interest groups that do follow the policies and laws carefully do not symmetrically reflect the wide array of interests in the voting population; and even the support of informed voters or groups rarely hinges on a specific policy proposal. Schacter concludes that the mechanisms of accountability, mainly elections, work best as mechanisms of representativeness. So long as voters understand the ideology and general character of the people they select to represent them, the system works fine — dynamic interpretation or not.

Evaluate the following case. Does a institutional cost-benefit analysis support the Court's approach and its trumping a dynamic agency interpretation? Does a textualist (Easterbrook), legislative intent (old Posner), or purposive (Macey, new Posner) approach support the majority? Or is the majority reading its own pro-business values into a public interest health-protective statute?

FDA v. BROWN & WILLIAMSON TOBACCO CORP.

U.S. Supreme Court, 2000
529 U.S. 120, 120 S.Ct. 1291, 146 L.Ed.2d 121

JUSTICE O'CONNOR delivered the opinion of the Court.

[The Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. § 301 et seq., grants the Food and Drug Administration (FDA) the authority to regulate, among other items, "drugs" and "devices," §§ 321(g)-(h), 393. In 1996, the FDA asserted jurisdiction to regulate tobacco products, concluding that, under the FDCA, nicotine is a "drug" and cigarettes and smokeless tobacco are "devices" that deliver nicotine to the body. Pursuant to this authority, the FDA promulgated regulations governing tobacco products' promotion, labeling, and accessibility to children and adolescents. The FDA found that tobacco use is the Nation's leading cause of premature death, resulting in more than 400,000 deaths annually, and that most adult smokers begin when they are minors. The regulations therefore aim to reduce tobacco use by minors so as to substantially reduce the prevalence of addiction in future generations, and thus the incidence of tobacco-related death and disease. Respondents, a group of tobacco manufacturers, retailers, and advertisers, filed this suit challenging the FDA's regulations. The Supreme Court held that Congress has not granted the FDA jurisdiction to regulate tobacco products.]

[II] In determining whether Congress has specifically addressed the question at issue, a reviewing court should not confine itself to examining a particular statutory provision in isolation. The meaning — or ambiguity — of certain words or phrases may only become evident when placed in context. See *Brown v. Gardner,* 513 U.S. 515, 518 (1994) ("Ambiguity is a creature not of definitional possibilities but of statutory context"). It is a "fundamental canon of statutory construction that the words of a statute must be read in their context and with a view to their place in the overall statutory scheme." *Davis v. Michigan Dept. of Treasury*, 489 U.S. 803, 809 (1989). A court must therefore interpret the statute "as a symmetrical and coherent regulatory scheme," *Gustafson v. Alloyd Co.,* 513 U.S. 561, 569 (1995),and "fit, if possible, all parts into an harmonious whole," *FTC v. Mandel Brothers, Inc.,* 359 U.S. 385, 389 (1959). Similarly, the meaning of one statute may be

affected by other Acts, particularly where Congress has spoken subsequently and more specifically to the topic at hand. See *United States v. Estate of Romani,* 523 U.S. 517, 530-31 (1998); *United States v. Fausto*, 484 U.S. 439, 453 (1988). In addition, we must be guided to a degree by common sense as to the manner in which Congress is likely to delegate a policy decision of such economic and political magnitude to an administrative agency. * * *

[In Part IIA, Justice O'Connor concluded that the FDCA assumes that the FDA will refuse to approve unsafe drugs or devices and will remove them from the market as soon as it determines they are unsafe. E.g., 21 U.S.C. § 355(e)(1)-(3). Congress has enacted six statutes that require disclosure of information regarding tobacco products but do not ban their sale. E.g., 15 U.S.C. § 1331. Given the assumption of the FDCA, these statutes disallow the agency from finding that tobacco products fall within its health and safety regime. "A fundamental precept of the FDCA is that any product regulated by the FDA — but not banned — must be safe for its intended use. * * * Consequently, if tobacco products were within the FDA's jurisdiction, the Act would require the FDA to remove them from the market entirely. But a ban would contradict Congress' clear intent as expressed in its more recent, tobacco-specific legislation. The inescapable conclusion is that there is no room for tobacco products within the FDCA's regulatory scheme."]

