

Smoking has long been the leading cause of preventable death in the United States, accounting for almost half a million fatalities per year, far more than those caused by firearms, illegal drug use, and motor vehicle accidents combined. Yet for most of the twentieth century, the tobacco industry enjoyed virtual immunity from litigation exposure and avoided stringent regulation by federal public health agencies. In the 1990s, spurred by new scientific findings about nicotine addiction, and emboldened by dramatic revelations of industry misconduct, the U.S. Food and Drug Administration sought to fill that regulatory vacuum by asserting jurisdiction over cigarettes as “delivery devices” for the drug nicotine. The agency was led by a dynamic and committed public health advocate, Dr. David Kessler, and in 1996 issued unprecedented regulations that would have severely restricted cigarette sales and marketing, particularly to the youth market.

The FDA had previously disclaimed jurisdiction over tobacco, however, and the governing statute was silent on that precise issue. The tobacco industry mounted a well-organized litigation challenge to the agency’s action, calling on three levels of federal courts to wrestle with the plain language of the Food, Drug & Cosmetic Act as well as several decades of countervailing Congressional and administrative practice. The resulting Supreme Court case fractured the justices into a 5-4 decision that struck down the new regulations, with the Court’s majority giving great weight to extrinsic legislative history and the FDA’s own previous disavowals of authority to regulate smoking. In this chapter, Professor Theodore Ruger tells the story of this dramatic episode of policymaking and litigation, and explains how the Supreme Court appeared willing to hold the FDA strictly to its previous statements of policy, even in the face of political change and new scientific understandings. In so doing the Court subverted the rationales of some of its leading precedents on judicial review of administrative action and enforced a requirement of bureaucratic continuity on important questions that has recurred in more recent cases.

The Story of *FDA v. Brown & Williamson*: The Norm of Agency Continuity

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In the hot early summer of 1994, two federal agents drove slowly down rural Highway 42 outside of Wilson, North Carolina, searching for a farm allegedly growing a dangerous and illicit new plant amidst its more regular crops. Tipped off by a confidential informant just days before, the agents sought to obtain evidence that the farmer was participating in a much larger program to surreptitiously import—and then grow and market—a South American plant varietal that produced an unusually addictive and damaging drug. Their investigative activity was authorized, and keenly monitored, by officials at the highest levels of the federal government and would eventually support law enforcement action that became the subject of a major Supreme Court case.¹

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This was far from an everyday drug bust, however. The agents worked for the U.S. Food and Drug Administration (FDA), the nation's pre-eminent food and pharmaceutical safety agency, an outfit that was rarely involved in such cloak-and-dagger investigatory techniques. The FDA by 1994 had decided to seriously investigate, and possibly regulate, the tobacco industry, which public health researchers in the mid-1990s identified as responsible for almost half a million preventable deaths per year, more than ten times the number of Americans who died annually in automobile accidents.² The agency's unusual methods in this case were spurred by a welter of new information leaking out of the files of the nation's largest tobacco manufacturers and suggesting that the companies had deliberately taken steps to increase the nicotine content of their cigarettes, and thus to enhance their addictive character. Hard evidence of such intentional nicotine manipulation was crucial to the FDA's contemplated regulation of cigarettes as drug-delivery devices under the federal Food, Drug and Cosmetic Act (FDCA), because the statute defined "drug" as any "substance ... intended to affect the structure or any function of the body."³ Nicotine's pharmacological effect was plain, but proof of manufacturer intent was less so, and the FDA sought evidence of such corporate design on multiple fronts. One elusive piece of evidence was a new tobacco varietal genetically engineered in Brazil to have particularly high nicotine levels and allegedly mixed into the cigarettes made by several companies in the United States. But no company would admit to using or possessing the secret new plants, called either "Y-1" or "Y-2," and the best hope the agency had was a tip obtained in June 1994 from a former tobacco company scientist who pointed the FDA investigators to this remote North Carolina farm.

