Cigarettes and Smokeless Tobacco Products, 60 Fed. Reg. 41,453, 41,522 (Aug. 11, 1995) [hereinafter FDA Jurisdictional Analysis]. The statutory definition of "device" includes:

[A]n instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is –

. . .

(3) 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 or man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.

21 U.S.C. § 321(h) (1994). I do not discuss this provision, except to suggest that if the FDA is authorized to define tobacco products as a drug, it is almost certainly authorized to treat such products as "combination products" subject to its device authority. *See* FDA Regulations, *supra* note 1, at 44,402 (explaining FDA jurisdiction over combination products).

9. In its remarkably broad opinion, completed as this Article went to press, the court of appeals invalidated the FDA regulation on various grounds. *See* *Brown & Williamson Tobacco Corp. v. FDA*, Nos. 97-1604, 97-1581, 97-1606, 97-1614, 97-1605, 1998 WL 473320, at \*1 (4th Cir. Aug. 14, 1998). The points made by the court are discussed at separate places below; I identify the elements of the court's analysis here, and also the places where these are addressed, and I make a few supplemental points.

The most striking feature of the court's approach is its failure to deal with the language of the key provision of the statute, an especially striking omission in light of the court's admission that the "literal" language of the statute strongly supports the FDA. *See* *Brown & Williamson*, 1998 WL 473320, at \*4. An especially disturbing feature of the court's opinion is the

of the set of questions raised in a whole semester of administrative law. Examples of these questions include the following: the power of an administrative agency to change its mind; the role of unenacted legislation; the extent to which subsequent legislative action can divest an agency of authority that it might otherwise have; the authority of an agency to define its own jurisdiction; and the law-interpreting power of agencies. The dispute over the FDA's authority could ultimately be resolved on these or any number of other grounds, and I will take up these and other questions in the course of the discussion.

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sheer number of arguments invoked on behalf of its conclusion; the court gives no sense of which of those arguments are necessary, or sufficient, for the outcome. In any case the following are the principal points.

First, the court suggested that the FDA's view was entitled to less than the usual level of deference because it involved a determination of its own jurisdiction. *See Brown & Williamson*, 1998 WL 473320, at \*3. Even if this suggestion is correct, the FDA should probably prevail under the narrow rationale urged below, in Part V.C.1.

Second, the court found "intrinsic evidence" against the assertion of authority by virtue of the fact that the FDA did not ban tobacco products after finding they qualified as combination products. *See Brown & Williamson*, 1998 WL 473320, at \*4-9. This was a structural argument. The court suggested that drugs and devices must be proved safe and effective before they can be sold, *see* 21 U.S.C. § 360c(a)(2) (1998); the fact that tobacco products are dangerous and unsafe, but were not banned, shows that the agency had acted unlawfully. The court invoked various provisions requiring certain restrictions on drugs and devices, such as a ban on misbranded drugs and devices, *see* 21 U.S.C. § 331(a) (1998), and a requirement that drugs contain adequate directions for use, *see* 21 U.S.C. § 352(f)(1) (1998); *see also* 21 U.S.C. § 352(f)(2) (1998) (requiring adequate warnings against use by children); 21 U.S.C. § 360c(b)(1) (1998) (requiring classifications of devices intended for human use); 21 U.S.C. § 360h(e)(1) (1998) (requiring "cease distribution" orders for products found to cause serious adverse health consequences). In the court's view, the FDA's failure to impose various disabilities on tobacco, including a ban, suggested that the FDA had violated the statute.

This is, however, an extremely puzzling argument. If the FDA concluded that some substance X is a drug, but did not ban X, it would not follow that the FDA lacked authority over X. It *might* follow that the FDA had acted unlawfully in failing to ban X; with respect to tobacco, it might also follow, from the court's arguments, that the FDA was required to engage in various other regulatory restrictions. But the FDA offered reasonable arguments for refusing to ban tobacco products, *see infra* notes 75-77 and accompanying text, or to require instructions on how to use cigarettes, *see* FDA Regulations, *supra* note 4, at 44,520-21, and in any case any inadequacy in these arguments would not justify a conclusion that the FDA lacked legal authority over tobacco products. It would merely justify a conclusion that the FDA was required to go further than it did.

Third, the court found "extrinsic evidence" against the regulation in the failure to mention tobacco in the text or history of the Act; in the FDA's historical practice; in congressional inaction; and in Congress's tobacco-specific legislation. *See Brown & Williamson*, 1998 WL 473320, at \*9-19. Each of these arguments is addressed below. *See infra* notes 53-61 and accompanying text (discussing the FDA's historical practice); *infra* notes 179-187 (discussing congressional inaction or the lack thereof); *infra* notes 188-190 (discussing Congress's tobacco-specific legislation).

My principal emphasis, however, will be on a conflict between two different styles of statutory interpretation.<sup>10</sup> The first is a form of literalism: it stresses the need to interpret statutory terms in accordance with their ordinary, plain meaning to speakers of English.<sup>11</sup> Because of the breadth of the language of the FDCA, this approach strongly supports the FDA. The second style of interpretation is more contextual: it emphasizes the need to understand statutory terms taken in their original context, in accordance with then-contemporary understandings of their meaning. This argument creates serious problems for the FDA because the context of the statute suggests a narrower reading than the text alone. These two styles produce conflicts in many different areas of statutory law. To take just two examples, the dispute between them accounts for internal disputes on the Supreme Court about the legality of affirmative action under a law forbidding “discrimination”<sup>12</sup> and also about whether someone “uses” a gun when he sells it for cash.<sup>13</sup>

There is no simple or easy choice between the two approaches. The literalist approach has many advantages. It enables diverse judges to coordinate about both method and outcomes, prevents guessing games about the nature of past contexts, and may well impose good incentives on the enacting legislature.<sup>14</sup> Its disadvantage is

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10. The statement in this paragraph is an oversimplification; a more precise explanation of the two styles may be found below, in Part IV.C.

11. Of course, this idea produces many puzzles of its own. In the context here, it is intelligible because the definition of “drug” does have such an ordinary meaning that, as we will see, becomes unsettled only by an investigation of context. For a discussion of the possibility of literal interpretation, see FREDERICK SCHAUER, *PLAYING BY THE RULES: A PHILOSOPHICAL EXAMINATION OF RULE-BASED DECISION-MAKING IN LAW AND IN LIFE* 215-18 (1991) (arguing that interpretation is difficult only in the rare case). A recent case strongly affirming the “plain meaning” approach to statutory interpretation is *Brogan v. United States*, 118 S. Ct. 805, 808 (1998) (stating that the Court should not infer unwritten limitations in an act when its language has a clear meaning). For a more detailed discussion of *Brogan*, see *infra* notes 161-168 and accompanying text.

12. See *United Steelworkers v. Weber*, 443 U.S. 193, 208 (1979) (holding that Title VII’s ban on racial discrimination does not encompass all private sector affirmative action programs). For a more detailed discussion of *Weber*, see *infra* notes 151-153 and accompanying text.

13. See *Smith v. United States*, 508 U.S. 223, 234-35 (1993) (holding that exchanging a gun for narcotics constitutes “use” of the gun within the meaning of 18 U.S.C. § 924(c)(1) (1994)). For a more detailed discussion of *Smith*, see *infra* notes 154-157 and accompanying text.

14. In this way the plain meaning approach might be justified as a kind of “penalty” or “information-eliciting” default rule. See Ian Ayres & Robert Gertner, *Filling Gaps in Incomplete Contracts: An Economic Theory of Default Rules*, 99 *YALE L.J.* 87, 91 (1989) (arguing that the plain meaning rule appropriately encourages bargain-makers to adequately express their intentions by penalizing them if they do not); Cass R. Sunstein, *Justice Scalia’s Democratic*

that, by wrenching statutory terms out of their context, it may well lead to understandings of statutory terms that are quite different from those of the enacting Congress and may, in that sense, produce significant mistakes.<sup>15</sup> The chief advantage of the contextual approach is that it builds on a sensible understanding of how the governing words were understood by ordinary people, including members of Congress, at the time of enactment.<sup>16</sup> Its disadvantage is that it increases the burdens of judicial judgments and may involve unreliable speculation about the nature of the relevant context.

In the abstract, the choice between the two approaches is very difficult.<sup>17</sup> A key question is whether Congress would respond to the literalist approach in the desired way, by legislating more clearly before the fact and by responding to any errors. To the extent that this kind of legislative response is likely and to the extent that agencies ought not be permitted to bring coercive power to bear in an area on which Congress has not focussed, a court—if forced to decide the tobacco question on its own—might do well to hold that despite the statute's literal language, tobacco is not a drug within the meaning of the FDCA because the term "drug" has a particular, highly contextual meaning.<sup>18</sup> But a court presented with this question is not making such a choice on its own.

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*Formalism*, 107 YALE L.J. 529, 557 (1997) [hereinafter Sunstein, *Democratic Formalism*] (explaining Justice Scalia's approach to statutory interpretation as, in part, "a series of information-eliciting default rules" which ideally "encourage Congress to state its will clearly"). It might also be justified as a low-cost method of allowing a wide range of people to converge on a particular outcome. See Frederick Schauer, *Ashwander Revisited*, 1995 SUP. CT. REV. 71, 74 (arguing that the costs of strained readings of statutes so as to avoid constitutional invalidation outweighs the benefits).

15. See, e.g., Peter L. Strauss, *On Resegregating the Worlds of Statute and Common Law*, 1994 Sup. Ct. Rev. 429, 527 (criticizing the Supreme Court's textualism for yielding decisions unresponsive to the organic development of statutes); Richard J. Pierce, *The Supreme Court's New Hypertextualism: An Invitation to Cacophony and Incoherence in the Administrative State*, 95 Colum. L. Rev. 749, 752 (1995) (claiming that the recent enthusiasm of the Supreme Court for textualism sometimes leads to "finding linguistic precision where it does not exist").

16. See Stephen Breyer, *On the Uses of Legislative History in Interpreting Statutes*, 65 S. CAL. L. REV. 845, 847 (1992) (defending the "classical practice" of using legislative history to clarify ambiguous statutory language).

17. This choice depends on many factors: the competence of courts in uncovering contextual meaning, the likelihood of judicial bias or willfulness; the possibility that literalism will in fact spur Congress to legislate more clearly, and the likelihood of congressional response to judicial mistakes. These are all, in large part, empirical issues, awaiting investigation. Some evidence is collected in William Eskridge, *Overriding Supreme Court Statutory Interpretation Decisions*, 101 YALE L.J. 331, 335-53 (1991) (examining empirical studies of congressional overrides of Supreme Court statutory interpretation decisions).

18. This contextual meaning is discussed below, in Part III.

The FDA has a large law-interpreting role and it has made some distinctive findings in the case of tobacco that support its regulations.<sup>19</sup> In light of those findings and that role, courts are not in a position to make independent judgments but only to say whether the FDA's interpretation is reasonable.<sup>20</sup> In the end, I will argue that reviewing courts should uphold the regulation, principally by reference to the appropriate role of contemporary administrative agencies.

### *C. Agencies as Common Law Courts*

A general claim underlies this conclusion: without much fanfare, agencies have become modern America's common law courts, and properly so. The basic task of common law courts is to specify abstract standards (often involving reasonableness) and to adapt legal rules to particular contexts as facts, social understandings of facts, and underlying values change over time. Operating as common law courts, agencies have, as they should, considerable power to adapt statutory language to changing understandings and circumstances. This is a conventional role, for example, of the National Labor Relations Board, the Federal Trade Commission, the Environmental Protection Agency, the Federal Communications Commission, the Department of Health and Human Services, the Immigration and Naturalization Service, and the Internal Revenue Service.<sup>21</sup> The FDA's conclusion that tobacco is a "drug" is merely an unusually dramatic and visible illustration of this proposition.

This general claim is connected to a more particular one: under the best reading of the FDCA, tobacco may or may not be a drug, but the FDA has the legal authority to treat tobacco as a drug if it

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19. The FDA first determined that nicotine in tobacco products is a drug. See FDA Regulations, *supra* note 1, at 44,403. The FDA then adopted regulations after finding that advertisements for tobacco products were specifically harming young people. See *id.* at 44,466-95.

20. This is the clear lesson of *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984).

21. See, e.g., *id.* (holding that the EPA's definition of the statutory term "stationary source" was a permissible construction); *Rust v. Sullivan*, 500 U.S. 173, 184-189 (1991) (holding that regulations issued by the Secretary of Health and Human Services were a permissible construction of Title X of the Public Health Services Act); *Good Samaritan Hosp. v. Shalala*, 508 U.S. 402, 414 (1993) (holding that when "[c]onfronted with an ambiguous statutory provision, we will generally defer to a permissible interpretation espoused by the agency entrusted with its implementation"); *Torrington Extend-A-Care Employee Ass'n v. NLRB*, 17 F.3d 580, 589 (2d Cir. 1994) (approving the NLRB's interpretation of a statutory "inability to pay" requirement); *Detroit/Wayne County Port Auth. v. ICC*, 59 F.3d 1314, 1317 (D.C. Cir. 1995) (sustaining the decision of the ICC because it adopted a reasonable interpretation of the statute in question).

chooses to do so. One of my principal goals here is to show why this is no contradiction. In the process I shall have occasion to discuss a number of important interpretive questions: the relevance of subsequent legislative events; the uses and limits of literalism;<sup>22</sup> the power of an agency to change its mind after Congress and others have been explicitly informed of the previous interpretation;<sup>23</sup> the nature of statutory default rules, operating as “information-eliciting” rules or as “intention-eliciting” rules,<sup>24</sup> and the exercise of dynamic statutory interpretation by administrative agencies rather than courts.<sup>25</sup>

## I. PRELIMINARIES

### A. *Notes on Smoking*

The problems posed by cigarette smoking might, of course, fill many volumes. I offer here a brief discussion as a way of providing some context. It was estimated in 1995 that about 529,000 deaths in the United States were attributable to smoking, about twenty-four percent of total mortality that year.<sup>26</sup> “Second-hand” smoke is said to be responsible for 3,000 deaths from lung cancer and 37,000 deaths from heart disease annually,<sup>27</sup> though these numbers are controversial.<sup>28</sup> In any case, there is general agreement that smoking is by far the largest of the preventable causes of death,<sup>29</sup> and “passive” smok-

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22. See *infra* Part IV.C.

23. See *infra* notes 93-102 and accompanying text.

24. See *infra* notes 196-200 and accompanying text.

25. See *infra* Part V.B. See generally WILLIAM N. ESKRIDGE, JR., DYNAMIC STATUTORY INTERPRETATION (1995) [hereinafter ESKRIDGE, DYNAMIC INTERPRETATION]. Professor Eskridge focuses on dynamic statutory interpretation by courts, where my emphasis is on dynamic interpretation by administrative agencies, a different and, I believe, more legitimate enterprise.

26. See WORLD HEALTH ORGANIZATION, TOBACCO OR HEALTH: A GLOBAL STATUS REPORT 223 (1998) [hereinafter WHO]; see also Jon D. Hanson & Kyle D. Logue, *The Costs of Cigarettes*, 107 YALE L.J. 1163, 1167 (1998) (claiming that smoking causes 420,000 annual deaths, about 20% of all U.S. deaths annually).

27. See Hanson & Logue, *supra* note 26, at 1167; see also ROBERT E. GOODIN, NO SMOKING 62 (1989) (estimating second-hand smoke as the cause of somewhere between 2,500 and 4,700 deaths per year).

28. See *Flue-Cured Tobacco Coop. Stabilization Corp. v. EPA*, 4 F. Supp.2d 435, 450-63 (M.D.N.C. 1998) (accepting the tobacco companies' assertion that the methodology used by the EPA in finding a correlation between lung cancer deaths and second-hand smoke was faulty).

29. See J. Michael McGinnis & William H. Foege, *Actual Causes of Death in the United States*, 270 JAMA 2207-08 (1993).

ing is sometimes described as the third leading preventable cause of deaths.<sup>30</sup>

A word about the prevalence of smoking is also in order.<sup>31</sup> As of about 1993, 25% of all Americans smoked; 27.7% of men and 22.5% of women.<sup>32</sup> This represents a decline from 44.1% of men and 31.5% of women in 1970.<sup>33</sup> Smoking among adult blacks is 26%, very close to that of adult whites at 25.4%,<sup>34</sup> but there was an intriguingly substantial decline among blacks between eighteen and twenty-four years old from 1965 to 1992. In that group, the rate fell from 37.1% in 1965, to 31.8% in 1979, to 20.4% in 1987, to 4.4% in 1993, while the rate among whites in the same age group fell from 38.4% in 1965 to 27.8% in 1987, but has remained more or less constant since that time.<sup>35</sup> Almost 80% of smokers began to smoke regularly at or before the age of sixteen.<sup>36</sup> In 1995, 21.6% of high school seniors smoked, a significant increase over the 17.2% rate in 1992.<sup>37</sup>

The causes of reductions in smoking are disputed. It appears that education, advertising restrictions, reduction of peer pressure, and taxes may all contribute to changes in smoking levels.<sup>38</sup> Social norms may, for example, operate as subsidies or taxes to smoking behavior, encouraging people to smoke when norms are a subsidy and encouraging them to cease smoking when norms are a tax.<sup>39</sup> Public percep-

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30. See Lisa Goldman & Stanton Glantz, *Evaluation of Antismoking Advertising Campaigns*, 279 JAMA 772, 772 (1998).