[B] In determining whether Congress has spoken directly to the FDA's authority to regulate tobacco, we must also consider in greater detail the tobacco-specific legislation that Congress has enacted over the past 35 years. At the time a statute is enacted, it may have a range of plausible meanings. Over time, however, subsequent acts can shape or focus those meanings. The "classic judicial task of reconciling many laws enacted over time, and getting them to 'make sense' in combination, necessarily assumes that the implications of a statute may be altered by the implications of a later statute." *Fausto.* This is particularly so where the scope of the earlier statute is broad but the subsequent statutes more specifically address the topic at hand. As we recognized recently in *United States v. Estate of Romani*, "a specific policy embodied in a later federal statute should control our construction of the earlier statute, even though it has not been expressly amended."

Congress has enacted six separate pieces of legislation since 1965 addressing the problem of tobacco use and human health. Those statutes, among other things, require that health warnings appear on all packaging and in all print and outdoor advertisements, see 15 U.S.C. §§ 1331, 1333, 4402; prohibit the advertisement of tobacco products through "any medium of electronic communication" subject to regulation by the Federal Communications Commission (FCC), see §§ 1335, 4402(f); require the Secretary of Health and Human Services (HHS) to report every three years to Congress on research findings concerning "the addictive property of tobacco," 42 U.S.C. § 290aa–2(b)(2); and make States' receipt of certain federal block grants contingent on their making it unlawful "for any manufacturer, retailer, or distributor of tobacco products to sell or distribute any such product to any individual under the age of 18," § 300x–26(a)(1).

In adopting each statute, Congress has acted against the backdrop of the FDA's consistent and repeated statements that it lacked authority under the FDCA to regulate tobacco absent claims of therapeutic benefit by the manufacturer. In fact, on several occasions over this period, and after the health consequences of tobacco use and nicotine's pharmacological effects had become well known, Congress considered and rejected bills that would have granted the FDA such jurisdiction. Under these circumstances, it is evident that Congress' tobacco-specific statutes have effectively ratified the FDA's long-held position that it lacks jurisdiction under the FDCA to regulate tobacco products. Congress has created a distinct regulatory scheme to address the problem of tobacco and health, and that scheme, as presently constructed, precludes any role for the FDA.

[In 1964 congressional hearings responding to the Surgeon General's opinion that cigarette smoking is hazardous to one's health, FDA representatives testified that the agency did not have authority to regulate cigarettes or smoking under the FDCA. This was consistent with the position taken by the FDA's predecessor agency, the Bureau of Chemistry under the Pure Food & Drug Act of 1906.] And, as the FDA admits, there is no evidence in the text of the FDCA or its legislative history that Congress in 1938 even considered the applicability of the Act to tobacco products. Given the economic and political significance of the tobacco industry at the time, it is extremely unlikely that Congress could have intended to place tobacco within the ambit of the FDCA absent any discussion of the matter. * * *

Moreover, before enacting the FCLAA [Federal Cigarette Labeling and Advertising Act] in 1965, Congress considered and rejected several proposals to give the FDA the authority to regulate tobacco. In April 1963, Representative Udall introduced a bill "to amend the Federal Food, Drug, and Cosmetic Act so as to make that Act applicable to smoking products." H. R. 5973, 88th Cong., 1st Sess., 1. Two months later, Senator Moss introduced an identical bill in the Senate. S. 1682, 88th Cong., 1st Sess. (1963). In discussing his proposal on the Senate floor, Senator Moss explained that "this amendment simply places smoking products under FDA jurisdiction, along with foods, drugs, and cosmetics." 109 Cong. Rec. 10322 (1963). In December 1963, Representative Rhodes introduced another bill that would have amended the FDCA "by striking out 'food, drug, device, or cosmetic,' each place where it appears therein and inserting in lieu thereof 'food, drug, device, cosmetic, or smoking product.' " H. R. 9512, 88th Cong., 1st Sess., § 3 (1963). And in January 1965, five months before passage of the FCLAA, Representative Udall again introduced a bill to amend the FDCA "to make that Act applicable to smoking products." H. R. 2248, 89th Cong., 1st Sess., 1. None of these proposals became law.