Ultimately the agents found confirmation of what they sought in Wilson, North Carolina. At the farmhouse door they were stonewalled by the farmer's wife, but interviews with a hired hand living in a tin shack near the field confirmed that the farm had indeed grown substantial amounts of Y-1 and Y-2 in prior years, an account confirmed by a cooperative neighbor.⁴ This finding formed one small link in a large chain of new evidence that the FDA and various private attorneys uncovered in the 1990s that implicated the tobacco industry in the knowing and intentional manipulation of the nicotine content of cigarettes marketed in the United States. Collectively this evidence was sufficient to induce FDA Commissioner David Kessler and his team of advisors to issue unprecedented regulations that asserted jurisdiction over cigarettes, with the full backing of President Bill Clinton's White House.⁵ These regulations characterized cigarettes as "delivery devices" for the drug nicotine and imposed stringent restrictions on their marketing and package design. Although popular with the American public and upheld by the first federal court to hear the case involving the industry's challenge to the new rules, the FDA regulations were ultimately struck down as exceeding the agency's

¹ The story about this episode is provided by David Kessler, the former FDA commissioner, in his book *A Question of Intent* 221-23 (2001).

² See Steven A. Schroeder, *Tobacco Control in the Wake of the 1998 Master Settlement Agreement*, 350 J.A.M.A. 293 (Jan. 15, 2004).

³ See 21 U.S.C. § 321(g)(1)(C).

⁴ See Kessler, *supra* note 1, at 223.

⁵ See 61 Fed. Reg. 44396 (1996).

statutory authority by a closely divided Supreme Court in the 2000 case of *FDA v. Brown & Williamson*.⁶

This is the story of that litigation, the FDA's regulatory initiative that provoked it, and the broader struggle of the American polity to meaningfully regulate an extremely dangerous and extremely popular product, tobacco. The salvo of regulation and litigation that culminated in the *Brown & Williamson* case resulted in a Supreme Court holding that thwarted the FDA's jurisdiction over cigarettes absent statutory change. But the case represents only one regulatory front in a much larger battle against tobacco's pernicious health effects that raged in the 1990s and continues today. Concurrent with the FDA's efforts to promulgate and defend its regulatory authority in the *Brown & Williamson* lawsuit, a mix of state attorneys general, private attorneys, and local governments deployed an innovative range of litigation strategies and new regulatory initiatives, coupled with a newly assertive public campaign to disseminate information about the clear health dangers of smoking. More recently, in a coda to the *Brown & Williamson* opinion, Congress by a 2009 statutory amendment has finally given the FDA the authority over tobacco that the Supreme Court denied it almost a decade before.

More recent events also shed light on the jurisprudential import of the *Brown & Williamson* Court's doctrinal reasoning. The Court's majority employed a legislative history analysis that was breathtaking in its wide scope, canvassing multiple statutes beyond the Food, Drug and Cosmetic Act and accounting for decades of congressional inaction and prior FDA statements on tobacco regulation, all in service of a ruling that denied the agency the fundamental power to alter its prior position on that crucial issue. Though highly controversial at the time, this mode of doctrinal analysis has been employed in other notable cases more recently, such as *Gonzales v. Oregon*⁷ and *Wyeth v. Levine*,⁸ in which the Court likewise struck down executive action on important topics that departed dramatically from prior agency practices of long standing. Couched in slightly different terms in each case, the common impulse that emerges is one of judicially enforced agency continuity on the most substantial public policy topics, particularly where the agency has publicly declared and strongly defended the prior position. Driven by the median votes of Justices Sandra Day O'Connor and Anthony Kennedy, this judicial supervision of agency action enforces an incrementalism in agency policymaking and demonstrates a distrust of rapid and sweeping policy change that resonates with those justices' "minimalism" in constitutional adjudication.⁹

BIG TOBACCO UNREGULATED

Although the regulatory and litigation pressure that the tobacco industry faced in the 1990s was of unprecedented intensity, debates over the safety, morality, and appropriate use of tobacco stretch back centuries, at least to the first European encounter with the drug that was used by native peoples in North and South America. One of

⁶ 529 U.S. 120 (2000).

⁷ 546 U.S. 243 (2006).

⁸ 129 S.Ct. 1187 (2009).

⁹ For a discussion of this style of adjudication more generally, see Cass R. Sunstein, *One Case at a Time: Judicial Minimalism on the Supreme Court* (1999).