31. Estimated smoking rates vary slightly between sources, but nevertheless remain within a fairly tight range. The data presented herein is drawn from diverse sources and is comparable to the data presented by Professor Hersch in this issue. See Joni Hersch, *Teen Smoking Behavior and the Regulatory Environment*, 47 DUKE L.J. 1143, 1145-46 (1998) (summarizing smoking data compiled by the Centers for Disease Control and the Census Bureau).

32. See WHO, *supra* note 26, at 221.

33. See *id.*

34. See *id.* at 222.

35. See BUREAU OF THE CENSUS, U.S. DEP'T OF COMMERCE, STATISTICAL ABSTRACT OF THE UNITED STATES 1995, at 144 (115th ed. 1995); see also Michael Ingrassia, *Waiting to Exhale*, NEWSWEEK, May 1, 1995, at 76, 76 (discussing the racial gap in youth smoking).

36. See WHO, *supra* note 26, at 222.

37. See *id.*

38. For various perspectives, see generally Hanson & Logue, *supra* note 26 (examining models of regulation and concluding that victim-initiated incentive systems are the most efficient forms of cigarette regulation); GOODIN, *supra* note 27, (developing arguments against smoking and moral explanations for anti-smoking efforts); W. KIP VISCUSI, SMOKING: MAKING THE RISKY DECISION 53-58 (1992) (showing a strong correlation between public awareness of smoking risks and declining consumption of cigarettes).

39. See Cass R. Sunstein, *Social Norms and Social Roles*, 96 COLUM. L. REV. 903, 910-14, 932-35 (1996) [hereinafter Sunstein, *Social Norms*] (discussing how social norms create a divi-

tions of greater hazard, in response to government action and other public health warnings, also contribute to drops in smoking rates.<sup>40</sup> Advertising bans appear to have had a significant effect in Canada, Finland, New Zealand, and Norway.<sup>41</sup> Antismoking advertising campaigns appear to have substantial effects as well. In particular, campaigns intended to delegitimize smoking by emphasizing the dangers of second-hand smoke and the industry's manipulation of smokers seem to have been especially effective.<sup>42</sup> Tobacco taxes also have been found to have substantial consequences.<sup>43</sup>

Currently a complex network of laws controls cigarette smoking. Every state now bans the sale and distribution of tobacco to those under the age of eighteen.<sup>44</sup> Congress has also enacted legislation controlling both cigarette labeling and advertising.<sup>45</sup> Current taxes range from 20% to 44% of the retail price of cigarettes, a sharp contrast to other industrialized nations, where taxes range from 50% to 86% of the retail price.<sup>46</sup> A variety of federal and state laws regulate smoking in public places.<sup>47</sup> As of this writing, there are continuing discussions

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sion between private judgments and public behavior by conferring benefits (subsidies) on appropriate behavior and imposing costs (taxes) on inappropriate behavior); *see also* Hersch, *supra* note 31, at 1158 (arguing that social norms—as reflected in state minimum age restrictions—are inversely correlated to teen smoking).

40. *See* VISCUSI, *supra* note 38, at 55 (noting that negative perceptions of smoking—and reduction in smoking rates—have been triggered by events such as the publication of influential reports like the 1953 Sloan-Kettering report linking smoking and lung cancer, the 1964 governmental report on smoking, and congressional action in 1965, 1969, and 1984 to impose cigarette or smoking warnings).

41. *See* WHO, *supra* note 22, at 61 (summarizing research results reported in LONDON ECON. & OPERATIONAL RES. DIV., DEP'T OF HEALTH, EFFECT OF TOBACCO ADVERTISING ON TOBACCO CONSUMPTION (1992)).

42. *See* Goldman & Glantz, *supra* note 30, at 776 (discussing the effectiveness of anti-tobacco messages addressing addiction, cessation, youth access, and short- and long-term health effects when targeted at youths and adults).

43. *See* Hersch, *supra* note 31, at 1167 (presenting evidence of a negative demand elasticity for tobacco and concluding that increased tobacco taxes would result in significant smoking reductions, especially among teens).

44. *See* WHO, *supra* note 26, at 223; *see also* Hersch, *supra* note 31, at 1149 & tbl.1 (listing state minimum smoking age provisions in force before 1992).

45. *See* Federal Cigarette Labeling and Advertising Act, Pub. L. No. 89-92, 79 Stat. 282 (1965) (codified as amended at 15 U.S.C. §§ 1331-1340 (1994)) (requiring that cigarette packaging bear a statement warning consumers that smoking may be hazardous to health); Comprehensive Smokeless Tobacco Health Education Act of 1986, Pub. L. No. 99-252, 100 Stat. 30 (codified at 15 U.S.C. §§ 4401-4408 (1994)) (requiring that smokeless tobacco packaging bear a label warning consumers of various health risks resulting from use).

46. *See* WHO, *supra* note 32, at 223.

47. *See id.* at 224 (noting that smoking has been banned in places ranging from the White House and military areas (by the federal government) to restaurants and workplaces (by state

about a tobacco “settlement” that would involve a resolution of pending civil cases against the tobacco industry, an increase in tobacco taxes, and the provision of funds for education and prevention of smoking by young people.<sup>48</sup>

There is a substantial debate about the appropriate role of government in regulating the sale and use of tobacco products. On one view, people are now adequately informed about the risks of smoking, and the basic task of government should be to promote the operation of the market for safer cigarettes.<sup>49</sup> Others believe that this argument understates the role of addiction and the motivational and cognitive issues raised by risk-taking by young people.<sup>50</sup> Still others focus on the possible existence of unrealistic optimism in risk-taking behavior and also on the problems presented by cumulative risks.<sup>51</sup> There is a further question about the government’s appropriate role when choices are a function of social norms over which people have little control, and which they wish to change; this phenomenon makes it unclear what it means to say that government should respect people’s preferences or choices.<sup>52</sup>

### B. What the FDA Did

For a number of decades, the FDA disclaimed the general legal authority to regulate tobacco, and Congress and others operated under the assumption that tobacco would not generally be subject to FDA authority. Until 1963, there was no serious discussion of whether tobacco products might generally qualify as a “drug.” In-

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and local governments)).

48. See, e.g., *Tobacco Settlement Excerpts*, *supra* note 5, at B8.

49. See VISCUSI, *supra* note 38, at 70-72, 146-49; W. Kip Viscusi, *Constructive Cigarette Regulation*, 47 DUKE L.J. 1095 (1998) (arguing for safety through market competition).

50. See GOODIN, *supra* note 27, at 20-30 (arguing that the incremental nature of both nicotine addiction and long-term health consequences of smoking raises questions about whether or not people “voluntarily” accept the risks of cigarette smoking).

51. See Paul Slovic, *Do Adolescent Smokers Know the Risks?*, 47 DUKE L.J. 1133, 1136-37 (1998) (discussing the effects of optimism biases and the tendency to perceive cumulative risks as less threatening than noncumulative risks).

52. See Lawrence Lessig, *The Regulation of Social Meaning*, 62 U. CHI. L. REV. 943, 1039-42 (1995) (discussing how, after the rejection of an anti-begging penal law on First Amendment grounds in *Loper v. New York City Police Department*, 999 F.2d 699 (2d Cir. 1993), the New York Transit Authority was able to curb the incidence of begging by promoting a social norm that made it acceptable to say no to panhandlers); Sunstein, *Social Norms*, *supra* note 39, at 939-41, 953-59 (discussing the connection between personal choices and prevailing social norms and positing that the government should engage in harm management to solve collective action problems).

deed, the only real assertion of FDA authority over tobacco products prior to that time occurred in 1959, when the since-renamed Federal Drug Administration claimed authority only because certain cigarette companies had advertised that their cigarettes would reduce body weight.<sup>53</sup> Between 1963 and 1988, FDA officials said explicitly that tobacco products did not otherwise qualify as drugs, devices, foods, or cosmetics.<sup>54</sup> Thus, the FDA Commissioner testified in 1972 that cigarettes would be counted as drugs if, and only if, claims about beneficial physical effects were made on their behalf;<sup>55</sup> that is to say that cigarettes would qualify as drugs only if tobacco companies marketed them by reference to their beneficial effects on the human body. This view was consistently maintained through 1988.<sup>56</sup>

In an important decision in the late 1970s, the FDA rejected petitions by an anti-smoking group—Action on Smoking and Health—to regulate cigarettes as drugs.<sup>57</sup> The FDA concluded that there was insufficient evidence that cigarettes were “intended” to affect the structure or function of the body.<sup>58</sup> By this, the FDA meant that those who sold cigarettes did not “intend,” by express representation or

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53. See *United States v. 354 Bulk Cartons . . . Trim Reducing-Aid Cigarettes*, 178 F. Supp. 847, 851 (D.N.J. 1959) (stating that, in light of the manufacturer's appetite suppression claims, the cigarettes seized were drugs within the meaning of the FDCA, 21 U.S.C. § 321(g)(1)); see also *United States v. 46 Cartons . . . Fairfax Cigarettes*, 113 F. Supp. 336, 339 (D.N.J. 1953) (finding that Fairfax Cigarettes fell within the statutory meaning of “drug” as leaflets seized with cigarettes described a “miracle vapor” that could reduce the frequency of respiratory diseases).

54. See Memorandum from Bureau of Enforcement, Food and Drug Administration, to Directors of Bureaus and Divisions and Directors of Districts, Food and Drug Administration (May 23, 1963), reprinted in *Public Health Cigarette Amendments of 1971: Hearings on S. 1454 Before the Consumer Subcomm. of the Senate Comm. on Commerce*, 92d Cong. 240 (1972) [hereinafter *Hearings on S. 1454*]; *Health Consequences of Smoking: Nicotine Addiction: Hearing Before the Subcomm. on Health & the Env't of the House Comm. on Energy & Commerce*, 100th Cong. 17 (1988) [hereinafter *Hearing on Health Consequences of Smoking*] (statement of Dr. Frank E. Young, Comm'r, FDA).

55. See *Hearings on S. 1454*, *supra* note 54, at 239 (statement of Dr. Charles C. Edwards, Comm'r, FDA).

56. See *Hearing on Health Consequences of Smoking*, *supra* note 54, at 17-19 (statement of Dr. Frank E. Young, Comm'r, FDA).

57. The history of this petition and its rejection is summarized in *Action on Smoking and Health v. Harris*, 655 F.2d 236, 237-38 (D.C. Cir. 1980), which affirmed the FDA's position that cigarettes containing nicotine could not be regulated as “drugs” under the FDCA. The plaintiffs had also asserted that cigarettes should be subject to regulation as “devices,” but the court expressly declined to decide that issue. See *id.* at 237 n.4.

58. See *id.* at 239 (noting that “[s]uch an understanding has now been accepted as a matter of statutory interpretation” and citing *National Nutritional Foods Association v. Mathews*, 557 F.2d 325, 333 (2d Cir. 1977) (“The vendors' intent in selling the product to the public is the key element in this statutory definition.”)).

otherwise, to affect people's bodies. Such an intention could, of course, be found when cigarettes were marketed and sold as a means of reducing weight, but not in the ordinary course of sale.<sup>59</sup> The FDA's decision was upheld on appeal.<sup>60</sup> The court said that the FDCA authorized the FDA to regulate tobacco only if tobacco companies were marketing cigarettes by reference to various physiological benefits of smoking, and if most smokers used a particular brand of cigarettes partly because of those supposed benefits.<sup>61</sup>

In 1988, the American Heart Association and other public health organizations petitioned the FDA to regulate low-tar cigarettes as drugs. The FDA responded by announcing its intention to reconsider whether it had jurisdiction over cigarettes and smokeless tobacco. In 1996, the FDA concluded that it did indeed have jurisdiction in a dense report of some seven hundred pages.<sup>62</sup>

The scientific and political background leading to this decision is undoubtedly worth an article, or perhaps a book, of its own.<sup>63</sup> For present purposes, two points seem both clear and highly relevant to the legal issue. First, this was an extremely visible political issue, one in which the President himself was heavily involved and one that played a serious part in the presidential election of 1996.<sup>64</sup> Second, the FDA's decision would not have been possible without a great deal of relatively new evidence about the effects of nicotine and the intentions of the tobacco industry. The evidence suggested that smoking is responsible for more than 400,000 premature deaths per year.<sup>65</sup> It also suggested that tobacco companies were well aware of the adverse

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59. See *supra* note 53 (citing cases).

60. See *Action on Smoking and Health*, 655 F.2d at 239.

61. See *id.*

62. See FDA Regulations, *supra* note 4, at 44,399-413. In 1995, the FDA had published a report finding probable jurisdiction over "nicotine in cigarettes and smokeless tobacco," but withheld a final assertion of jurisdiction at that time, "recogniz[ing] the unique importance of the jurisdictional issue as well as the factual justification for any proposed rule in this area." See FDA Jurisdictional Analysis, *supra* note 8, at 41,453.

63. At least one author has found it worthy of a book. See RICHARD KLUGER, *ASHES TO ASHES: AMERICA'S HUNDRED-YEAR CIGARETTE WAR, THE PUBLIC HEALTH, AND THE UNABASHED TRIUMPH OF PHILIP MORRIS* (1996).

64. See, e.g., William Neikirk, *Clinton Readies Tobacco Crackdown: Proposed Rules Take Aim at Teen Smoking and Could Open the Door to FDA Regulation*, CHI. TRIB., Aug. 22, 1996, at 1.

65. See FDA Regulations, *supra* note 4, at 44,398 (citing CENTERS FOR DISEASE CONTROL, DEP'T OF HEALTH & HUMAN SERVS., *Cigarette Smoking - Attributable Mortality and Years of Potential Life Lost - United States 1990*, 42 MORBIDITY & MORTALITY WKLY. REP. 645, 645-49 (1993)).

physical effects of smoking.<sup>66</sup> The FDA stressed its conviction by stating that smoking was a far more important public health problem than those to which it ordinarily devoted its attention. Thus, in its own statement, the FDA said that smoking causes more deaths annually in the United States than AIDS, car accidents, murders, suicides, fires, alcohol, and illegal drugs combined.<sup>67</sup> Nonetheless, about fifty million Americans continue to smoke cigarettes, and 3,000 minors begin to smoke every day.<sup>68</sup>

With respect to the jurisdictional issue, the FDA supported its view with two central conclusions. First, it said that tobacco affects the structure or function of the body because (a) it causes and sustains addiction, (b) it has mood-altering affects, such as stimulation and tranquilization, and (c) it controls weight.<sup>69</sup> Second, and most important for purposes of its change in view, the FDA stressed that tobacco products are intended to have these effects.<sup>70</sup> This conclusion resulted from new evidence of the foreseeability of these various physical effects, new evidence of consumer use, and new evidence of manufacturer intent, stemming from three decades of industry statements and research.<sup>71</sup>

The FDA emphasized that the situation had changed dramatically from 1980,<sup>72</sup> when no major health organization had determined that nicotine was addictive, to 1995, by which time most major public health organizations—including the American Psychiatric Association, the U.S. Surgeon General, and the American Psychological Association—had concluded that tobacco was addictive.<sup>73</sup> There was also a great deal of emerging evidence, since 1980, to support this conclusion—and the conclusion that smoking had various stimulating and sedating effects, effects intended by tobacco companies.<sup>74</sup>

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66. See, e.g., *id.* at 44,870-71 (discussing internal memoranda circulating within the R.J. Reynolds Tobacco Co. which made reference to the “undesirable” physical effects of smoking).

67. See *id.* at 44,398. Note, however, that smoking may also control behavior that would otherwise lead to premature deaths, such as obesity; the figure of 400,000 lives lost does not take account of losses that would be produced in any case, as a result of substitute or offsetting behavior.