Congress ultimately decided in 1965 to subject tobacco products to the less extensive regulatory scheme of the FCLAA, which created a "comprehensive Federal program to deal with cigarette labeling and advertising with respect to any relationship between smoking and health." Pub. L. 89–92, § 2, 79 Stat. 282. The FCLAA rejected any regulation of advertising, but it required the warning, "Caution: Cigarette Smoking May Be Hazardous to Your Health," to

appear on all cigarette packages. *Id.*, § 4, 79 Stat. 283. In the Act's "Declaration of Policy," Congress stated that its objective was to balance the goals of ensuring that "the public may be adequately informed that cigarette smoking may be hazardous to health" and protecting "commerce and the national economy . . . to the maximum extent." *Id.*, § 2, 79 Stat. 282 (codified at 15 U.S.C. § 1331).

Not only did Congress reject the proposals to grant the FDA jurisdiction, but it explicitly preempted any other regulation of cigarette labeling: "No statement relating to smoking and health, other than the statement required by . . . this Act, shall be required on any cigarette package." *Id.*, § 5(a), 79 Stat. 283. The regulation of product labeling, however, is an integral aspect of the FDCA, both as it existed in 1965 and today. The labeling requirements currently imposed by the FDCA, which are essentially identical to those in force in 1965, require the FDA to regulate the labeling of drugs and devices to protect the safety of consumers. See 21 U.S.C. § 352; 21 U.S.C. § 352 (1964 ed. and Supp. IV). As discussed earlier, the Act requires that all products bear "adequate directions for use . . . as are necessary for the protection of users," 21 U.S.C. § 352(f)(1); 21 U.S.C. § 352(f)(1) (1964 ed.); requires that all products provide "adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health," 21 U.S.C. § 352(f)(2); 21 U.S.C. § 352(f)(2) (1964 ed.); and deems a product misbranded "if it is dangerous to health when used in the dosage or manner, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof," 21 U.S.C. § 352(j); 21 U.S.C. § 352(j) (1964 ed.). In this sense, the FCLAA was — and remains — incompatible with FDA regulation of tobacco products. This is not to say that the FCLAA's preemption provision by itself necessarily foreclosed FDA jurisdiction. But it is an important factor in assessing whether Congress ratified the agency's position — that is, whether Congress adopted a regulatory approach to the problem of tobacco and health that contemplated no role for the FDA. * * *

Four years later, after Congress had transferred the authority to regulate substances covered by the Hazardous Substances Act (HSA) from the FDA to the Consumer Products Safety Commission (CPSC), the American Public Health Association, joined by Senator Moss, petitioned the CPSC to regulate cigarettes yielding more than 21 milligrams of tar. After the CPSC determined that it lacked authority under the HSA to regulate cigarettes, a District Court held that the Act did, in fact, grant the CPSC such jurisdiction and ordered it to reexamine the petition. Before the CPSC could take any action, however, Congress mooted the issue by adopting legislation that eliminated the agency's authority to regulate "tobacco and tobacco products." Consumer Product Safety Commission Improvements Act of 1976, Pub. L. 94–284, § 3(c), 90 Stat. 503 (codified at 15 U.S.C. § 1261(f)(2)). Senator Moss acknowledged that the "legislation, in effect, reversed" the District Court's decision, 121 Cong. Rec. 23563 (1975), and the FDA later observed that the episode was "particularly indicative of the policy of Congress to limit the regulatory authority over cigarettes by Federal Agencies," Letter to Action on Smoking and Health (ASH) Executive Director Banzhaf from FDA Commissioner Goyan (Nov. 25, 1980), App. 59. A separate statement in the Senate Report

underscored that the legislation's purpose was to "unmistakably reaffirm the clear mandate of the Congress that the basic regulation of tobacco and tobacco products is governed by the legislation dealing with the subject, . . . and that any further regulation in this sensitive and complex area must be reserved for specific Congressional action." S. Rep. No. 94–251, p. 43 (1975) (additional views of Sens. Hartke, Hollings, Ford, Stevens, and Beall).