Christopher Columbus' scribes on his 1492 expedition recounted native residents carrying "glowing coal in their hands," which they called "tobacco" and which were shaped like "small muskets made of paper." The natives "set one end on fire and inhaled and drank the smoke on the other," thus becoming "sleepy and drunk."¹⁰ When Columbus and other explorers brought the product back with them to Europe, controversy over its health effects and impact on civic morality ensued. One of Columbus' sailors, Rodrigo de Xerez, stored ample quantities for the return voyage and smoked profusely in the months following his return to his native Spain. This so perplexed and annoyed his Spanish neighbors that they reported him to the Inquisition, whose officials stripped him of his landholdings and sent him to jail for several years as the price of his tobacco addiction.¹¹

In subsequent centuries tobacco gained greater popularity and official acceptance across Europe, but remained controversial. By the seventeenth century in England, smoking ranked among the nation's most popular leisure activities, with tobacco sold at more than 7,000 establishments in London alone.¹² It is estimated that by 1670 half of the adult male population in England smoked daily, and national consumption reached a per capita rate of two pounds per person per year.¹³ Such prevalence produced early anti-smoking advocates in high places—King James I in 1604 issued a "counterblaste to tobacco," describing smoking in terms familiar to later public health opposition as "a custom loathsome to the eye, hateful to the nose, harmful to the brain, [and] dangerous to the lung."¹⁴

In the American colonies and the new United States, tobacco's popularity was similarly widespread, and questions over the legitimate time, place, and manner of its use hotly debated. The colony of Connecticut produced perhaps the first anti-smoking law in colonial America: Seventeenth century New Haven punished smoking with an escalating series of fines enforceable by other citizens through a private right of action.¹⁵ Willem Kieft, the Dutch director-general of "New Amsterdam"—soon to become New York City—went one step further and enacted a total ban of all tobacco use, whether smoking or chewing, in the city. Then, as now, however, efforts to restrict tobacco use were met with fierce opposition by proponents of the practice. Washington Irving reports that in the aftermath of the New York anti-tobacco edict:

The populace was in as violent a turmoil as the constitutional gravity of their department would permit—a mob of factious citizens had even the hardiness to assemble around the little governor's house, where settling themselves resolutely down, like a besieging army before a fortress, they one

¹⁰ See Eric Burns, *The Smoke of the Gods: A Social History of Tobacco 16-17* (2007) (quoting Spanish writer Bartoleme de las Casas).

¹¹ See *id.* at 18-19.

¹² See Robert K. Heimann, *Tobacco and Americans* (1960).

¹³ See Allan M. Brandt, *Cigarette Century: The Rise, Fall, and Deadly Persistence of the Product that Defined America* 21 (2007).

¹⁴ See *id.*

¹⁵ See Burns, *supra* note 10, at 101.

and all fell to smoking with a determined perseverance, that plainly evinced it was their intention to funk him into terms.¹⁶

The issue of tobacco regulation even divided the framers of the U.S. Constitution. Benjamin Franklin and Alexander Hamilton, both nonsmokers and friends of the prominent Philadelphia surgeon and ardent tobacco opponent Benjamin Rush, supported a hefty tobacco tax as an early federal revenue-raising and behavior-altering measure. James Madison opposed the tax in Congress in 1794 on a rationale evocative of arguments against similar levies two centuries later, arguing that the burden would fall heaviest “upon the poor, on sailors, day-laborers, and other people of these classes, while the rich will often escape it.”¹⁷ That Madison represented Virginia, then and now one of the largest tobacco-growing states, may also have motivated his opposition. Indeed, it was not until 1862, when most of the tobacco-growing states had seceded during the Civil War, that the U.S. Congress enacted a general tobacco tax.¹⁸

THE RISE OF “BIG TOBACCO”