68. See *id.*

69. See FDA Jurisdictional Analysis, *supra* note 8, at 41,524-28, 41,534-79.

70. See *id.* at 41,471-91.

71. See *id.* at 41,582-779.

72. This was the year that the court decided *Action on Smoking and Health v. Harris*, 655 F.2d 236 (D.C. Cir. 1980).

73. See Jurisdictional Analysis, *supra* note 5, at 41,539-46.

74. A set of internal documents showed that tobacco manufacturers had called nicotine

The FDA did not, however, ban nicotine.<sup>75</sup> It concluded that a ban would be ineffective, because it would produce black markets and smuggling, and that it would be undesirable, because it would create adverse health consequences for the millions now dependent on nicotine.<sup>76</sup> It decided that the best response would be to prevent children and adolescents from beginning to use cigarettes at all.<sup>77</sup> To this end, the FDA invoked its “restricted device” authority<sup>78</sup> and adopted a regulatory strategy with two principal components.<sup>79</sup> First, the FDA attempted to limit the access of young people to cigarettes in the following ways: by prohibiting the sale of cigarettes to people under eighteen years of age; by requiring retailers to check photographic identification; by banning free samples; by requiring retailers to remove self-service displays; and by prohibiting the use of vending machines for selling cigarettes.<sup>80</sup> Second, the FDA attempted to limit the desire of young people to smoke by restricting cigarette advertising and promotion. The restrictions included a requirement that advertising use a black and white, text-only format;<sup>81</sup> a ban on outdoor advertising near schools and playgrounds;<sup>82</sup> a prohibition on the sale or distribution of non-tobacco products, such as hats or T-shirts, with a tobacco product brand name or logo;<sup>83</sup> and a prohibition on tobacco brand name sponsorship of athletic, cultural, or similar events.<sup>84</sup>

## II. TEXTUALISM AND HISTORY

Now let us turn to the legal issues. The critical language of the FDCA defines “drugs” as “articles . . . intended to affect the structure or any function of the body.”<sup>85</sup> Is tobacco an article that is in-

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habit-forming, with the power to sedate or tranquilize its users. *See id.* at 41,591.

75. My focus here is purely *whether* tobacco products can be regulated as “drugs,” and hence I do not discuss, except in passing, the more specific questions raised by the particular way in which the FDA chose to regulate such products.

76. *See* FDA Regulations, *supra* note 1, at 44,398.

77. *See id.*

78. Recall that the court had expressly declined to decide this issue in *Action on Smoking and Health v. Harris*, 655 F.2d 236, 237 n.4 (D.C. Cir. 1980).

79. *See* FDA Regulations, *supra* note 1, at 44,403-07.

80. *See* 21 C.F.R. § 897.14 (1996).

81. *See* 21 C.F.R. § 897.32(a) (1996).

82. *See* 21 C.F.R. § 897.30(b) (1996).

83. *See* 21 C.F.R. § 897.34(a) (1996).

84. *See* 21 C.F.R. § 897.34(c) (1996).

85. 21 U.S.C. § 321(g)(1)(C) (1994). For the reasons given above in note 8, I do not deal

tended to affect the structure or any function of the body? Let us begin by generating an argument on behalf of the FDA, emphasizing the apparently literal meaning of the statutory text and attempting to account for the change in the FDA's position over time.

*A. Text*

At first glance, the text of the definition of "drug" plainly includes tobacco, or so a reasonable FDA, acting on the basis of plausible factual assumptions, could find.

The statute appears to require two and only two findings: (1) an effect on the structure or any function of the body and (2) an intention to produce that effect. Tobacco has a series of effects on the human body, at least on one reading of the evidence. Nicotine may reasonably be found to work as both a stimulant and a sedative and also to have addictive properties. On the question of intent, things are a bit more complicated. What is the precise meaning of "intended"? Does this term require knowledge, motivation, or something else? By itself, the text does not make this clear. In the context of tobacco, however, there is evidence that tobacco companies not only knew about but also desired the various effects of nicotine.<sup>86</sup>

Thus, the natural reading of the text appears to be strongly supportive of the FDA. It suggests not ambiguity but a relatively clear understanding like that of the current FDA. An ordinary English reader would probably find that tobacco is a drug in light of the two statutory requirements.

*B. The Original Understanding of FDA Authority Over Tobacco*

The text of the statute may not be decisive if the traditional tools of statutory construction lead to a contrary result. In Part II, I will discuss this point in connection with the strongest argument against the FDA. But it makes sense to begin with a simpler, more straightforward, and, in a way, more obvious set of questions: What of the original understanding about whether tobacco fell within the term "drug?" Does Congress's original understanding of the place of to-

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here with the issue of whether cigarettes are "devices" as that term is defined under 21 U.S.C. § 321(h) (1994).

86. See *Nicotine in Cigarettes and Smokeless Tobacco Is a Drug and These Products Are Nicotine Delivery Devices Under the Federal Food, Drug, and Cosmetic Act: Jurisdictional Determination*, 61 Fed. Reg. 44,619, 44,690-806, 44,847-45,097, 45,098-150 (1996) [hereinafter *Jurisdictional Determination*]; FDA *Jurisdictional Analysis*, *supra* note 8, at 41,582-803.

bacco argue against a literal interpretation of the text? What is the importance of the (exceedingly likely) fact that the enacting Congress did not intend to give the FDA power over tobacco?

When the definition of “drug” was originally enacted in 1938, it seems clear at first glance that the term was not understood to include tobacco products.<sup>87</sup> There was no discussion of the FDA’s authority over tobacco products in Congress that year, and the silence is highly relevant: in view of the importance and high visibility of the tobacco industry, it defies belief to suggest that Congress was conferring that authority without debate or by inadvertence. It is entirely reasonable to think that the battle over the 1938 bill would have been far more intense if the bill was meant to give the FDA this kind of regulatory control; it is even reasonable to think that a statute giving the FDA such authority could not possibly have been enacted. Moreover, the FDA’s predecessor agency said in 1914 that it could not regulate tobacco products under the 1906 Act,<sup>88</sup> and Congress did not enact an explicit proposal in 1929 that would have amended the 1906 Act to cover tobacco products.<sup>89</sup>

Thus, it could be argued that the statutory term should be understood by reference to its original meaning, which did not include tobacco. By itself, however, this argument is quite weak. The basic reason is simple: Congress enacted general words, not its beliefs about particular applications of those general words, and Congress’s unenacted beliefs about those applications need not control. When Congress enacts such general words, it is usually their present meaning that governs,<sup>90</sup> at least if the question is whether the agency charged

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87. The qualification “at first glance” is necessary because it is unclear whether at that time Congress would have been taken to have referred to existing understandings of what counted as drugs and devices, or to have set out a general concept whose particular content would and should vary over time, with new understandings of facts and values. If the second view, which envisions an evolving definition of what constitutes a “drug” under the Act, is correct, then *Coyne Beahm, Inc. v. FDA* is rightly decided even under Justice Scalia’s view of interpretation, rooted, as it is, in textualism. 966 F. Supp. 1374 (M.D.N.C. 1997). The court in *Beahm* adopted an expansive view of the term “drug” as used within the FDCA and concluded that Congress’s failure to address tobacco within the Act when enacted did not withhold FDA authority to regulate tobacco products today. *See id.* at 1380-81. In reality, it is unlikely that there was a general understanding on Congress’s part about whether the statutory definition was static or meant to change over time.

88. *See id.* at 1381.

89. *See id.*

90. *See, e.g., Oncale v. Sundowner Offshore Servs.*, 118 S. Ct. 998, 1001-02 (1998) (holding that workplace harassment can violate Title VII’s prohibition against discrimination “because of sex” when the harasser and the harassed employee are of the same sex);

with their interpretation may so conclude.<sup>91</sup> History may help in sorting out ambiguities, but when they are unambiguous, general words are frequently applied in ways that enacting legislatures could not have anticipated and would not, on their particular, time-bound understanding of facts and even values, have approved.<sup>92</sup> The validity of such applications is especially clear where, as here, factual understandings have changed dramatically since the statute was written.

We might make several distinctions here. Sometimes agencies alter their interpretation of law because the facts have changed or have been understood in a new way.<sup>93</sup> Sometimes agencies change their interpretations of law because of new values.<sup>94</sup> Sometimes agencies change their interpretations not because of new facts or new values but because of a somewhat different evaluation of the evidence.<sup>95</sup>

Consider that it is generally agreed that the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)<sup>96</sup> authorizes the EPA to regulate DDT as a product raising “a substantial question” of human safety,<sup>97</sup> but that this authority does not rest on a judgment that the

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91. See *Bob Jones Univ. v. United States*, 461 U.S. 574, 605 (1983) (upholding the IRS's decision not to grant tax exempt status to a university which did not permit partners in interracial marriages to enroll because the university's practice was “contrary to public policy”); *Environmental Defense Fund, Inc. v. Ruckelshaus*, 439 F.2d 584, 593 (D.C. Cir. 1971) (holding that the Secretary of Agriculture's interpretation of the Federal Insecticide, Fungicide, and Rodenticide Act governs except in cases of abuse of discretion). *But see Boutilier v. INS*, 387 U.S. 118, 118 (1967) (holding that an “alien who was a homosexual over a continuous and uninterrupted period prior to and at time of entry was ‘afflicted’ with psychopathic personality within terms of [the INS's interpretation of the] statute excluding such persons from admission into United States”)

92. See, e.g., *Bob Jones*, 461 U.S. at 592-93, 598-99 (holding that prohibition of interracial marriages within educational institutions is contrary to public policy despite the fact that such discrimination was thought consistent with public policy in the first half of this century); *Environmental Defense Fund*, 439 F.2d at 593-95 (noting that despite an administrative recognition of “a substantial question concerning the safety of DDT” that was not present at the time of the enactment of the Federal Insecticide, Fungicide, and Rodenticide Act, the pesticide's registration was not suspended); *Oncale*, 118 S. Ct. at 1001-02 (holding that although Title VII was not enacted with such a claim in mind, “nothing in Title VII necessarily bars a claim of discrimination ‘because . . . of sex’ merely because the plaintiff and the defendant . . . are of the same sex”).

93. See, e.g., *Environmental Defense Fund*, 439 F.2d at 596-97 (recognizing agency's interpretation of factors determined to be relevant in implementing statutory purpose).

94. See, e.g., *Rust v. Sullivan*, 500 U.S. 173 (1991) (upholding changed interpretation of law prohibiting grant of federal funds to clinics where abortion is a “method of family planning”).

95. See, e.g., *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 865 (1984) (upholding new EPA air quality regulations in light of new scientific understanding).

96. Pub. L. No. 92-516, 86 Stat. 973 (1972) (codified at 7 U.S.C. §§ 136-136y (1994)).

97. *Environmental Defense Fund*, 439 F.2d at 593-95 & n.3 (construing the EPA's author-

Congress that enacted FIFRA believed that the EPA could regulate DDT. On the contrary, when introduced, DDT was thought to be unproblematic and entirely safe,<sup>98</sup> and hence the enacting Congress did not contemplate that FIFRA would authorize EPA regulation of DDT. The EPA nevertheless possesses just such authority. Statutes regulating health and safety quite routinely contain broad language authorizing agencies to regulate articles or substances if the statutory criteria are met. Whether Congress believed that the statutory criteria were met when it enacted the relevant legislation is beside the point unless Congress embodied that belief in law. Consider, as well, the prominent example of *Bob Jones University v. United States*,<sup>99</sup> in which the Court held that a public policy exception to the category of charitable deductions disallowed deductions for gifts to schools prohibiting interracial marriages—notwithstanding the fact that when the charitable deduction was first enacted in 1918, segregated schools were thought entirely consistent with public policy.<sup>100</sup> As the Court wrote in 1998, “statutory prohibitions often go beyond the principal evil to cover reasonably comparable evils, and it is ultimately the provisions of our laws rather than the principal concerns of our legislators by which we are governed.”<sup>101</sup> Then the Court held that the 1964 Civil Rights Act bans same-sex harassment, even though the 1964 Congress did not in the least have that problem in mind, or intend to cover it.<sup>102</sup>

We can make the point more plain by supposing that in floor debates in 1938, members of Congress expressly stated the view that the Act did not authorize the FDA to regulate tobacco, on the ground (for example) that tobacco did not create a serious health threat or did not “affect the structure or function of the body.”<sup>103</sup> A scenario of this sort would be at least as strong and perhaps even stronger for those attacking the FDA regulation than the actual case, for, in the hypothesized situation, there would be explicit legislative history against the FDA’s view. Even if, however, there were an express statement to this effect in the legislative history, it would not be con-

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ity under FIFRA).

98. See AARON WILDAVSKY, *BUT IS IT TRUE?* 55-57 (1996).

99. 461 U.S. 574 (1983).

100. See *id.* at 592-93, 598-99.

101. *Oncle v. Sundowner Offshore Servs.*, 118 S. Ct. 998, 1002-03 (1998) (concluding that “sex discrimination consisting of same-sex sexual harassment is actionable under Title VII”).

102. See *id.* at 1002.

103. 21 U.S.C. § 321(g)(1)(C) (1994).

trolling. What matters is the language of the enactment, not the particular, unenacted understanding of how that language applies to a particular case.<sup>104</sup> Congress's judgment that tobacco was not a "drug" would, in the hypothesized case, have been a product of certain factual judgments, judgments that have proved inaccurate. It does no violence to the statute to read it to authorize a different decision about tobacco once the facts have been revealed to be otherwise.

If the language were ambiguous, the legislative understanding could be helpful in untangling the ambiguity.<sup>105</sup> But if the language is general, and if it invites the FDA to inquire into relevant issues of fact, then there is no problem with an interpretation by the FDA that understands the ban to apply to articles not originally thought, by Congress, to be subject to ban. The enterprise proposed by the tobacco industry is not the legitimate one of using legislative history to untangle ambiguities, but the illegitimate one of using it to decide on appropriate application, which, under the statute, is the FDA's job.

All this leads to a simple conclusion. The text of the statute favors the FDA's approach; the literal meaning argues strongly in its direction. While the history of the statute suggests that Congress did not contemplate FDA regulation of tobacco, what is controlling is the language, not Congress's understanding of how the language would be applied. Since the underlying facts have come to be understood in a new way,<sup>106</sup> the FDA regulation is lawful. It is easy to imagine a straightforward opinion that would affirm the FDA's authority on the basis of an argument like this.

This argument is quite formalistic in the sense that it deals with words and definitions rather than with goals and policies. Perhaps its formal character is an advantage; certainly recent Supreme Court opinions so suggest.<sup>107</sup> But the formal argument might be strength-

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104. This view should hold even for those who believe that legislative history is entitled to weight in resolving ambiguities; I am supposing here that the text is unambiguous.

105. See Breyer, *supra* note 16, at 848 (defending the use of "legislative history to help interpret unclear statutory language").

106. See FDA Jurisdictional Analysis, *supra* note 5 at 41,539-46, 41,591 (presenting evidence that major public health organizations have recently become aware that tobacco companies intended for smoking to have various stimulating and sedating effects).

107. See *Oncale*, 118 S. Ct. at 1002 (arguing that "it is ultimately the provisions of our laws rather than the principal concerns of our legislators by which we are governed"); see also ANTONIN SCALIA, A MATTER OF INTERPRETATION 16-23 (1997) [hereinafter SCALIA, INTERPRETATION] (defending formalism). For an illuminating discussion of literal interpretations, see Frederick Schauer & Virginia J. Wise, *Legal Positivism as Legal Information*, 82 CORNELL L. REV. 1080, 1083-96 (1997) (suggesting that positivism entails a constraint on the

ened, rather than weakened, with a more pragmatic understanding of why it might make sense for Congress to have given the FDA authority in certain kinds of cases. Very plausibly, the purpose of the FDCA<sup>108</sup> is to allow the FDA to act in circumstances in which consumers are unlikely to be well informed about products with physiological effects; foods, drugs, and cosmetics are substances for which the risk of poor information and poor information processing are especially high. On this view, the FDA's proper business goes well beyond the prevention of fraud and deception, a task that it shares with other administrative agencies such as the FTC. The FDA's jurisdiction is properly invoked by products with medicinal or therapeutic effects, or products otherwise intended to affect bodily structure or function, because it is in these cases that full information may be hard for consumers to obtain or to process, and the risk of harm is especially great.

The regulation of tobacco as a drug fits comfortably with this rationale for FDA authority. Those who smoke may well be unlikely to know the various effects of smoking, or to admit that those risks apply to them as individuals.<sup>109</sup> Perhaps the risks of smoking are well-understood,<sup>110</sup> and perhaps Congress should not allow regulation in such contexts; but the FDA has been granted the relevant power in a whole class of cases involving effects on the structure or function of the body.<sup>111</sup> It is also irrelevant to complain that the FDA, thus understood, is unacceptably paternalistic. That may be true, but Congress granted the FDA authority to act even if the action appears pa-

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sources to which judges may look in deciding legal questions).

108. The purpose is not a "fact" to be "found," of course; it is something to be characterized, consistently with the relevant legal materials.

109. See Slovic, *supra* note 51, at 1142 (concluding that young smokers, despite a general recognition of the risks associated with smoking, nevertheless fail to appreciate the "severity of the disease consequences, . . . the cumulative nature of smoking risks, and . . . the difficulty of stopping the behavior once it has been initiated"); see also GOODIN, *supra* note 27, at 20 (arguing that individuals may not know the risks because "tobacco companies in effect are giving out . . . conflicting information . . . [because] implicit health claims of the advertising imagery conflict with explicit health warnings"). But see VISCUSI, *supra* note 38, at 61-86 (reporting the risk perceptions of smokers and noting that many overestimate the risks of smoking, which include lung cancer and shortened life).

110. See VISCUSI, *supra* note 38, at 70-72 (reporting that "[a]pproximately 70 percent of the population has heard that cigarette smoking is dangerous to your health").