[Justice O'Connor assembled a boatload of subsequent statutes regulating smoking and drew extensively from their legislative history the proposition that Congress was consistently following a disclosure strategy and rejecting broader regulations of cigarettes and smoking. At various points, the FDA or other observers reminded congressional committees holding hearings on the tobacco problem that the FDA could not regulate the drug. The FDA also, in 1977, denied a citizen petition asking it to regulate cigarettes, on the ground that "[t]he interpretation of the Act by FDA consistently has been that cigarettes are not a drug unless health claims are made by the vendors." When the citizen group challenged the agency, the government argued that Congress had "acquiesced" in the FDA's no-jurisdiction stance, and the D.C. Circuit affirmed on that ground. The HHS Assistant Secretary told a congressional committee in 1983 that smoking had horrible health effects but that Congress's early legislation deprived HHS of any authority to regulate those ill effects. Congress incrementally expanded its regulation of tobacco with statutes authorizing and funding anti-smoking educational campaigns in the 1980s.]

In 1988, the Surgeon General released a report summarizing the abundant scientific literature demonstrating that "cigarettes and other forms of tobacco are addicting," and that "nicotine is psychoactive" and "causes physical dependence characterized by a withdrawal syndrome that usually accompanies nicotine abstinence." 1988 Surgeon General's Report 14. The report further concluded that the "pharmacologic and behavioral processes that determine tobacco addiction are similar to those that determine addiction to drugs such as heroin and cocaine." *Id.*, at 15. In the same year, FDA Commissioner Young stated before Congress that "it doesn't look like it is possible to regulate tobacco under the Food, Drug and Cosmetic Act even though smoking, I think, has been widely recognized as being harmful to human health." [House Appropriations Subcomm. Hearing.] At the same hearing, the FDA's General Counsel testified that "what is fairly important in FDA law is whether a product has a therapeutic purpose," and "cigarettes themselves are not used for a therapeutic purpose as that concept is ordinarily understood." Between 1987 and 1989, Congress considered three more bills that would have amended the FDCA to grant the FDA jurisdiction to regulate tobacco products. See H. R. 3294, 100th Cong., 1st Sess. (1987); H. R. 1494, 101st Cong., 1st Sess. (1989); S. 769, 101st Cong., 1st Sess. (1989). As before, Congress rejected the proposals. In 1992, Congress instead adopted the Alcohol, Drug Abuse, and Mental Health Administration Reorganization Act, Pub. L. 102–321, § 202, 106 Stat. 394 (codified at 42 U.S.C. § 300x *et seq.*), which creates incentives for States to regulate the retail sale of tobacco products by making States' receipt of certain block grants contingent on their prohibiting the sale of tobacco products to minors.

Taken together, these actions by Congress over the past 35 years preclude an interpretation of the FDCA that grants the FDA jurisdiction to regulate tobacco products. We do not rely on Congress' failure to act — its consideration and rejection of bills that would have given the FDA this authority — in reaching this conclusion. Indeed, this is not a case of simple inaction by Congress that purportedly represents its acquiescence in an agency's position. To the contrary, Congress has enacted several statutes addressing the particular subject of tobacco and health, creating a distinct regulatory scheme for cigarettes and smokeless tobacco. In doing so, Congress has been aware of tobacco's health hazards and its pharmacological effects. It has also enacted this legislation against the background of the FDA repeatedly and consistently asserting that it lacks jurisdiction under the FDCA to regulate tobacco products as customarily marketed. Further, Congress has persistently acted to preclude a meaningful role for *any* administrative agency in making policy on the subject of tobacco and health. Moreover, the substance of Congress' regulatory scheme is, in an important respect, incompatible with FDA jurisdiction. Although the supervision of product labeling to protect consumer health is a substantial component of the FDA's regulation of drugs and devices, see 21 U.S.C. § 352 (1994 ed. and Supp. III), the FCLAA and the CSTHEA [Comprehensive Smokeless Tobacco Health Education Act] explicitly prohibit any federal agency from imposing any health-related labeling requirements on cigarettes or smokeless tobacco products, see 15 U. S C. §§ 1334(a), 4406(a).
* * *