Debates in the United States about restriction and taxation of tobacco raged through the nineteenth century and into the twentieth, but two economic developments operated to entrench tobacco’s place in American life and broaden its appeal to the mass of citizens. The first of these was centuries in the making: the gradual but influential place of tobacco growing in the agricultural economies of several key Southern states. Tobacco ranked second only to cotton in terms of output and cash value in the South, and the fact that the industry was centralized in a few key states only heightened its legislative influence.¹⁹ More dramatic in creating rapid change was the invention at the end of the nineteenth century of a mechanized rolling machine for cigarettes, which was quickly incorporated into the factory operations of James Duke, a North Carolina tobacco magnate and head of the huge American Tobacco Company (and later the primary benefactor of the university that bears his name). Duke’s industrial vision enabled the mass production of cigarettes on a scale never seen before, and other manufacturers soon struggled to keep pace.²⁰

This increased production capacity impelled the industry to engage in vigorous mass marketing throughout the twentieth century, using famous movie stars, athletes, and even physicians to plug its products. By the mid-century the cigarette was ascendant in American life. In 1955 (the high point of tobacco use among American men), almost 60% of the men in America smoked. Women trailed slightly behind, reaching a peak smoking prevalence of 34% in 1965.²¹ And Americans did not merely smoke occasionally; they

¹⁶ See *id.* at 102.

¹⁷ Annals of Congress, May 2, 1794, quoted in Joseph C. Robert, *The Story of Tobacco in America* 100 (1949).

¹⁸ See Carl Avery Werner, *Tobaccoland* (1922), at 559. Federal taxes on tobacco were increased in 1865, 1866, and 1875, such that by 1880 tobacco taxes accounted for 31% of the total federal tax receipts. See Heimann, *supra* note 12, at 156.

¹⁹ See Brandt, *supra* note 13, at 23-24.

²⁰ See *id.* at 27-43.

²¹ See Steven A. Schroeder, *We Can Do Better—Improving the Health of the American People*, 357 N.E.J.M. 1221 (Sep. 20, 2007).

smoked often—by 1950 averaging 2,500 cigarettes per person per year.²² As historian Allen Brandt declares in the title of his important overview of tobacco use and regulation in the past 100 years, this truly was “the Cigarette Century.” Collectively, the several large companies that dominated the industry would come to be colloquially known as “Big Tobacco,” a moniker that spoke both to the prominent influence of the companies, as well as their habit of speaking with a unified voice on legal, regulatory, and scientific matters even as they competed for sales and market share.²³

CONTESTING THE SCIENCE AND THE LAW

Also by mid-century, the rise of scientific and epidemiological tools to track lung cancer causation gave rise to a growing chorus of voices in the scientific and medical communities that associated high smoking rates with rising lung cancer rates. Despite this growing public health consensus, however, for several decades the tobacco industry proved remarkably adept at avoiding meaningful exposure to regulation or litigation even in the face of increased awareness of tobacco’s adverse health effects. Decades-old industry documents reveal various concerted strategies the companies employed to ameliorate claims of a link between smoking and lung cancer. The industry countered the emerging science with its own pseudo-scientific studies, often funding research and directing the ultimate findings of the studies. Although respected scientists and physicians, including the U.S. surgeon general, were increasingly convinced from the 1950s onward that tobacco caused lung cancer, the industry’s efforts were successful in thwarting more intensive regulation so long as they raised an element of uncertainty among enough members of the public and the relevant political institutions. According to a now-disclosed 1969 Brown & Williamson document that mapped out the industry’s defensive strategy, “[d]oubt is our product, since it is the best means of competing with the ‘body of fact’ that exists in the mind of the general public.”²⁴

This concerted campaign of scientific obfuscation bore tangible deregulatory fruit for the companies. In 1965, after Surgeon General Lester Terry had flatly concluded that “[n]o reasonable person should dispute that smoking is a serious health hazard” and proposed strong remedial labeling requirements, the industry scored a well-orchestrated legislative victory in the Federal Cigarette Labeling and Advertising Act of 1965, which diluted the mandatory cigarette package warning to state only that smoking “may be” hazardous to health. The powerful Senator Sam Ervin (D-N.C.) was instrumental in watering down the warning, and he parroted the industry’s line with precision in a committee statement, opining that “[t]he Surgeon General ... is treading on questionable ground when he begins to impose [his own conclusions] on the public, without acknowledging the fact that this matter is in controversy among scientists.”²⁵

The industry’s success in the halls of Congress was predictable, and grimly impressive, given its battalions of lobbyists and the influence of key tobacco-state

²² See Brandt, *supra* note 13, at 160.