111. See, e.g., *United States v. Pro-Ag, Inc.*, 968 F.2d 681 (8th Cir. 1992) (affirming FDA jurisdiction over products designed to increase animals' milk production by altering structure or function of their bodies); *United States v. Undetermined Quantities of Cal-Ban 3000*, 776 F. Supp. 249 (E.D.N.C. 1991) (affirming FDA jurisdiction over products marketed for purposes of weight reduction, appetite suppression, and cancer prevention).

ternalistic, and there is at least an intelligible account, stemming from an absence of consumer information, for such a grant of authority.

### III. CONTEXTUALISM AND THE ORDINARY PICTURE IN THE COMMON MIND

What is the best response to this argument? As noted, the FDCA defines “drug” in relevant part to include articles “intended to affect the structure or any function of the body,”<sup>112</sup> but these words were written in a particular setting, and they may not mean all of what they appear to mean. Would it follow from a literal interpretation that the FDA could, or perhaps must, define as “drugs” exercise machines, chewing tobacco, certain bracelets said to counteract arthritis, bras, word processors, even radio and television? If at least some of these “articles” are not within FDA authority, what, in a world of literalism, can prevent the FDA from so concluding?

#### A. *From Text to Context: The Contextual Understanding of “Drug”*

The answer might involve starting not only with text, but also with context, placing particular emphasis on the ordinary understanding of the controlling statutory term: “drug.” Of course, Congress, like Lewis Carroll’s famous Humpty Dumpty in *Through the Looking Glass*,<sup>113</sup> can define terms however it wishes; it might define “drugs” to include horses, bulletin boards, works by Oliver Wendell Holmes, Jr., or law reviews if it wishes. But ordinary usage surely matters, and we should not lightly assume that Congress has defined the term “drug” in a way that departs radically from the ordinary understanding of the term. The argument made in Part II—with its extremely expansive conception of what can be counted as a drug—might be seen to make this error. Congress’s definition does, of course, govern; but in case of doubt, there is reason to favor an understanding of that definition that conforms to and does not violate the ordinary understanding.

In the specific context of a regulatory agency charged with the task of regulating “food” and “drugs,” an ordinary English-language reader, in 1906, 1938, or 1998, would think that the basic cases in-

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112. 21 U.S.C. § 321(g)(1)(C) (1994).

113. “‘When I use a word,’ Humpty Dumpty said in a rather scornful tone, ‘it means just what I choose it to mean—nothing more or less.’” LEWIS CARROLL, *THROUGH THE LOOKING GLASS AND WHAT ALICE FOUND THERE*, in *THE ILLUSTRATED LEWIS CARROLL* 103, 168 (Roy Gasson ed., 1978) (1872).

volving a “drug” refer to articles used to help cure or alleviate some illness, disease, or medical condition.<sup>114</sup> These are the basic exemplars from which interpretation should proceed.<sup>115</sup> Indeed, the statute defines “drugs” to include articles of exactly this kind.<sup>116</sup> The specific subsection with which we have been dealing is a separate one, applying not to articles that help with a disease or illness but to “articles (other than food) intended to affect the structure or any function of the body.”<sup>117</sup>

In the particular context of a statutory definition of “drug,” what is the basic purpose or function of this subsection? Without looking at history, but instead looking at the context (this is after all an attempted definition of “drug”), it seems reasonable to think that the provision covers products that would not cure or alleviate an illness or disease, but that are nonetheless marketed (or “intended”) to alter body structure or function by, for example, fighting colds,<sup>118</sup> smoothing skin,<sup>119</sup> helping to produce weight loss,<sup>120</sup> reducing odors,<sup>121</sup> or (more exotically) tying off severed blood vessels during medical procedures.<sup>122</sup> All of these cases involve “drugs” in the ordinary English

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114. It might be possible to respond that the term “drug” can be understood to refer to cocaine, heroin, marijuana, and so forth, and thus that the FDA definition of tobacco as a drug is not so counterintuitive after all. In ordinary language, “drug” has come to refer to narcotics. I am speaking of the ordinary meaning of drug in the context of the FDCA, where the term drug is not rooted in illegal substances, but quasi-medical ones.

115. Cf. H.L.A. HART, *THE CONCEPT OF LAW* 124-32 (2d ed. 1994) (discussing the communication of general legal standards through individuals’ recognition of verbal terms). For psychological work in this vein, see PAUL M. CHURCHLAND, *THE ENGINE OF REASON, THE SEAT OF THE SOUL: A PHILOSOPHICAL JOURNEY INTO THE BRAIN* 253-98 (1995) (discussing the human ability to interpret information based on dynamic paradigms or prototypes).

116. See 21 U.S.C. § 321(g)(1)(B) (1994) (“articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals”).

117. *Id.* § 321(g)(1)(C).

118. See *United States v. 46 Cartons . . . Fairfax Cigarettes*, 113 F. Supp. 336, 339 (D.N.J. 1953) (holding that cigarettes are within statutory meaning of “drug” when advertisement’s “clear import” is that smoking will prevent colds or other viral infections).

119. See *United States v. An Article . . . “Sudden Change”*, 409 F.2d 734, 742 (2d Cir. 1969) (holding that a product which claims to “lift out puffs” and to give a “face lift without surgery” is a drug).

120. See *United States v. 354 Bulk Cartons . . . Trim Reducing-Aid Cigarettes*, 178 F. Supp. 847, 851 (D.N.J. 1959) (holding that the “Trim cigarette” is a drug because it is intended to promote weight loss).

121. See *United States v. Undetermined Quantities . . . “Pet Smellfree,”* 22 F.3d 235, 239 (10th Cir. 1994) (holding that a food additive for pets was a “drug” because it contained an antibiotic to reduce pet odors).

122. See *AMP, Inc. v. Gardner*, 389 F.2d 825, 830 (2d Cir. 1968) (holding that products used for tying off several blood vessels during surgery were “drugs”).

language sense because the relevant articles are marketed in order to alter bodily structure or function in a certain desirable way and, thus, belong in the same basic family as the ordinary exemplars of drugs in the specific context of a regulatory agency charged with regulating “food” and “drugs.”

On this count, cigarettes are altogether different. Manufacturers may know about the addictive properties of cigarettes and may even be delighted with those effects. Cigarettes are not, however, sold and purchased because of a promotional campaign emphasizing their drug-like effects, that is, their effects on the structure and function of the human body. If and when they are so treated, they might fit within the category “drug”—otherwise not.

### *B. History*

This is the start of a less literal and more contextual understanding of the definition of “drug;” it is strongly supported by the history of the FDCA. In fact, an investigation of the history provides some support for the general view, associated with Justice Breyer, that investigations of this kind can help illuminate the meaning of statutory provisions that might otherwise be misunderstood.<sup>123</sup>

In 1906, the term “drug” had been defined to mean “all medicines and preparations recognized in the United States Pharmacopoeia or National Formulary for internal or external use, and any substance or mixture of substances intended to be used for the cure, mitigation, or prevention of disease in man or other animals.”<sup>124</sup> This relatively narrow definition led to a concern about the need for a broader definition to enable the FDA to control remedies for obesity and cosmetics.<sup>125</sup> The expanded definition, enacted in 1938, with its

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123. See Breyer, *supra* note 16, at 851-53 (noting the value of looking to legislative history to establish the “specialized meanings” of certain terms as they are used in specific statutes).

124. Pure Food and Drug Act, Pub. L. No. 59-384, § 6, ch. 3915, 24 Stat. 768, 769 (1906). This early definition remains strongly echoed in the current provision, see 21 U.S.C. § 321(g)(1)(A)-(B) (1994), which is quoted above in the text accompanying note 7.

125. This concern was noted as early as 1917 by the Chief of the Bureau of Chemistry, the precursor to the FDA responsible for enforcing the 1906 Act:

While the accomplishments of the Food and Drugs Act have been considerable, it must be admitted that it has its serious limitations. Especially conspicuous ones are . . . the limitations placed upon the term “drug” by definition which render it difficult to control injurious cosmetics, fraudulent mechanical devices used for therapeutic purposes, as well as fraudulent remedies for obesity and leanness.

BUREAU OF CHEMISTRY, U.S. DEP’T OF AGRIC., 1917 BUREAU OF CHEMISTRY ANN. REP., reprinted in FEDERAL FOOD, DRUG AND COSMETIC LAW—ADMIN. REPS., 1907-1949, at 355,

addition of “articles (other than food) intended to affect the structure or any function of the body,”<sup>126</sup> was designed partly to enable the FDA to control “slenderizing” remedies and related practices.<sup>127</sup> Thus, the Chief of the FDA, W.G. Campbell, explained in a key statement:

Let me tell you the purpose of that [expanded definition]. There are products on the market now that escape control under [existing law], such as slenderizing products, reducing products. Obesity is not itself a disease in all instances and products advocated and sold for the treatment of obesity, as a matter of fact, are not always subject to the terms of this act.

In regard to slenderizing products, it is fashionable, on the part of girls, or it has been, to attain a sylphlike slender figure. They are victims, in such circumstances, of the sale of products that are capable of really injuring their health. There was one such article . . . , “Marmola” . . . . That product is a powerful drug. It ought not to be administered except under the direction of physicians. . . . Now, the purpose of that paragraph (3) is to give jurisdiction over that product.<sup>128</sup>

Campbell indicated that when questions arose about whether a hard case involved a statutory drug, the FDA would focus on the nature of representations made by the manufacturer.<sup>129</sup> Hence, a chiropractor’s table would not qualify as a drug unless the manufacturer decided “to ship that table into interstate commerce, and say that that table would cure various ills.”<sup>130</sup> The FDA’s jurisdiction “would depend al-

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370 (1951).

126. 21 U.S.C. § 321(g)(1)(C) (1994).

127. See S. Rep. No. 73-493, at 2 (1934) (“Such expansion of the definition of the term ‘drug’ is essential if the consumer is to be protected against a multiplicity of devices and such preparations as ‘slenderizers,’ many of which are worthless at best and some of which are distinctly dangerous to health.”).

128. *Foods, Drugs and Cosmetics: Hearings on S. 2800 Before the Senate Comm. on Commerce*, 73d Cong. 516 (1934) [hereinafter *Hearings on S. 2800*] (statement of W.G. Campbell, Chief, FDA). The paragraph to which Dr. Campbell referred listed one of the alternative definitions of “drug” offered in S. 2800: “[t]he term ‘drug’ . . . includes . . . (3) all substances and preparations, other than food, and all devices intended to affect the structure or any function of the body.” *Id.* at 1 (quoting S. 2800, 73d Cong. § 2 (1933)).

129. See *id.* at 514-16 (statement of W.G. Campbell, Chief, FDA) (discussing whiskey, a product generally regarded as a drug but purchased as a beverage, and indicating that if sold as a beverage it would not fall within the definition of “drug” provided in the bill).

130. *Id.* at 517 (statement of W.G. Campbell, Chief, FDA).

together on the character of the representation.”<sup>131</sup> Campbell said, in response to a question about the extent of jurisdiction:

[There] is no interference at all with the manufacture, with the marketing, with the use of such product. This is only when someone goes to the extreme of converting that thing into a drug, according to this definition, and making preposterous and ridiculous representations about it that there would be any jurisdiction under this law.<sup>132</sup>

The product referred to in the quoted passage was an ordinary lamp. Campbell suggested that such an ordinary product would qualify for regulation if and only if it were marketed under “a preposterous representation,” for example as a cure for blindness.<sup>133</sup> Even a belt, used to help fix an injured back, was “admittedly a drug in some circumstances.”<sup>134</sup>

These are highly suggestive comments. They suggest that the statutory phrase “intended to affect the structure or function of the body” was not designed to authorize the FDA to affect every item or “article,” other than food, that affected bodies. Instead, it was intended to allow the FDA to go beyond articles that are responsive to a preexisting medical condition by regulating those that are alleged to have beneficial or therapeutic effects on the body.

### C. Practice

Past FDA practice is consistent with this view. In every judicial decision upholding FDA authority, the product held to fall within the “intended to affect” provision had been marketed pursuant to manufacturer representations about its intended use.<sup>135</sup> In such cases, the FDA asserted authority over products said, implicitly or explicitly, to

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131. *Id.* (statement of W.G. Campbell, Chief, FDA).

132. *Id.* at 518 (statement of W.G. Campbell, Chief, FDA).

133. *Id.* (statement of W.G. Campbell, Chief, FDA).

134. *Id.* at 516 (statement of W.G. Campbell, Chief, FDA).

135. *See, e.g.*, *United States v. An Article . . . “Sudden Change”*, 409 F.2d 734, 739 (2d Cir. 1969) (upholding FDA jurisdiction over a cosmetic product because manufacturer represented it as able to provide a “face lift without surgery”); *National Nutritional Foods Ass’n v. FDA*, 504 F.2d 761, 789 (2d Cir. 1974) (modifying the FDA’s classification of high-dosage vitamin products as drugs, because manufacturer had not intended them for therapeutic use); *Action on Smoking and Health v. Harris*, 655 F.2d 236, 239 (D.C. Cir 1980) (upholding the FDA’s refusal to regulate cigarettes, because manufacturers had not represented product as “intended to affect the structure or any function of the body”). *But see* *Coyne Beahm, Inc. v. FDA*, 966 F. Supp. 1374, 1389 (M.D.N.C. 1997) (upholding FDA jurisdiction over cigarettes, and determining a product’s “intended use” by evidence other than manufacturer representations).

have beneficial effects on the human body. This practice is entirely compatible with the legislative history and the contextual understanding of “drug” because a product is so characterized if it is used with the suggestion that it will have some kind of desirable effect on the body. This general idea also fits extremely well with the FDA’s governing regulations.<sup>136</sup>

More particularly, the FDA’s practice with respect to tobacco products has been entirely consistent with this understanding. The FDA did regulate cigarettes in the past. When it did so, though, it invoked a specific ground, pointing to various manufacturers’ claims about the beneficial effects of smoking, including its usefulness in helping people to lose weight.<sup>137</sup> In such cases, cigarettes were intended to affect the structure or function of the body in the same sense as a “slenderizer” or the hypothesized “preposterous” chiropractic table.<sup>138</sup> With both the slenderizer and the table, the product was regulable to the extent that it was sold on the ground that it would have the stated desirable physical effects. The key past federal court of appeals case involving tobacco products endorsed this basic understanding: “In cases such as the one at hand, consumers must use the product predominantly, and in fact nearly exclusively with the appropriate intent before the requisite statutory intent can be inferred.”<sup>139</sup>

How does this bear on the FDA’s current assertion of jurisdiction over tobacco? Note that in its jurisdictional statements, the FDA emphasized that tobacco has various addictive and toxic properties, and these factual claims are not in serious dispute.<sup>140</sup> In order, how-

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136. FDA regulations use the same language to explain the meaning of “intended uses” for both drugs and devices. See 21 C.F.R. § 201.128 (1997) (drugs); *id.* § 801.4 (devices). While both regulations state that this term “refer[s] to the objective intent of the persons legally responsible for the labeling of [the drugs or devices, respectively],” this intent may be shown either explicitly “by such persons’ expressions” or may be inferred “by the circumstances surrounding the use of the article.” *Id.* §§ 201.128, 801.4 (1997). Specifically, “[i]t may be shown by the circumstances that the article is, with the knowledge of such persons or their representatives, offered and used for a purpose for which it is neither labeled nor advertised.” *Id.* Thus, a product not explicitly sold as a fat reducer may be implicitly understood in this way, and the manufacturers’ intention that it be so understood and used would be sufficient. Tobacco is very different because tobacco is not used on the understanding that it would produce addiction.

137. See *United States v. 354 Bulk Cartons . . . Trim Reducing-Aid Cigarettes*, 178 F. Supp. 847 (D.N.J. 1959); *United States v. 46 Cartons . . . Fairfax Cigarettes*, 113 F. Supp. 336 (D.N.J. 1953).

138. See *supra* notes 130-132.

139. *Action on Smoking and Health*, 655 F.2d at 240.

140. See, e.g., *Jurisdictional Determination*, *supra* note 86, at 44,634 (describing “[t]he sci-

ever, to fit tobacco products within the statutory definition of “drug,” this is insufficient (on the interpretation I am now offering). Manufacturers must sell tobacco with some reference to those addictive and toxic properties; they must, in other words, sell tobacco by, in some sense, invoking or stressing those properties. It is this kind of sale that would make tobacco into a “drug.” This, of course, they have not done (and needless to say this would be a self-defeating strategy).

In a nutshell, this argument runs, the fact that tobacco does affect the structure or function of the body and that tobacco companies “intend” this effect is not decisive. While a literalist interpretation is a linguistically plausible reading of the statute, it wrenches the word “drug” out of its context and turns the statute into a basis for regulating anything at all that (knowingly) affects the bodies of human beings or animals. Perhaps the statutory terms should be understood in their context, which involves the regulation of drugs, and should be defined in a way that is consistent with that context. It would not be at all difficult to imagine an opinion rejecting FDA authority over tobacco on the basis of an analysis of this kind.