JUSTICE BREYER, joined by JUSTICE STEVENS, JUSTICE SOUTER, and JUSTICE GINSBURG, dissenting.

The Food and Drug Administration (FDA) has the authority to regulate "articles (other than food) intended to affect the structure or any function of the body . . . ." Federal Food, Drug and Cosmetic Act (FDCA), 21 U.S.C. § 321(g)(1)(C). Unlike the majority, I believe that tobacco products fit within this statutory language.

In its own interpretation, the majority nowhere denies the following two salient points. First, tobacco products (including cigarettes) fall within the scope of this statutory definition, read literally. Cigarettes achieve their mood-stabilizing effects through the interaction of the chemical nicotine and the cells of the central nervous system. Both cigarette manufacturers and smokers alike know of, and desire, that chemically induced result. Hence, cigarettes are "intended to affect" the body's "structure" and "function," in the literal sense of these words.

Second, the statute's basic purpose — the protection of public health — supports the inclusion of cigarettes within its scope. See *United States* v. *Article of Drug . . . Bacto-Unidisk,* 394 U.S. 784, 798 (1969) (FDCA "is to be given *a liberal construction consistent with [its] overriding purpose to protect the public health*" (emphasis added)). Unregulated tobacco use causes "more than 400,000 people [to] die each year from tobacco-related illnesses, such as cancer, respiratory illnesses, and heart disease." 61 Fed. Reg. 44398 (1996). Indeed, tobacco products kill more people in this country every year

"than . . . AIDS, car accidents, alcohol, homicides, illegal drugs, suicides, and fires, *combined*." *Ibid.* (emphasis added).

Despite the FDCA's literal language and general purpose (both of which support the FDA's finding that cigarettes come within its statutory authority), the majority nonetheless reads the statute as *excluding* tobacco products for two basic reasons:

(1) the FDCA does not "fit" the case of tobacco because the statute requires the FDA to prohibit dangerous drugs or devices (like cigarettes) outright, and the agency concedes that simply banning the sale of cigarettes is not a proper remedy; and

(2) Congress has enacted other statutes, which, when viewed in light of the FDA's long history of denying tobacco-related jurisdiction and considered together with Congress' failure explicitly to grant the agency tobacco-specific authority, demonstrate that Congress did not intend for the FDA to exercise jurisdiction over tobacco.

In my view, neither of these propositions is valid. Rather, the FDCA does not significantly limit the FDA's remedial alternatives. And the later statutes do not tell the FDA it cannot exercise jurisdiction, but simply leave FDA jurisdictional law where Congress found it. [C]f. Food and Drug Administration Modernization Act of 1997, 111 Stat. 2380 (codified at note following 21 U.S.C. § 321 (1994 ed., Supp. III)) (statute "shall" *not* "be construed to affect the question of whether" the FDA "has any authority to regulate any tobacco product").

The bulk of the opinion that follows will explain the basis for these latter conclusions. In short, I believe that the most important indicia of statutory meaning — language and purpose — along with the FDCA's legislative history (described briefly in Part I) are sufficient to establish that the FDA has authority to regulate tobacco. The statute-specific arguments against jurisdiction that the tobacco companies and the majority rely upon (discussed in Part II) are based on erroneous assumptions and, thus, do not defeat the jurisdiction-supporting thrust of the FDCA's language and purpose. The inferences that the majority draws from later legislative history are not persuasive, since (as I point out in Part III) one can just as easily infer from the later laws that Congress did not intend to affect the FDA's tobacco-related authority at all. And the fact that the FDA changed its mind about the scope of its own jurisdiction is legally insignificant because (as Part IV establishes) the agency's reasons for changing course are fully justified. [The FDA's stated reasons for not regulating were that it did not have evidence that the cigarette manufacturers "intended" for their product to have a medical effect; by the 1990s, there was ample evidence of such intent.]