²³ See, e.g., S.A. Glantz, *The Truth About Big Tobacco in Its Own Words*, 321 B.M.J. 313 (Aug. 2000).

²⁴ See Brandt, *supra* note 13, at 210.

²⁵ See Statement of Sen. Sam Ervin, Hearing of the Senate Subcommittee on Commerce, Mar. 29, 1965, *quoted in* Brandt, *supra* note 13, at 240.

legislators. Big Tobacco's record of courtroom success over the same decades preceding the 1990s was even more striking. The years following 1960 had seen a gradual expansion of tort liability on industry in general, and new theories proliferated in courts and in academic literature that forced product makers to internalize the costs of products that caused harm. Individual tobacco lawsuits stood apart from this general trend, however, and more than three hundred lawsuits filed in the thirty years before 1980 resulted in not a single plaintiff's verdict. According to law professor Donald Garner, who studied this phenomenon at the time, the industry that marketed "the most dangerous product sold in America" had been anomalously "completely sheltered from the storm of twentieth-century product liability."²⁶

In addition to playing up doubts (whether real or fabricated) about tobacco's overall potential for harm, tobacco company attorneys succeeded in leveraging a key doubt about individual causation in such lawsuits. Because lung cancer can arise without smoking, no individual plaintiff could prove conclusively that her cancer was linked to cigarettes. Ironically, the growing societal consensus about cigarette harm actually worked *for* the industry in such cases, as defense attorneys were able to argue that smokers assumed the well-known risk of harm from smoking. Taken together, the tobacco industry that existed in the early 1990s when the FDA first contemplated aggressive regulation was a powerful and well-organized cohort of companies with a long history of avoiding regulation and litigation exposure.

THE FDA AND ITS COMMISSIONER

For all of this industry might at the close of the twentieth century, the federal Food and Drug Administration was a rare federal agency with the public stature and scientific prestige to take a stand against the tobacco companies. Working with a relatively small staff and budget, the FDA regulates a broad swath of consumer products—including foods, pharmaceuticals, medical devices, and cosmetics—which taken together account for almost 25% of every dollar spent by American consumers each year.²⁷ Although federal food and drug-safety regulation dates back to the Pure Foods Act of 1906, the FDA began to take its modern form with the passage of its framework statute—the Food, Drug and Cosmetic Act—in 1938, which was significantly amended in 1962, as well as more incrementally modified in years since.

By the 1990s, FDA scientists and regulators had earned a reputation for impartiality and vigilance in protecting America's public health, spurred in part by high-profile successes, such as the agency's refusal to permit the sale of thalidomide in 1961 despite concurrent approval by most European drug-safety agencies, with resulting widespread birth defects in Europe. Indeed, President John F. Kennedy awarded FDA scientist Frances Kelsey the President's Medal for Distinguished Civilian Service in 1962 for her role in avoiding a thalidomide tragedy in the U.S.²⁸ Public opinion polls reflected

²⁶ See Donald W. Garner, *Cigarette Dependency and Civil Liability: A Modest Proposal*, 53 S. Cal. L. Rev. 1423, 1424 (1980).

²⁷ See Eve E. Slater, *Today's FDA*, 352 N.E.J.M. 293 (Jan. 20, 2005).

²⁸ See Karen Geraghty, *Protecting the Public: Profile of Frances Oldham Kelsey*, Virtual Mentor (July 2001).

the high stature of the FDA and its regulatory integrity: The FDA ranked near the top of all federal agencies in terms of public trust. This opinion was shared by top White House officials who worked with President Clinton, even to the point of making a basic administrative law mistake: New Commissioner David Kessler recalls Lloyd Cutler, then the White House counsel, characterizing the FDA as an “independent agency”—an inaccurate label because the FDA is part of the Department of Health and Human Services, but one that is reflective of the agency’s general reputation for independence and expertise.²⁹