This, then, is the conflict raised by the FDA’s assertion of authority over tobacco. On the one hand, the ordinary meaning of the statutory terms plainly supports the FDA. On the other hand, the best understanding of the statutory terms, taken in their context, plausibly argues against the FDA’s interpretation. It is easy to imagine reasonable opinions both ways. Moreover, democratic considerations might themselves be marshaled in both directions. The FDA is, of course, subject to democratic influences, and its assertion of jurisdiction over tobacco is closely connected to perceived judgments from the electorate and to the values of the President, who has taken a strong personal interest in the regulation of tobacco products. On the other hand, it might be said that a statute designed to regulate drugs ought not be understood to authorize FDA control of tobacco and tobacco products unless and until Congress, the most representative institution in the federal government and the constitutionally designated lawmaker, has made that specific decision.

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entific consensus that cigarettes and smokeless tobacco cause addiction to nicotine”).

*D. Purpose*

The contextual understanding of the FDCA offers a distinctive interpretation of the Act's purpose, one that competes with the broader argument, based on information failure, that was offered above. On this view, Congress was concerned, first and foremost, with ensuring that the FDA had authority over products billed as medicines or as otherwise therapeutic,<sup>141</sup> where the likelihood of fraud, deception, confusion, and harm is especially high, as are the stakes. But Congress was also concerned with the kind of fraud and deception that comes when products are marketed as affecting the body in a beneficial way,<sup>142</sup> because this kind of misrepresentation, whether or not based on explicit language, is in the same family of harmfulness as the core or defining case.

On this view, Congress did not give the FDA a roving authority to regulate all products that have effects on the human body, when those effects are known and desired. The statute's goal—to permit controls on medical, therapeutic, or other similar products—was far narrower than that.

## IV. RESOLUTIONS

It thus emerges that there are two competing understandings of the relevant provision of the FDCA, with different assessments of the language and of the underlying purpose of the Act. In a familiar formulation, a court might resolve the dispute by asking which is a better constructive interpretation, that is, by asking which interpretation best fits the relevant statutory materials and which interpretation makes best sense of those materials.<sup>143</sup> In a conflict of this kind, there are several natural places to look for assistance. I discuss several possible strategies for resolving the case: analogies, diverse tie breakers, and a narrow argument by the FDA that attempts to draw on the contextual interpretation described above. I ultimately conclude that

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141. See 21 U.S.C. § 321(g)(1)(A)-(B) (1994) (“(A) articles recognized in the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals”).

142. See *id.* § 321(g)(1)(C) (“articles (other than food) intended to affect the structure or any function of the body of man or other animals”).

143. For an illuminating discussion of “constructive” statutory interpretation, see RONALD DWORIN, *LAW'S EMPIRE* 313-54 (1986).

the narrow argument, combined with an understanding of the common law role of modern agencies, is sufficient to support the FDA's assertion of jurisdiction.

*A. Analogies*

In one form or another, the conflict under discussion comes up in many areas. Consider, for example, *McDoyle v. United States*,<sup>144</sup> an important case in the law of statutory construction. The issue in *McDoyle* involved the meaning of the statutory term "motor vehicle," defined as including "an automobile, automobile truck, automobile wagon, motorcycle, or any other self-propelled vehicle not designed for running on rails."<sup>145</sup> The relevant statute made it a federal crime to transport a motor vehicle, thus defined, known by the transporter to be stolen.<sup>146</sup> The question in the case was simple: did an airplane qualify as a "motor vehicle"? In one sense, the answer would seem to be yes, since an airplane is a self-propelled vehicle emphatically not designed for running on rails. In an opinion by Justice Holmes, the Court acknowledged that it was possible to understand an airplane to be a vehicle, but concluded that in its context the term had a narrower scope:

When a rule of conduct is laid down in words that evoke in the common mind only the picture of vehicles moving on land, the statute should not be extended to aircraft, simply because it may seem to us that a similar policy applies, or upon the speculation that, if the legislature had thought of it, very likely broader words would have been used.<sup>147</sup>

Thus, Justice Holmes suggested that a statutory term would be understood by reference to exemplar cases and, in particular, to the "picture" that is "evoked in the common mind."<sup>148</sup> Perhaps this idea supports the attack on the FDA regulation, suggesting that despite the literal language of the FDCA, tobacco is simply too far afield from the "picture" called up by the contextual understanding of the term "drug."

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144. 283 U.S. 25 (1931).

145. *Id.* at 26 (construing the National Motor Vehicle Theft (Dyer) Act, ch. 89, 41 Stat. 324 (1919) (codified as amended at 18 U.S.C. § 2312 (1994))).

146. *See id.*

147. *Id.* at 27.

148. *Id.*

Consider two more recent cases: the famous affirmative action decision *United Steelworkers of America v. Weber*<sup>149</sup> and the less famous but very similar interpretive problem in *Smith v. United States*.<sup>150</sup>

In *Weber*, the Court held that a statutory ban on “discrimination” did not forbid a voluntary, race-conscious affirmative action program.<sup>151</sup> The Court understood “discrimination” in a highly contextual manner. It concluded that despite its literal breadth, the term should not be wrenched out of context to forbid conduct that Congress had not chosen to forbid.<sup>152</sup> The Court rejected what it saw as an excessively literal and insufficiently purposive reading of the statute. Justice Rehnquist wrote a vigorous dissenting opinion, contending, among other things, that the word “discrimination” should be interpreted in its ordinary English sense.<sup>153</sup> Whether or not *Weber* was correctly decided, the basic approach was far from exotic, and it provided a possible foundation on which to build an outcome unfavorable to the FDA in the tobacco litigation.

In *Smith*, the Court was asked to decide whether a statutory ban on the “use” of a firearm in connection with a drug offense applied to the “use” of a firearm as an object of barter.<sup>154</sup> Invoking the literal meaning of the word “use” and the dictionary, the Court held that the statutory ban did indeed apply.<sup>155</sup> Justice Scalia wrote a vigorous dissenting opinion, arguing that while trading a firearm could be understood as a use, the statutory context suggested that the term was best understood to mean “used as a firearm,” not as a commodity.<sup>156</sup>

*Weber* suggests the important point stressed by Justice Holmes: that language is often understood by reference to the paradigm or exemplar cases that it was written in order to cover. In *Weber*, the Court might be taken to have said that the 1964 Civil Rights Act was designed to forbid discrimination against blacks—that this was the paradigm or exemplar case—and that the literal meaning of the word “discrimination” would not be taken out of its context in order to re-

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149. 443 U.S. 193 (1979).

150. 508 U.S. 223 (1993).

151. See *Weber*, 443 U.S. at 208.

152. See *id.* at 201.

153. See *id.* at 220 (Rehnquist, J., dissenting).

154. See *Smith*, 508 U.S. at 225.

155. See *id.* at 228-29, 241.

156. See *id.* at 241-43 (Scalia, J., dissenting).

solve a question to which Congress had given little or no attention. In *Smith*, Justice Scalia's approach was similar. The paradigm case involved the use of a gun as a firearm, and the word "use" should be understood in the setting in which it was written, which included, not incidentally, a substantial mandatory minimum sentence.<sup>157</sup> While it would take a lengthy argument to establish this claim, I believe that *Weber* was correctly decided and that *Smith* was wrong. The basic reason is that when there is ambiguity, a statute generally should not be taken to extend to a case that Congress did not consider, at least if there is an arguable difference between that case and the exemplar cases covered by the rule. Congress should not be taken to have made certain acts unlawful if it has had no occasion to focus on those particular acts.<sup>158</sup>

A judgment of this kind might well suggest that the FDA has no authority to regulate tobacco, on the theory that the contextual understanding of "drug" suggests a narrower definition, and that Congress should not be taken to have authorized the FDA to undertake such regulation by a kind of inadvertence. There are, however, two crucial differences between the FDA case on the one hand and *Weber* and *Smith* on the other. First, the definition of "drug" offers far stronger support for the FDA than did the terms "discrimination"<sup>159</sup> and "use" for *Weber* and *Smith*. In this respect, the best precedent for the FDA may be *Oncale*, holding, on the basis of text, that the ban on sex discrimination applies to same-sex harassment, even though that problem was far from the specific intention of the passing Congress.<sup>160</sup> Second, an administrative agency entrusted with rulemaking authority is involved in the FDA case, whereas it was not in the latter two. The strongest argument on behalf of the FDA emphasizes this point, as we will shortly see.

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157. See 18 U.S.C. § 924(c)(1) (1994) (providing that "[w]hoever, during and in relation to any crime of violence or drug trafficking crime . . . uses or carries a firearm, shall, in addition to the punishment provided for such crime of violence or drug trafficking crime, be sentenced to imprisonment for five years").

158. I argue these points in some detail in CASS R. SUNSTEIN, *LEGAL REASONING AND POLITICAL CONFLICT* (1996).

159. The majority wrote as if this word supported *Weber*. See *United Steelworkers v. Weber*, 443 U.S. 193, 201 (1979). In my view, this was a mistake, for that word is highly ambiguous in the context of a civil rights act. An ordinary English speaker might well conclude, without revealing his ignorance of English, that affirmative action programs are not a form of "discrimination" on the basis of race.

160. See *Oncale v. Sundowner Offshore Servs.*, 118 S. Ct. 998, 1002 (1998).

An interesting analogy in this regard is *Brogan v. United States*.<sup>161</sup> There the Court was asked to construe a federal perjury statute providing that “[w]hoever, in any matter within the jurisdiction of any department or agency of the United States knowingly and willfully . . . makes any false, fictitious or fraudulent statements or representations . . . shall be fined not more than \$10,000 or imprisoned not more than five years, or both.”<sup>162</sup> Lower courts had, since 1962, found an exception to this prohibition when the defendant issued a simple denial of guilt: the “exculpatory no.”<sup>163</sup> The lower courts reasoned that an “exculpatory no” was far afield from Congress’s purposes in enacting the statute.<sup>164</sup> The statute had originally been enacted as part of the prohibition on filing fraudulent claims with the government, and the ban on false statements was limited to statements that related to these filings.<sup>165</sup> In 1918 the statute was broadened to apply to other false statements designed to swindle or defraud the government, and in 1934 it was broadened to its present form, apparently with the goal of protecting the government “from the affirmative, aggressive, and voluntary actions of persons who take the initiative.”<sup>166</sup> In this way, the statute was designed to prevent the perversion of governmental functions through affirmative lies, not to allow the government to convert protected acts into crimes by obtaining “no” answers to incriminating questions.

In *Brogan*, the Court rejected a purposive understanding of the statute: “[I]t is not, and cannot be, our practice to restrict the unqualified language of a statute to the particular evil that Congress was trying to remedy.”<sup>167</sup> In so saying, the Court found it irrelevant that courts had been interpreting the statute to exempt the “exculpatory no” for well over thirty years. *Brogan* thus suggests an interpretive method that strongly favors the FDA. On the other hand, the text of the false statements statute in *Brogan* was clear, and at most created a problem of excessive generality, as in Wittgenstein’s famous “gaming with dice” example;<sup>168</sup> the FDCA has greater

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161. 118 S. Ct. 805 (1998).

162. 18 U.S.C. § 1001 (1988) (amended 1996).

163. See *Brogan*, 118 S. Ct. at 808.

164. See *id.*

165. See *id.* at 813 (Ginsburg, J., concurring).

166. *Id.* at 814 (Ginsburg, J., concurring) (quoting *Paterno v. United States*, 311 F.2d 298, 302 (5th Cir. 1962)).

167. *Id.* at 809.

168. “Someone says to me: ‘Shew the children a game.’ I teach them gaming with dice, and

ambiguity, and the case for a contextual limitation on its reach is therefore stronger. *Oncala* is closer to the tobacco case on this count.

I conclude that the analogous cases do not favor one result or the other. In some cases, literal language has been understood literally; in others, courts have proceeded more purposively and contextually. Of course, literalism is rejected when it would produce absurd results.<sup>169</sup> Of course, purpose and context is considered when the language is ambiguous. But when the language seems to support an agency's view, and when the context raises doubt, there is no clear line of authority.

*B. Of Stare Decisis, Legislative Acquiescence, and Comprehensive Deals*

Perhaps the tiebreaker lies in subsequent developments. Indeed, the tiebreaker may be more than that.

For the past several decades, the FDA has consistently disavowed authority over tobacco,<sup>170</sup> and Congress has refused to enact legislation that would give FDA this authority.<sup>171</sup> Congress has repeatedly been presented with such legislation, and it has gone nowhere. Perhaps Congress can be said to have acquiesced in, or ratified, the FDA's previous interpretation. Some cases find a kind of acquiescence in similar circumstances.<sup>172</sup> For the FDA, though, things are worse than that. Congress has not merely refused to act; it has also enacted a great deal of legislation against the backdrop set by

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the other says 'I didn't mean that sort of game.' Must the exclusion of the game with dice have come before his mind when he gave me the order?" LUDWIG WITTGENSTEIN, *PHILOSOPHICAL INVESTIGATIONS* 33 n.68 (1968).

169. See *Riggs v. Palmer*, 22 N.E. 188, 189-90 (N.Y. 1889) (holding that equity and public policy dictate that one who murders the testator to receive an inheritance shall not be entitled to that inheritance although a literal statutory reading dictates otherwise).

170. See *Hearings on S. 1454*, *supra* note 54, at 239-42 (statement of Dr. Charles Edwards, Comm'r, FDA) (asserting that FDA jurisdiction over cigarettes would be inconsistent with clear congressional intent); Susan H. Carchman, *Should the FDA Regulate Nicotine-Containing Cigarettes?*, 51 *FOOD & DRUG L.J.* 85, 121 n.281 (1996) (citing a 1980 letter from FDA Commissioner Goyan, which asserted that Congress was aware that the FDA disavowed jurisdiction over cigarettes); see also *supra* notes 49-58 and accompanying text.

171. See H.R. 11280, 84th Cong. (1956); H.R. 5973, 88th Cong. (1963); S. 1682, 88th Cong. (1963); H.R. 2248, 89th Cong. (1965).

172. See *Bob Jones Univ. v. United States*, 461 U.S. 574, 600-02 (1983) (using congressional inaction on bills regarding the tax status of discriminatory private schools as support for conclusion that Congress acquiesced in IRS rulings); *United States v. Riverside Bayview Homes, Inc.*, 474 U.S. 121, 137 (1985) (holding that Congress's refusal to overrule an agency's construction of legislation provides some evidence of the reasonableness of that construction).

the FDA's claim that it cannot exercise authority over tobacco as a drug. Examples are the Federal Cigarette Labeling and Advertising Act of 1965,<sup>173</sup> the Comprehensive Smokeless Tobacco Health Education Act of 1986,<sup>174</sup> and the Alcohol, Drug Abuse, and Mental Health Reorganization Act of 1992.<sup>175</sup> The basic functions of this legislation are to control tobacco advertising and to ensure disclosure of health information, functions that overlap with some of the FDA's recent requirements. Even if the case were otherwise in equipoise, one might argue, the background of a consistent FDA interpretation, at least when combined with actual congressional enactments that might well coexist uneasily with FDA action, is sufficient to resolve the case against the FDA.

It is therefore possible to imagine an opinion that would strengthen the contextual understanding of the statutory terms with the observation that the FDA has long understood the Act not to apply to tobacco. Such an opinion would emphasize that Congress has legislated with the understanding that the FDA lacks that authority. The result is a system of regulation that reflects Congress's considered judgments—a system which would be rendered nonsensical by allowing two layers of controls, both statutory and administrative.<sup>176</sup> Indeed, such an opinion need not rely on the contextual understanding at all. The argument could simply be that the longstanding FDA opinion was part of a settlement that produced substantial legislation and that the FDA cannot suddenly change its mind and interfere with the congressionally chosen enforcement scheme.

This is a reasonable argument, but it has several problems. First, the FDA's position was not unambiguous. The FDA did not disclaim all authority over tobacco. It said that it would not exercise its authority unless tobacco companies made representations of physical

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173. Pub. L. No. 89-92, 79 Stat. 282 (1965) (codified as amended at 15 U.S.C. §§ 1331-1340 (1994)) (requiring a health-related warning label on all cigarette packaging and advertising).

174. Pub. L. No. 99-252, 100 Stat. 30 (1986) (codified at 15 U.S.C. §§ 4401-4408 (1994)) (requiring warning labels and ingredient disclosure on smokeless tobacco products and establishing a public health education program to increase risk awareness).

175. Pub. L. No. 102-321, § 202, 106 Stat. 323, 394-95 (1992) (codified at 42 U.S.C. § 300x-26 (1994)) (requiring states to prohibit the sale of tobacco products to individuals under eighteen in order to receive federal mental health funds under the act).

176. See *Kent v. Dulles*, 357 U.S. 116, 128 (1958) (requiring consistency over time in the breadth of the exercise of the Secretary of State's discretionary power to issue passports); *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto Ins. Co.*, 463 U.S. 29, 41-42 (1983) (holding that the rescission or modification of administrative rules is subject to the same procedures as their promulgation under the Administrative Procedure Act).

effects of some kind.<sup>177</sup> The FDA's current assertion of authority over tobacco is based largely on a claim that tobacco companies made, and intended to make, that kind of representation.<sup>178</sup> No doubt this was a change in the FDA's position, but there was some ambiguity in the former disclaimer of authority, and there is something less than complete discontinuity between the FDA's past and current positions.