In the majority's view, laws enacted since 1965 require us to deny jurisdiction, whatever the FDCA might mean in their absence. But why? Do those laws contain language barring FDA jurisdiction? The majority must concede that they do not. Do they contain provisions that are inconsistent with the FDA's exercise of jurisdiction? With one exception, the majority points to no such provision. Do they somehow repeal the principles of law * * * that

otherwise would lead to the conclusion that the FDA has jurisdiction in this area? The companies themselves deny making any such claim. See Tr. of Oral Arg. 27 (denying reliance on doctrine of "partial repeal"). Perhaps the later laws "shape" and "focus" what the 1938 Congress meant a generation earlier. But this Court has warned against using the views of a later Congress to construe a statute enacted many years before. See *Pension Benefit Guaranty Corporation v. LTV Corp.,* 496 U.S. 633, 650 (1990) (later history is " 'a hazardous basis for inferring the intent of an earlier' Congress" (quoting *United States v. Price,* 361 U.S. 304, 313 (1960)). And, while the majority suggests that the subsequent history "controls our construction" of the FDCA, this Court expressly has held that such subsequent views are not "controlling." *Haynes v. United States,* 390 U.S. 85, 87–88 n.4 (1968). Regardless, the later statutes do not support the majority's conclusion. That is because, whatever individual Members of Congress after 1964 may have assumed about the FDA's jurisdiction, the laws they enacted did not embody any such "no jurisdiction" assumption. And one cannot automatically *infer* an antijurisdiction intent, as the majority does, for the later statutes are both (and similarly) consistent with quite a different congressional desire, namely, the intent to proceed without interfering with whatever authority the FDA otherwise may have possessed. As I demonstrate below, the subsequent legislative history is critically ambivalent, for it can be read *either* as (a) "ratifying" a no-jurisdiction assumption, *or* as (b) leaving the jurisdictional question just where Congress found it. And the fact that both inferences are "equally tenable," *Pension Benefit Guaranty Corp.*, prevents the majority from drawing from the later statutes the firm, antijurisdiction implication that it needs.

Consider, for example, Congress' failure to provide the FDA with express authority to regulate tobacco — a circumstance that the majority finds significant. In fact, Congress *both* failed to grant express authority to the FDA when the FDA denied it had jurisdiction over tobacco *and* failed to take that authority expressly away when the agency later asserted jurisdiction. See, *e.g.*, S. 1262, 104th Cong., 1st Sess., § 906 (1995) (failed bill seeking to amend FDCA to say that "nothing in this Act or any other Act shall provide the [FDA] with any authority to regulate in any manner tobacco or tobacco products"); see also H. R. 516, 105th Cong., 1st Sess., § 2 (1997) (similar); H. R. Res. 980, reprinted in 142 Cong. Rec. 5018 (1996) (Georgia legislators unsuccessfully requested that Congress "rescind any action giving the FDA authority" over tobacco); H. R. 2283, 104th Cong., 1st Sess. (1995) (failed bill "to prohibit the [FDA] regulation of the sale or use of tobacco"); H. R. 2414, 104th Cong., 1st Sess., § 2(a) (1995) (similar). Consequently, the defeat of various different proposed jurisdictional changes proves nothing. This history shows only that Congress could not muster the votes necessary either to grant or to deny the FDA the relevant authority. It neither favors nor disfavors the majority's position.

[We omit the remainder of Justice Breyer's lengthy opinion, but like Justice O'Connor's opinion it is worth reading in its entirety.]