Second, the idea of ratification or acquiescence is strongest when legitimate reliance interests have been built up around the previous view. If, for example, private actors have ordered their affairs on a certain understanding of the law, then a change in that understanding could defeat legitimate expectations. And while tobacco companies have assumed that the FDA would not be regulating them, the landscape of regulation of the world of cigarette smoking has been shifting rapidly (to say the least), and it would be extravagant to suggest that the assertion of FDA authority would defeat reasonable expectations.

Third, agencies are, with respect to *stare decisis*, in a very different position from courts. Agencies are permitted to change their minds, especially under the Supreme Court's decision in the *Chevron* case,<sup>179</sup> on which more is said below. It is one thing to say that judicial interpretations can be "frozen" by legislative inaction that might be taken to represent acquiescence in the judicial judgments; this idea is part of a strong principle of *stare decisis* for statutory meaning, designed to limit judicial discretion.<sup>180</sup> But agencies are in a different position, and when the change in view is associated with changed understandings of legally relevant facts, there is no problem with that change. Indeed, such changes in view, even when they alter the interpretation of a statute, are perfectly acceptable when motivated by judgements about values, as *Chevron* itself makes entirely clear.<sup>181</sup> There, too, the agency changed its interpretation, and there, too, the

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177. See *supra* notes 49-52 and accompanying text.

178. See Jurisdictional Analysis, *supra* note 5, at 41,522; Jurisdictional Determination, *supra* note 82, at 44,690-806, 44,847-45,097, 45,171-78.

179. *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984). *Chevron* is discussed in greater detail *infra* in the text accompanying notes 209-221.

180. See Antonin Scalia, *Judicial Deference to Administrative Interpretations of Law*, 1989 DUKE L.J. 511, 517-20 (1989) [hereinafter Scalia, *Judicial Deference*]; David M. Gossett, Comment, *Chevron, Take Two: Deference to Revised Agency Interpretation of Statutes*, 64 U. CHI. L. REV. 681, 688, 701 (1997).

181. See *Chevron*, 467 U.S. at 857-58, 863-64 (reaffirming deference to an agency "primarily responsible for administering" legislation, where the agency has reasonably interpreted the legislation).

interpretation was made public, and Congress could easily have been made aware of it.<sup>182</sup> Here the FDA's change was self-consciously motivated by new understandings of the effects of tobacco and of tobacco companies' intentions with respect to those effects.

These points would not be controlling if Congress had endorsed or ratified the FDA's prior position. How might any such ratification have come about? There are two separate possibilities: Congress may have ratified the FDA's view by failing to enact proposed legislation that would overturn it,<sup>183</sup> or Congress may have ratified the FDA's view by enacting legislation that was preemptive or comprehensive, in the sense that it reflected a settlement of the question of tobacco regulation, a settlement of which the absence of FDA authority was a part. Let us examine these points in order.

To say the least, there are many complexities in drawing inferences from the mere fact that Congress debated whether to regulate tobacco in certain ways, with the apparent understanding that the FDA would not be involved. Some cases have found a kind of "acquiescence" in longstanding interpretations; they suggest that a settled pattern of agency interpretations, which Congress considered overruling but did not overrule, is relevant to judicial interpretation.<sup>184</sup> This approach is especially reasonable where there has been detrimental reliance on the previous interpretation. But other cases point in the opposite direction.<sup>185</sup> Certainly Congress does not legislate by failing to legislate.<sup>186</sup> The failure to enact certain bills involving tobacco, by itself, does not divest the FDA of authority that it would otherwise have. There is little authority, and properly so, for the proposition that congressional acquiescence in administrative interpretations, in the form of inaction, works to bind an agency to those interpretations. Nor is this a case in which the FDCA has been reenacted against the background set by the FDA's interpretation.<sup>187</sup> A claim of acquiescence is especially weak in a case in which there have

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182. See *id.* at 857-59.

183. Examples of such refusals are listed above in note 171.

184. See *Coyne Beahm, Inc. v. FDA*, 966 F. Supp. 1374, 1381-83 (M.D.N.C. 1997) (discussing this theory and listing cases in which this argument was made).

185. See *id.* at 1382-83 (citing *Central Bank v. First Interstate Bank*, 511 U.S. 164, 187 (1994)); *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto Ins. Co.*, 463 U.S. 29, 45 (1983)).

186. See *Central Bank*, 511 U.S. at 187 ("[F]ailed legislative proposals are a particularly dangerous ground on which to rest an interpretation of a prior statute.").

187. See ESKRIDGE, *DYNAMIC INTERPRETATION*, *supra* note 25, at 243-44, 311-12 (listing Supreme Court decisions applying the reenactment rule finding ratification). *But see id.* at 312 (discussing Supreme Court decisions applying the reenactment rule finding no ratification).

been new understandings of statutorily relevant facts; the FDA did not disclaim all authority over tobacco for all time, and hence it is not even clear that a reenactment would have frozen the preexisting FDA view.

Subsequent legislation on the general topic is the strongest basis for holding against the FDA. If the legislation could be treated as a comprehensive settlement, and if an absence of FDA authority was a part of that settlement, then the new regulation would be invalid. But this would be an extravagant inference from what Congress has actually done. The preemption provision in the Federal Cigarette Labeling and Advertising Act of 1986, for example, is quite narrow,<sup>188</sup> and the Comprehensive Smokeless Tobacco Health Education Act reads in similar terms.<sup>189</sup> Hence, the relevant legislation should not by itself eliminate FDA authority, even if that legislation was enacted with the understanding that the FDA would not regulate tobacco. The strongest argument from subsequent legislation would rest on an actual conflict between the legislation and FDA regulations; to the extent that there is such a conflict, the regulations are preempted. At the very least, though, most of what the FDA has done can coexist comfortably with the relevant statutes, and hence the most that can be said is that some of the FDA regulations might be subject to challenge as applied. Repeals by implication are disfavored,<sup>190</sup> and the

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188. It provides that "[n]o statement relating to smoking and health, other than the statement required by section 1333 of this title, shall be required on any cigarette package." 15 U.S.C. § 1334(a) (1994).

189. "No statement relating to the use of smokeless tobacco products and health, other than the statements required by section 4402 of this title, shall be required by any Federal agency to appear on any package or in any advertisement . . ." 15 U.S.C. § 4406(a) (1994). Note also that a recent act, which requires that a state must prohibit the sale of tobacco products to individuals under eighteen in order to receive federal funding under the act, includes federal funding and does not preempt FDA regulatory authority. *See* Alcohol, Drug Abuse, and Mental Health Reorganization Act, Pub. L. No. 102-321, § 202, 106 Stat. 323, 394-95 (1992) (codified at 42 U.S.C. § 300x-26 (1994)). This point is fortified by a 1997 enactment suggesting that FDA authority is unsettled. The Food and Drug Administration Act of 1997, Pub. L. No. 105-115, § 422, 111 Stat. 2296, 2380 (codified at 21 U.S.C.A. § 321 note (West Supp. 1998)), provides that:

Nothing in this Act or the amendments made by this Act shall be construed to affect the question of whether the Secretary of Health and Human Services has any authority to regulate any tobacco product, tobacco ingredient, or tobacco additive. Such authority, if any, shall be exercised under the Federal Food, Drug, and Cosmetic Act, ch. 675, 52 Stat. 1040 (1938) as in effect on the day before the date of the enactment this Act [Nov. 21, 1997].

190. *See* *Tennessee Valley Auth. v. Hill*, 437 U.S. 153, 189-90 (1978) (stating that repeals by implication are disfavored and are only permissible when earlier and later statutes cannot be reconciled).

claim that the FDA has been divested of authority by subsequent legislation looks very similar to a claim for implied repeal.

I conclude that the subsequent legislation makes for a plausible argument against the FDA. But outside of the context of a direct conflict, that plausible argument is not convincing.

*C. Pragmatic Considerations: Legislative Responsiveness and Judicial Capacity*

A natural way to resolve the dispute between a more literal and more contextual understanding is to ask some questions about institutional capacity. First, which approach would lead to more mistakes and more serious mistakes? This is a question about “error costs.” Second, which approach would lead to more costly and more difficult decisions? This is a question about “decision costs.”

To approach these questions, it is necessary to refine the distinction between the two approaches; they represent a continuum rather than a sharp dichotomy. Some literal interpretations would be ruled out by context, regardless of one’s general approach. This is true not only for scrivener’s errors,<sup>191</sup> but also for terms whose meaning becomes plain only by context.<sup>192</sup> Context is always present and always helps inform the understanding of meaning. In some cases the literal meaning would make no sense; even the most enthusiastic textualists accept this point.<sup>193</sup> By the same token, contextual interpretation becomes quite contentious if it is understood to entail a rejection of the plain meaning of the text on the basis of the legislative history. The form of contextualism that argues against the FDA is more modest: it is merely a suggestion that an apparently broad text should be understood by reference to its purpose and background and that the context, including the history, supports a narrower understanding than the language alone suggests. The debate here is not between rigid lit-

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191. These are to be fixed via contextual interpretation. See SCALIA, INTERPRETATION, *supra* note 107, at 20-21.

192. Consider, for example, the term “use” in *Smith*. See *supra* notes 154-156 and accompanying text.

193. Justice Scalia, for example, a self-described textualist, acknowledges that context is a critical tool to be used in interpreting the meaning of a word. See *Smith v. United States*, 508 U.S. 223, 241-47 (1993) (Scalia, J., dissenting) (arguing that the majority’s literal definition of the word “use” is inaccurate given its ordinary contextual meaning); see also SCALIA, INTERPRETATION, *supra* note 102, at 23-24 (criticizing the majority’s strict construction in *Smith* and stating that a text should be interpreted “reasonably, to contain all that it fairly means,” a goal which neither strict nor lenient construction achieves).

eralists and text-rejecting contextualists—two pretty absurd camps—but between two emphatically reasonable opponents: those who would stress the ordinary meaning of the statutory terms and those who would stress contextual factors suggesting a narrower view than the words alone support.

In ordinary communication, of course, literal interpretation is infrequent, and likely unsuccessful: “don’t leave the house” (but what if there is a fire?); “let’s play a game, any game you like” (but what if Russian roulette is proposed?). In ordinary communication, people understand words very much in context, with reference to presumed intentions. Genuine “literalism” is a province of androids and robots in science fiction, who do not really understand how language works, and of eight-year-old children, who derive considerable humor and mischief from literal interpretation.<sup>194</sup> The point suggests a pervasive problem with literalism: it may generate mistakes, in the form of inaccurate understandings of Congress’s instructions. We can talk all we like of the difficulty of discovering the “intention” of a multimember decisionmaking body; the point still holds.

Thus, the defense of a contextual understanding depends on the view that it is likely to produce more accurate interpretations, where accuracy is assessed by reference to Congress’s judgments about what it is seeking to accomplish.<sup>195</sup> On this view, an emphasis on context is part of any approach to interpretation that seeks to elicit actual judgments and understandings. Contextual interpretation is thus analogous to “market-mimicking” or “intention-eliciting” default rules in the law of contract.<sup>196</sup> In contract law, as in statutory interpretation, default rules and interpretive strategies might be intended to figure out what the parties are likely to have wanted to have done. Indeed, it would be possible to conclude that all understanding is contextual and that literalism, in the tobacco case or anywhere else, is obtuse, something to be used only when there is reason to think that the literal interpretation has a good claim to being the contextual one too.

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194. Personal experience confirms this point!

195. Justice Scalia, importantly, is not a literalist; he counsels attention to context. See SCALIA, INTERPRETATION, *supra* note 107, at 37 (“In textual interpretation, context is everything, and the context of the Constitution tells us not to expect nit-picking detail, and to give words and phrases an expansive rather than narrow interpretation—though not an interpretation that the language will not bear.”).

196. See generally Ayres & Gertner, *supra* note 14 (discussing various possible default rules in the law of contracts).

But this view is far too simple.<sup>197</sup> Suppose, for example, that the more contextual interpretation depends on resort to the legislative history, and that the statute's text alone, as enacted in 1938, cannot support that interpretation. It is entirely reasonable to think that the text should prevail. A refusal to give the words their ordinary meaning may create bad incentives for Congress; perhaps a more literal reading would encourage Congress to speak more clearly. A literal reading may also greatly simplify the process of judicial judgment. Freed from reliance on the ordinary meaning of the text, contextualist courts might produce mistakes, partly through simple error, partly through willfulness, even if some contextualist courts might also make some better decisions than literalist ones. In other words, literalists cannot be perfect; but perhaps they will be better, on balance, than their adversaries. Here as elsewhere, the perfect can be the enemy of the good. On this view, (reasonable, rather than science fictional) literalism can be justified as analogous to an information-eliciting rule in the law of contract, designed to force the parties (or in this case, the Congress) to speak with greater clarity.<sup>198</sup> It can be so justified with the additional claim that if intention-eliciting is important, literalism is no worse than the alternative, and perhaps better, at least as a general rule.<sup>199</sup>

It is hard to resolve this dispute in the abstract. An obvious question is whether Congress will in fact respond to literal interpretations by legislating with greater care and clarity; there is little evidence that it will. Another question is whether Congress will respond to judicial mistakes, and here there is no systematic evidence. These points suggest that the contextual approach is more reasonable, at least where the court is confident that the resulting interpretation is really a fairly accurate conception of Congress's instructions and where the notion of contextual interpretation is not a guise for unreliable inferences based on legislative history.

This conclusion suggests that if the courts were deciding the issue in the first instance, tobacco products could not be regulated without a convincing showing that they were being sold with some

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197. See SCHAUER, *supra* note 11, at 196-200 (defending formalism).

198. See Ayres & Gertner, *supra* note 14, at 104 (arguing that courts should choose clear rules which "promote information revelation").

199. See Adrian Vermeule, *Legislative History and the Limits of Judicial Competence: The Untold Story of Holy Trinity Church*, 50 STAN. L. REV. 1833 (1998) (criticizing intentionalist courts' use of legislative history in statutory interpretation cases based upon their inability to cope with the volume and heterogeneity of prior statutes).

kind of representation about their beneficial medical or therapeutic effects, making them analogous to slenderizers.<sup>200</sup> But courts are not deciding this issue in the first instance—an important fact of life in the administrative state,<sup>201</sup> as we shall soon see.

*D. A Narrower Reading by the FDA?*

Is it possible to accept the contextual interpretation offered in Part III while, at the same time, upholding the FDA's treatment of cigarettes as drugs? Might the FDA endorse a narrower understanding of the statute and still prevail? This would be the most promising route; it would make the basic conflict about styles of interpretation irrelevant, or nearly so.

To the extent that the FDA is emphasizing the addictive properties of tobacco, this question is hard to answer affirmatively. If tobacco companies urged that smoking helps to prevent colds, cigarettes would fit within the contextual meaning of the term "use." But addiction is altogether different, since no one contends that tobacco companies successfully encouraged people to smoke on the ground that smokers would become addicts. Things are, however, a bit more complicated for those challenging the FDA regulation. In its ruling, the FDA referred not only to addiction but also to two other undisputed changes that tobacco produces in the function of the body: the effects of smoking in producing both tranquillity and stimulation and the effects of smoking in producing weight control.<sup>202</sup> There can be no question that the FDA would have the power to treat tobacco products as drugs if they were sold with the representation, express or implied, that they help people to control weight. Nor can there be much doubt that the FDA would be authorized to treat tobacco as a drug if it were sold as a method for producing stimulation or tranquillity. Could the FDA find that these effects were intended by manufacturers and understood by consumers, so that cigarettes would be akin to slenderizers after all? A reading of the rationale in support of the regulations suggests that the FDA did make this finding.

This is far from a frivolous argument. Many people use cigarettes because of their effects on the functions of the body—usually for producing either stimulation or tranquillity, sometimes for helping to

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200. See *supra* notes 49-57 and accompanying text.

201. See *infra* Part III.

202. See Jurisdictional Determination, *supra* note 86, at 44,666.

prevent weight gain. A reasonable person could find that manufacturers intend these effects and that many consumers smoke with these effects in mind. Indeed, common advertisements for cigarettes can be seen to be emphasizing, explicitly or implicitly, the tranquilizing and stimulating effects of smoking,<sup>203</sup> and there is evidence that tobacco companies have been entirely aware of these effects.<sup>204</sup> Thus, for example, the FDA reported survey evidence that over seventy percent of young people who are daily smokers said that they smoked for relaxation.<sup>205</sup> The narrowest decision upholding FDA authority would emphasize these points, which provide a much stronger foundation for the FDA's assertion of jurisdiction than does addiction.<sup>206</sup>

## V. AGENCIES AS COMMON LAW COURTS

### A. A Reading of *Chevron*

Thus far the discussion has proceeded as if this were a case of statutory interpretation, but it is also one of administrative law, and the FDA's position is much fortified if we expand the lens in this way. In the modern era, most of the key work of statutory interpretation is, of course, not done by courts, but rather by federal agencies. Most of these interpretive acts never face judicial review, and those who challenge such acts face a high burden.<sup>207</sup> Realistically speaking, general and ambiguous terms are given their meaning by agency officials who adapt those terms to changing facts and values. Thus, the business of a wide range of agencies—the NLRB, the FCC, the FTC, the SEC, the IRS, the EPA, the CPSC, and many more—involves the specification of general statutory terms, the resolution of ambiguities,

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203. See, e.g., KLUGER, *supra* note 63, at 295, 443-45 (noting especially that the Marlboro Man is capable of both 'action' and 'repose,' suggesting both stimulation and tranquillity); Irene Scharf, *Breathe Deeply: The Tort of Smokers' Battery*, 32 HOUS. L. REV. 615, 631-60 (1995) (discussing advertising thoroughly, and noting specific campaigns based on the weight control properties of cigarettes).

204. See Jurisdictional Determination, *supra* note 86, at 44,668-69.

205. See *id.* at 44,814.

206. The narrow argument I am endorsing here does not rely on the addictive properties of tobacco, because reliance on those properties stretches the contextual meaning of the statute further than does an interpretation that relies on tobacco's sedating and stimulating properties.

207. See *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 842-45 (1984) (requiring "deference to administrative interpretations").

and the adaptation of legal texts (their enabling statutes) to new circumstances and new social understandings.<sup>208</sup>

The point is, of course, recognized in *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, which, it is becoming increasingly clear, stands as the most important case about legal interpretation in the last thirty years.<sup>209</sup> *Chevron* holds that where statutes are ambiguous, courts should accept any reasonable interpretation by the agency charged with their implementation.<sup>210</sup> Agencies are to prevail whenever statutes are subject to diverse, plausible readings. This idea is of course strongly supportive of the FDA's position that tobacco can be treated as a drug.

The central idea behind *Chevron* is that where underlying statutes are ambiguous, Congress should be taken to have decided that agencies are in a better position to make judgments about their meaning than are courts.<sup>211</sup> Agencies are in that better position because, *Chevron* emphasizes, the President is generally in charge of their policy judgments, and hence agencies have a kind of democratic pedigree, certainly a better one than the courts.<sup>212</sup> Administrative

208. See *infra* notes 229-233 and accompanying text.

209. There is, of course, much debate about the precise meaning and consequences of the decision. See, e.g., Thomas W. Merrill, *Textualism and the Future of the Chevron Doctrine*, 72 WASH. U. L.Q. 351 (1994) (discussing implications for textualism); Thomas W. Merrill, *Judicial Deference to Executive Precedent*, 101 YALE L.J. 969 (1992) (arguing that the Supreme Court has not rigorously followed *Chevron*); Peter H. Schuck & E. Donald Elliott, *To the Chevron Station: An Empirical Study of Federal Administrative Law*, 1990 DUKE L.J. 984 (presenting empirical evidence about the impact of *Chevron* on administrative law).

210. See *Chevron*, 467 U.S. at 842-45. This statement simplifies some complex issues. For more comprehensive discussions, see 1 RICHARD J. PIERCE & KENNETH CULP DAVIS, *ADMINISTRATIVE LAW TREATISE* §§ 3.1-3.7 (1994 & Supp. 1997); Cass R. Sunstein, *Law and Administration after Chevron*, 90 COLUM. L. REV. 2071 (1990) [hereinafter Sunstein, *Law and Administration*].

211. See *Chevron*, 467 U.S. at 843-44 (discussing "implicit" delegation of power to "elucidate" statutes). Although not on the *Chevron* Court, Justice Scalia argues that *Chevron* is best taken to hold that the question of deference will be resolved by reference to Congress's instructions. Of course, when Congress passes an ambiguous statute, it fails to give clear instructions. Thus, both in light of the value of providing a clear background rule and because *Chevron* is a reasonable understanding of Congress's views about relevant institutional capacities, statutes will generally be read to require courts to defer to reasonable agency interpretations of law. See Scalia, *Judicial Deference*, *supra* note 180, at 516.

212. In the Court's words:

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.

*Chevron*, 467 U.S. at 865-66. In some ways, perhaps, agencies have a stronger democratic pedi-

agencies are, of course, influenced by shifting public judgments, and their approaches are likely to reflect the President's basic commitments.<sup>213</sup> This was, no doubt, true in *Chevron* itself, where the cost-saving innovation there at issue responded to President Reagan's concern with expensive regulations. In the context of the tobacco controversy, the point is highly relevant, for there can be little doubt that the FDA's position is highly responsive to the views of President Clinton, who has made regulation of tobacco a central issue, not least in the context of the presidential campaign of 1996.<sup>214</sup> *Chevron* appears in this way to accept the suggestion that deciding how to read ambiguities in a law involves no brooding omnipresence in the sky but an emphatically human judgment about policy or principle.<sup>215</sup> This suggestion was of course central to the legal realist movement, but it is now supported by a wide range of people<sup>216</sup> and it obviously bears on the question of whether and how the FDA can interpret the word "drug."

*Chevron* also has a technocratic (as opposed to democratic) justification: judgments about the best meaning of statutory terms may well turn on an understanding of underlying facts. A decision about which articles affect the structure or function of the body will inevitably turn on judgments about facts, not only about the particular consequences of using the relevant articles, but also on the consequences, for regulatory policy, of a judgment one way or the other. This point is closely connected to the question of whether the FDA has authority over tobacco, since the FDA's decision turned partly on judgments about the facts.<sup>217</sup>

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gree than Congress itself, though the *Chevron* Court does not so argue. For an argument to this effect, see JERRY L. MASHAW, GREED, CHAOS, AND GOVERNANCE 131-157 (1997).

213. See MASHAW, *supra* note 212, at 131-157.

214. See, e.g., Glenn Frankel, *Decades After Declaration, War on Smoking Begins*, WASH. POST, Aug. 24, 1996, at A1 (discussing President Clinton's support for the FDA's assertion of regulatory authority over tobacco and its relationship to the presidential campaign).

215. *Chevron* thus has much in common with *Erie Railroad Co. v. Tompkins*, 304 U.S. 64 (1938). Both cases involve a rejection of the view that federal courts could neutrally declare "the law," and both cases, following that rejection, reallocate legal authority from federal courts to other institutions. For a provocative general discussion of the "Erie effect," see Lawrence Lessig, *Erie-Effects of Volume 110: An Essay on Context in Interpretive Theory*, 110 HARV. L. REV. 1785, 1795-1801 (1997).

216. See DWORKIN, *supra* note 143, at 36-37. There is an interesting relation between Dworkin and *Chevron*: both acknowledge the constructive aspects of interpretation, but *Chevron* sees this as a reason for administrative rather than judicial judgment.

217. Here, however, it seems mostly to be a political rather than technocratic judgment.

In this and other disputes, the importance of the *Chevron* decision cannot be overstated: in its relatively short period on the scene, *Chevron*, a kind of counter-*Marbury*<sup>218</sup> for the administrative state, has been cited more frequently than *Marbury v. Madison*, *Brown v. Board of Education*,<sup>219</sup> or *Roe v. Wade*,<sup>220</sup> and, if present trends continue, it may ultimately be cited more frequently than all those cases put together.<sup>221</sup> Of course, there are limits to what citation rates show, but, at the very least, *Chevron* has become the framework through which agency interpretations of law are reviewed.

For present purposes, the basic point is that in establishing the power of administrative agencies to resolve statutory ambiguities, *Chevron* has recognized that the resolution of such ambiguities is largely a judgment of policy, to be made by institutions with democratic accountability and technical expertise. In this way, *Chevron* has granted agencies two important common law functions, those of specifying statutory terms and of adapting those terms to new facts and values. The question for post-*Chevron* law has involved the identification of limits on those common law functions.

### *B. Deference and Updating*

We are thus left with the question of whether the FDA is bound by what may appear to be the most reasonable interpretation of the statutory terms, taken in their context and understood by reference to the traditional tools of statutory construction, or whether the FDA may adopt an interpretation that, whether or not the very best, seems consistent with the language of the statute and that does not violate any unambiguously expressed will of Congress. So phrased, *Chevron* seems to supply the answer: the FDA should prevail.

The narrowest understanding of the FDA's interpretation is that when an article has a range of physical effects, including beneficial effects, when the manufacturer intends those effects, and when a substantial number of consumers purchase the article because of those effects, the article satisfies the definition of "drug." It does not matter that many consumers are unaware of or uninterested in those effects;

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218. *Marbury v. Madison*, 5 U.S. (1 Cranch) 137 (1803).

219. 347 U.S. 483 (1954).

220. 410 U.S. 113 (1973).

221. A Westlaw search (limited to federal cases) conducted on April 19, 1998 produced the following results: *Chevron*, 6252 references; *Marbury*, 3818 references; *Brown*, 3455 references; and *Roe*, 4885 references.

the fact that many consumers are aware of them and smoke because of them is sufficient if the manufacturer intends those effects. To uphold the FDA regulation, this narrow understanding is sufficient.

A large advantage of this route is that it does not threaten to give rise to implausible hypotheticals. Indeed, it is hard to specify implausible outcomes that would follow from this understanding of FDA authority or even from a somewhat more expansive understanding.<sup>222</sup> Even a definition of exercise machines as drugs would, under certain factual assumptions, fit well not merely with the statutory text but also with context, history, and longstanding practice.

It is possible to draw from this discussion a more general lesson, which I can describe only briefly here. In the modern era, administrative agencies have become America's common law courts. In the eighteenth and nineteenth centuries, common law courts, of course, had a kind of updating and particularizing function. In a common law era, it was the job of common law judges to apply incompletely specified legal doctrines to new contexts and to supply new understandings of those doctrines, which were typically phrased as abstractions. These new understandings sometimes amounted to reversals of pre-existing doctrines, both general and particular. Often, judges schooled in the common law tradition undertook a similar approach to statutory terms, as in the great cases of *Riggs v. Palmer*<sup>223</sup> and *Church of the Holy Trinity v. United States*.<sup>224</sup> To some degree, courts have exercised this common law function in the twentieth century as well,<sup>225</sup> but in a way that has been highly controversial. Some people

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222. If the article in question is a food, it cannot count as a drug. See 21 U.S.C. §§ 321f-g (1994) (“[A] food or dietary supplement . . . is not a drug . . . solely because the label or labeling contains . . . a statement [calling the food or dietary supplement a drug].”). Moreover, exercise machines and other “articles” that are marketed as having beneficial effects qualify as drugs even under the narrower, more contextual understanding; hence, these do not count as implausible hypotheticals. It should be noted that there simply are not many cases of articles that are ingested, that do not count as foods, that have various effects on bodies, and that it seems unreasonable to think that the FDA may treat as drugs. Note that a recent statute has expressly exempted various dietary supplements. See Dietary Supplement Health and Education Act of 1994, Pub. L. No. 103-147, § 3, 108 Stat. 4325, 4327 (codified at 21 U.S.C. § 321(ff) (1994)).

223. 22 N.E. 188 (N.Y. 1889) (rejecting a literal interpretation of a probate statute that would allow a person's murderer to receive an inheritance from that person).

224. 143 U.S. 457 (1892) (rejecting a literal interpretation of a statute when it was evident that Congress did not intend the statute to be interpreted literally).

225. Consider, for example, a fairly conventional case, *American Mining Congress v. EPA*, 824 F.2d 1177 (D.C. Cir. 1987). Congress had not clearly dealt with the problem of how to handle materials held for recycling, and the relevant EPA regulation defined certain materials involved in recycling as “solid waste.” *Id.* at 1179. In particular, it said that spent materials,

have urged that it is entirely illegitimate for judges to continue their common law role,<sup>226</sup> while others have argued for a form of “dynamic” statutory interpretation,<sup>227</sup> and still others have gone so far as to urge a judicial power to nullify statutes on the ground that they are out of accord with the existing legal landscape.<sup>228</sup>

In the modern period, however, dynamic interpretation is—simply as a matter of actual practice—an administrative task, not a judicial one. This is least controversially the case when agencies are deciding how to apply general terms to new problems or old problems that appear in new lights. In the late twentieth century, administrative agencies have undertaken most of the functions of common law courts, adapting general principles to various contexts, often in ways that produce substantial reversals. This is an omnipresent feature of the modern legal landscape. Consider just a few examples. The public interest standard for regulation of the broadcasting indus-

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sludges, scrap metal, and the like would be treated as solid waste if they were not directly reused but were instead held as part of an industry’s ongoing production process. *See id.* at 1180. The EPA reasoned that materials that were stored, transported, and held for recycling were associated with the same kinds of environmental harms as materials that were abandoned or disposed of in some final way. The court of appeals struck down the EPA regulation on the ground that the governing statute defined solid waste as “garbage, refuse, sludge . . . and other discarded material,” *id.* at 1179. For the court, material held for recycling was not “discarded.” *Id.* at 1193. Citing the dictionary, the court thought that the “ordinary, plain-English meaning” was decisive. *Id.* at 1184. If the question was an internal dispute on a court of appeals about the best interpretation of a statutory term, perhaps the majority would be right. But the question involved the validity of an EPA regulation, produced after a complex process involving a number of political interests, an extended process of intergovernmental deliberation, and an elaborate inquiry into the underlying issues of substance. Even if a court would be reluctant to adapt the meaning of a term like “discarded” to fit with context, is it not hubristic for judges, not elected and knowing little about the enormously complex subject at hand, to invoke dictionaries (compiled, after all, by human beings) to invalidate executive branch decisions that cannot reasonably be said to run afoul of any judgment made by Congress? The EPA’s decision followed a sustained period of public comment, and undoubtedly the government would be held accountable for any decision about the reach of the enabling statute. If the EPA’s definitions runs afoul of dictionary decisions but of no actual decision by Congress, should it really be struck down? *See also, e.g.,* *Industrial Union Dep’t, AFL-CIO v. American Petroleum Inst.*, 448 U.S. 607, 659-62 (1980) (rejecting a literal interpretation of the OSH Act).

226. *See* SCALIA, INTERPRETATION, *supra* note 107, at 12-14. Justice Scalia questions “whether the attitude of the common law judge—the mindset that asks ‘what is the most desirable resolution of this case and how can any impediment to [its] achievement . . . be evaded?’—is appropriate for the work that [he does] and much of the work that state judges do.” *Id.* at 13. “All of this [judges interpreting the law in order to accomplish a goal] would be an unqualified good, were it not for a trend in government in recent centuries, called democracy.” *Id.* at 9.

227. *See* ESKRIDGE, *supra* note 25, at 11 (defining “dynamic statutory interpretation” as the divergence of the perspectives of the interpreter from that of the statute when written, often because text takes on a new meaning due to subsequent social and ideological changes).

228. *See* GUIDO CALABRESI, A COMMON LAW FOR THE AGE OF STATUTES 164 (1983).

try has been subject to a common-law-like process of specification on the part of the FCC, embodying recognition of new values and facts. Thus, the FCC originally created and then eliminated the fairness doctrine, and new public interest obligations have grown up in the wake of the elimination.<sup>229</sup> The EPA's regulations for protecting the public health through national ambient air quality standards are hardly static; even if the governing statutory term is taken to be clear and firm, the agency's practice has been otherwise.<sup>230</sup> The NLRB operates, in practice, as a common law court, adapting statutory terms to new facts and values.<sup>231</sup> The principal judgments about what qualifies as a "drug" have come from the FDA, not from courts, which have played a supplemental role. The FDA's assertion of jurisdiction over tobacco is merely an unusually visible and dramatic instance of this phenomenon.

Is this shift undesirable or illegitimate? It might be argued that the process of common law judgment by administrative agencies is unacceptable because agencies are subject to the influence of powerful private interests, or factions, while independent courts are far less vulnerable to such influence. On one view, both the vulnerability of agencies to factions and the interest of agencies in increasing their own power and authority argue against the common law analogy; at least common law judges had, and have, the virtues of comparative independence. The susceptibility of agencies to "faction" is a persistent theme in administrative law,<sup>232</sup> and those who emphasize that theme would be likely to favor the more contextual interpretation offered in Part I, to seek express legislative authorization for the new FDA interpretation, and to be unconvinced by the pro-deference argument I am urging here.

The basic claim on behalf of the transformation I am describing is rooted directly in *Chevron*; it emphasizes both democratic and technocratic values. When compared with common law courts, agencies have a greater understanding of relevant facts, and they also have a degree of political responsiveness, which is a virtue as well as a

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229. See Glen O. Robinson, *The Electronic First Amendment: An Essay for the New Age*, 47 DUKE L.J. 899, 926-930 (1998).

230. See *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 857-58 (1984).

231. See ROBERT A. GORMAN, *BASIC TEXT ON LABOR LAW UNIONIZATION AND COLLECTIVE BARGAINING* 13 (1976).

232. See Richard B. Stewart, *The Reformation of American Administrative Law*, 88 HARV. L. REV. 1667, 1684-85 (1975); JAMES O. FREEDMAN, *CRISIS AND LEGITIMACY* 158 (1978).

potential vice. The common law role of agencies is a function of specifications of statutory terms that result either from new factual knowledge or from changes in values, or from some combination of the two. The reversal in *Chevron* itself—from a smokestack definition of “source” to a plant-wide definition of “source”—was partly a product of technocratic values suggesting that this strategy would work best;<sup>233</sup> it was also undoubtedly a product of political values and interests calling for less costly means of achieving environmental protection. To the suggestion that this position means that some statutes (more accurately, their terms in some applications) might be lost or misdirected as a result of new agency rulings, a response might be given in Justice Scalia’s words: “[L]ots of once-heralded programs ought to get lost or misdirected, in vast hallways or elsewhere. Yesterday’s herald is today’s bore—although we judges, in the seclusion of our chambers, may not be *au courant* enough to realize it.”<sup>234</sup>

The FDCA was of course written many years ago, and it defies belief to suggest that there is, in the background of that Act, any clear or simple legislative intent<sup>235</sup> about whether tobacco might be counted as a drug in light of modern understandings of the effects of tobacco and of the understandings and desires of cigarette companies about those effects. The FDA is in an unusually good position to obtain information about those effects, understandings, and desires. Its assertion of regulatory power has already received and will inevitably continue to receive an enormously high degree of political attention, from Congress as well as from the President, not to mention the relevant groups that appear before the FDA itself. The ordinary understanding of the statutory text supports the FDA’s position, and nothing in subsequent developments in Congress has divested the FDA of the authority that it would otherwise have. In applying the FDCA to tobacco, the FDA performed a lawful common law function, one that also has a high degree of democratic legitimacy. Where Congress has not spoken clearly, the role of the reviewing court is to

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233. See *Chevron*, 467 U.S. at 857-58 (discussing the rationale underlying the new definition of “source”).

234. See Antonin Scalia, *The Doctrine of Standing As An Essential Element of the Separation of Powers*, 17 SUFFOLK U. L. REV. 881, 897 (1983).

235. There are of course both practical and theoretical questions involved in the use of the word “intent.” Some people doubt that legislatures, as collective bodies, have intentions. See Max Radin, *Statutory Interpretation*, 43 HARV. L. REV. 863, 881 (1930). Others doubt the relevance of intention even if there is such a thing. See Oliver Wendell Holmes, *The Theory of Legal Interpretation*, 12 HARV. L. REV. 417, 419 (1899).

obtain assurance of the reasonableness of the agency's decision in terms of facts, policy, and law, and there can be no doubt that the FDA's judgment was reasonable here.

### C. Counters to *Chevron*

There are several possible responses to the argument rooted in *Chevron*.

1. *Jurisdiction*. It might be argued that the FDA has, by its own lights, made a jurisdictional determination, and perhaps an agency does not have, under *Chevron*, the power to determine its own jurisdiction. As a matter of first principles, it is unclear whether *Chevron* deference should be due to an agency involved in a jurisdictional determination.

This continues to be a disputed question.<sup>236</sup> On the one hand, it might be thought that courts should not presume that Congress intended to give agencies the power to decide the extent of their own jurisdiction.<sup>237</sup> The likelihood of bias and self-dealing might well be taken to argue against deference to jurisdictional judgments. On the other hand, two points argue in favor of granting deference to agency interpretations even when jurisdiction is at issue.<sup>238</sup> First, a prime argument for *Chevron* is its relative simplicity, and if courts were to attempt to distinguish between jurisdictional and nonjurisdictional determinations, that advantage might well be lost. This is a thin and shifting line; most assertions of agency power can be deemed

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236. See Sunstein, *Law and Administration*, *supra* note 210, at 2097-2100.

237. See *Mississippi Power & Light Co. v. Mississippi*, 487 U.S. 354, 383-388 (1988) (Brennan, J., dissenting) (arguing that Federal Power Act did not confer such power on the Federal Energy Regulatory Commission); *Business Roundtable v. SEC*, 905 F.2d 406, 413-14 (D.C. Cir. 1990) (refusing to permit the SEC to "advance into an area not contemplated by Congress"); cf. *National Wildlife Found. v. ICC*, 850 F.2d 694, 699 n.6 (D.C. Cir. 1988) (noting that *Chevron* may require deference to jurisdictional determinations, but stating that it need not decide the point because the agency is disclaiming authority (citing *Schwabacker v. United States*, 334 U.S. 182, 204 (1948) (Frankfurter, J., dissenting)); *New York Shipping Ass'n v. Federal Maritime Comm'n*, 854 F.2d 1338, 1363-65 (D.C. Cir. 1988) (giving "no special deference to an agency's interpretation of labor laws when those laws were not committed to that agency for enforcement"); see also Clark Byse, *Judicial Review of Administrative Interpretation of Statutes: An Analysis of Chevron's Step Two*, 2 ADMIN. L.J. 255, 260-61 (1988) (criticizing judicial acceptance of all agencies' reasonable interpretations of ambiguous language as too simple and indiscriminate).

238. See *Dole v. United Steelworkers*, 494 U.S. 26, 53-54 (1990) (White, J., dissenting) (listing numerous cases which grant this deference); *Mississippi Power & Light*, 487 U.S. 354, 377-83 (Scalia, J., concurring) (stating it is "both necessary and appropriate" to defer to agencies' interpretation of their statutory jurisdiction).

“jurisdictional.” Second, *Chevron* is in part a recognition of the comparative advantages of agencies over courts, stemming from the agencies’ greater factfinding power and electoral legitimacy, and those comparative advantages seem to apply to jurisdictional determinations as well. An extension of jurisdiction is likely to reflect political judgments, assessments of underlying facts, or both; the assertion of jurisdiction over tobacco products is certainly a case in point. In any event, the cases appear to have settled, at least implicitly, on the view that jurisdictional determinations are not entitled to less deference.

It is also possible to question whether the determination in the FDA case is truly “jurisdictional” in the sense relevant to the dispute over *Chevron*’s scope. To be sure, the FDA has labeled its determination “jurisdictional.” At the same time, is every FDA decision to consider some article a drug “jurisdictional” in the sense that it calls into question the applicability of *Chevron*? Perhaps this determination is more in the nature of an application of a statutory term to a disputed case than a judgment that the FDA has authority over a whole class of cases that may or may not fit within a statutory term. When the FDA asserts authority over any particular article of commerce, its assertion might be described as “jurisdictional”; but if FDA assertions of this kind are jurisdictional, then deference will not be due to the FDA in a wide range of cases that call for distinctly administrative competence.

2. *Change in Agency’s Position.* Before *Chevron*, agency interpretations were entitled to little or no deference if they were inconsistent or if the agency’s current interpretation departed from longstanding agency understandings.<sup>239</sup> After *Chevron*, however, the cases are ambiguous, some suggesting that inconsistency does not eliminate deference and others suggesting that the case for deference is significantly reduced if the agency has changed its mind.<sup>240</sup> Here, it might be urged that the fact that the FDA has departed from a longstanding interpretation is sufficient to reduce the level of deference under *Chevron*.

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239. See Gossett, *supra* note 180, at 681.

240. See *Chevron*, 467 U.S. at 842 (upholding changed agency interpretation); *INS v. Cardoza-Fonseca*, 480 U.S. 421, 445 (1987) (rejecting a new agency interpretation that was not in line with congressional intent); Gossett, *supra* note 180, at 698 (examining cases in which the agency interpretation was rejected for reasons other than the interpretation’s revision).

It probably makes sense to say that a steady course of administrative interpretation is entitled to an unusually high level of deference. If the agency's course has been steady, then reliance interests may have built up around it; there may be special reason to think the old interpretation makes sense; and Congress and relevant interests have not, by hypothesis, showed dissatisfaction with it, even though they have had some time in which to do so. It does not, however, make sense to say that a new interpretation is entitled to no deference at all. *Chevron* itself was a case in which the agency changed its mind, partly because of political judgments, partly because of technical ones; consider, as well, *Rust v. Sullivan*, upholding the so-called "abortion gag rule," a new administrative interpretation driven largely by political judgments. The case for deference is of course heightened when the area involves a high degree of political visibility or technical complexity, and the FDA rule involves both. I conclude that the fact that the FDA changed its mind is relevant and justifies less deference than an unbroken pattern of interpretation, but it provides insufficient reason to disallow the FDA from adopting a reasonable understanding of the statutory terms.

3. *Other canons?* *Chevron* is not of course the only canon of construction. There are many others, and sometimes they trump *Chevron*. For example, the idea that statutes will be construed to avoid serious constitutional doubts seems to defeat agency interpretations,<sup>241</sup> in part on the theory that Congress, rather than agencies, should deliberate explicitly on questions that are close to the constitutional line. This notion operates as a more targeted and narrower version of the nondelegation doctrine, requiring legislative focus on certain issues. The notion that statutes will not ordinarily be taken to apply outside the territorial boundaries of the United States—a notion that is also intended to ensure legislative focus on the relevant question—also seems to prevail over agency interpretations.<sup>242</sup>

If there were an applicable canon of construction that would trump the FDA's interpretation, then the FDA should not prevail. It is difficult, however, to find any such canon in this case. To be sure, the FDA's assertion of authority over tobacco places some federal

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241. See *Edward J. DeBartolo Corp. v. Florida Gulf Coast Bldg. & Constr. Trades Council*, 485 U.S. 568, 574-75 (1988).

242. See *EEOC v. Arabian Am. Oil Co.*, 499 U.S. 244, 248 (1991); see also *California State Bd. of Optometry v. FTC*, 910 F.2d 976, 981-82 (D.C. Cir. 1990) (holding that a federal agency may not displace state power through its rulemaking authority unless specifically granted the power to do so by Congress).

authority in an area that has also been regulated by the states. It would be implausible, however, to say that the FDA's decision triggers a relevant canon of construction, as in the idea that ambiguous statutes should not lightly be taken to preempt state law. No counter-vailing canon of construction defeats the application of *Chevron*.

Compare, in this regard, the question of whether the FDA has the authority to restrict the promotion and advertising of tobacco products through a ban on the sale to people under the age of eighteen, detailed verification requirements, bans on sales through vending machines, requirements of black-and-white text-only advertising, and prohibitions of use of brand names to sponsor entries, teams, sporting, and other events.<sup>243</sup> The relevant statute allows the FDA to "require that a device be restricted to sale, distribution or use . . . upon such . . . conditions as the" FDA may prescribe by regulation.<sup>244</sup> The FDA argued that restrictions on promotion and advertising are restrictions on the conditions of sale, designed to ensure the safety of tobacco products by preventing children and adolescents from using them and becoming addicted to them.<sup>245</sup> The district court rejected this argument on the ground that "sale" does not include "advertising" and with the suggestion that "conditions" could not be construed to allow restrictions on advertising and promotion.<sup>246</sup>

The analysis here suggests that that court was probably wrong under *Chevron*: the statute has considerable ambiguity here, and the term "conditions" on "sale, distribution, or use" can reasonably be understood to include restrictions on advertising and promotion. The court's decision would, however, be strengthened if it were thought that some or all of these restrictions raised serious questions under the First Amendment. A claim to this effect raises many issues by itself, and I do not believe that the First Amendment obstacles are in fact serious.<sup>247</sup> This is, however, a controversial view of the First

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243. See *Coyne Beahm, Inc. v. FDA*, 966 F. Supp. 1374, 1397 nn.20-21 (M.D.N.C. 1997).

244. 21 U.S.C. § 360j(e) (1994).

245. See *Coyne Beahm*, 966 F. Supp. at 1398.

246. See *id.* at 1398-99.

247. See *Posadas de Puerto Rico Assocs. v. Tourism Co.*, 478 U.S. 328, 344 (1986) (holding that a Puerto Rican law prohibiting local advertisements inviting residents of Puerto Rico to visit casinos did not violate the First Amendment). Thus the case is, on this dimension, akin to *Rust v. Sullivan*, 500 U.S. 173 (1991), where the Court found the constitutional issue insufficiently serious to justify a rejection of the agency's interpretation. See *id.* at 203.

1998]

*IS TOBACCO A DRUG?*

1067

Amendment,<sup>248</sup> and the best argument against the FDA's position on this count would invoke the constitutional background.

*D. Summary*

There have been many strands in the foregoing argument, and by way of summary, it may be useful to outline the most plausible opinions and surrounding rationales against and for the FDA (in ascending order of persuasiveness).

The FDA's regulation might be invalidated on the following grounds:

1. It might be held that in the view of the enacting Congress, tobacco did not count as a "drug" and that this original understanding is decisive. This is the weakest argument against the FDA because the general terms are what matter, and because the original understanding about the applications of those terms were not enacted into law.

2. It might be held that the FDA's longstanding interpretation, and Congress's failure to enact legislation against the background of that interpretation, foreclose a definition of "drug" that includes tobacco. This argument is not entirely without force, but in the end, it is unconvincing, because agencies are allowed to change their mind, and Congress does not legislate by failing to legislate.

3. It might be held that the FDA's longstanding interpretation and Congress's actual enactment of tobacco regulation work to prevent the FDA from regulating tobacco. This argument is convincing insofar as there is a direct conflict between the FDA regulation and congressional enactments. It also has some force as applied to the regulation as a whole. In the end, however, it is also unconvincing, because it is too close to an argument for an implied repeal and because agencies should be entitled to change their minds about the meaning of an ambiguous statute in the face of response to new understandings of underlying facts (and new values as well).

4. It might be held that the contextual understanding of the definition of "drug" suggests that to qualify as such, articles must be sold with some kind of representation of actual beneficial effects on the human body and that tobacco is not, realistically speaking, being sold with any such representation. If a court were interpreting the statute

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248. See 44 *Liquormart, Inc. v. Rhode Island*, 517 U.S. 484, 509-12 (1996) (criticizing the reasoning in *Posadas*).

in the first instance, this argument would have considerable weight, especially when combined with argument (3) above. In light, however, of the FDA's factual findings and the appropriate judicial posture in reviewing an agency interpretation of general statutory terms after *Chevron*, that argument is not persuasive.

On behalf of the FDA, the following arguments are available:

1. It might be held that the plain statutory terms suggest that tobacco must be treated as a drug, as Action for Smoking and Health urged long ago. This argument is not entirely without force, but the terms contain ambiguity, and the FDA should be authorized to decide otherwise, as it did until 1996.

2. It might be held that the statutory terms permit the FDA to find both an actual effect on the function of the body, because of tobacco's addictive properties, and an intention to affect the function of the body, because of the knowledge of those properties on the part of tobacco companies. This argument is unnecessarily broad, and the contextual understanding of the term "drug" makes it at least unclear whether the FDA could adopt this interpretation.

3. It might be held that the FDA has the authority to include tobacco within the category "drug" if and to the extent that the FDA can point to tobacco companies' knowledge of the tranquilizing and stimulating properties of nicotine and advertising that suggests, explicitly or implicitly, that smoking has those properties. This would be the best approach, because it is the narrowest basis for upholding FDA authority.

#### CONCLUSION

As a matter of simple practice, administrative agencies have become America's common law courts. The task of adapting the law to new circumstances, of both value and of fact, is largely an administrative responsibility. Agencies specify general statutory terms and are engaged in continuing processes of both "updating" and particularization.

In view of agency self-interest and the exercise of power by self-interested private groups, this development is not without risks. On balance, however, it is highly salutary. In an era that prizes both democratic accountability and the technical knowledge that comes from specialization, it is only natural that the process of updating the law and adapting it to the particulars of individual cases will fall to administrative agencies. Administrative agencies have, however, be-

come our common law courts in a distinctive sense. On the one hand, it is legitimate for them to undertake relatively rapid changes over time, accountable as they are to the current administration—more legitimate than it is for common law courts to do the same thing.<sup>249</sup> On the other hand, the updating and particularizing functions of administrative agencies must be disciplined by statutory boundaries, by “clear statement” principles, and by requirements of reasoned decisionmaking, requirements with both substantive and procedural components.

These points very much bear on the multiple government efforts to regulate tobacco. The regulation of tobacco is best treated as a political rather than a judicial task (however active common law courts have become in the context of tort actions). Statutory language is best understood contextually, and, as a general rule, ambiguous terms should not be taken to cover cases far beyond the contemplation of the enacting legislature. As a matter of administrative law, however, the assertion of jurisdiction by the FDA is a largely ordinary adaptation of general statutory text to a particular article, understood as a “drug” both because of new understandings of facts and because of a wide range of democratic pressures and influences. The FDA is authorized to adapt the statutory terms in this way in light of the general character of those terms and in light of its findings with respect to the tranquilizing and stimulating effects of nicotine. This argument, largely institutional in character, is the narrowest and, in the end, the most convincing one on the FDA’s behalf.

On an independent reading of the FDCA, there is an argument that tobacco is not a “drug” within the meaning of the Act, understood in its historical context. But the best reading of the FDCA, understood in the context of the modern regulatory state, is that the FDA has the authority to conclude otherwise, and to treat tobacco as a drug if it chooses to do so.

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249. See *Chevron U.S.A., Inc. v. Natural Resources Defense Council*, 467 U.S. 837, 844-45 (1984); *Motor Vehicle Mfrs. Ass’n. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 59 (1983) (Rehnquist, J., concurring in part and dissenting in part).