If the FDA was the right agency to take on Big Tobacco, David Kessler was by both experience and temperament the right commissioner to lead its efforts. A pediatrician and medical school professor, Kessler was trained as both a doctor and a lawyer, receiving his M.D. from Harvard and a J.D. from the University of Chicago, where he had written a student law review note on FDA regulation of carcinogens in food. As an adjunct professor at Columbia Law School in the 1980s, he had taught a course on FDA jurisdiction and explored with students the question of whether the FDA could regulate cigarettes under its existing statutory authority.³⁰

Kessler was appointed as FDA commissioner in 1990 by President George H.W. Bush and was one of the few top Bush officials to be reappointed by President Clinton after his election in 1992—a circumstance that gave his later efforts to regulate tobacco an element of bipartisan legitimacy. He was surrounded at the FDA by a cohort of experienced and motivated legal and policy staff who worked tirelessly as a team on the massive fact gathering that preceded the tobacco rulemaking process. Finally, and importantly given the storm of resistance the FDA would face in attempting to regulate tobacco, Kessler harbored no doubt about the moral legitimacy of his agency’s position in relation to the industry it sought to regulate. Kessler began his 2001 autobiographical memoir about the FDA’s tobacco battles with a pointed quotation from the *Odes of Horace* that reflected his view of the industry, “The guilty have a head start, and retribution [i]s always slow of foot, but it catches up.”³¹

Kessler did not embark on his tenure as FDA commissioner in 1990 with the intention of regulating tobacco, or with the legal understanding that the agency could do so without additional statutory authority from Congress. As he recounts the story, a handful of key career staffers first suggested that the FDA consider tobacco regulations in various office conversations that predated Kessler’s reappointment by President Clinton. The clear adverse health impact of cigarette smoking led Kessler and his staff to take the question of FDA regulation seriously, but initially they harbored doubts about the FDA’s existing authority to reach tobacco products. In 1991 Kessler told the National Cancer Advisory Board that a decision on cigarette regulation was “out of [the FDA’s] hands.” Despite the breadth of the FDA’s jurisdiction over a wide swath of health-related products, Kessler opined, “[T]here are a few things in life that probably aren’t foods,

²⁹ See Kessler, *supra* note 1, at 107.

³⁰ See *id.* at 27-28. Much of the factual narrative in the pages that follow about the FDA’s internal deliberations and negotiations with other executive branch officials is drawn from David Kessler’s book on this episode, *A Question of Intent* (2000).

³¹ See *id.* at vii.

drugs, medical devices, or cosmetics, things that fall between the cracks. A cigarette is one.”³² Presaging an argument that would ultimately prove important for the majority in the 1999 Supreme Court *Brown & Williamson* ruling against FDA jurisdiction, Kessler concluded that, if the FDA did assert regulatory jurisdiction over cigarettes, it would have no choice but to ban them altogether because they emphatically were not “safe” or “effective.”

THE LIMITS OF FDA AUTHORITY

Kessler’s early impressions of the jurisdictional limits of FDA authority—which he would soon revise under a new theory of manufacturer intent—illustrate a key conceptual hurdle to the FDA’s assertion of power over the tobacco industry, and one that has both a general and specific manifestation. As a general matter, FDA jurisdiction is categorical rather than functional; although its authority over the nation’s public health is vast, numerous important health issues fall outside of its purview for reasons of statutory history and interest-group influence. So, for instance, the FDA exerts a key gate-keeping power over new pharmaceutical products and medical devices, requiring that each new compound meet scientific standards of safety and effectiveness before being used in patients. But once the FDA approves a drug, the agency has no authority to control the manner of its therapeutic use, so physicians are free to use the drug in doses, classes of patients, and for conditions on which the drug was never tested and approved, and such “off label” use is prevalent. From the early days of the agency, the powerful American medical profession resisted any hint that the FDA might directly regulate medical practice, and the FDA’s authority has been constructed to avoid such conflict. This limitation of centralized authority over drug uses differs from the broader authority over use exerted by analogous agencies in countries in Europe and elsewhere.

Similarly, the food side of FDA’s jurisdiction reflects a patchwork of inconsistent categorical line drawing driven more by political and statutory history than by coherent food-safety policy. The FDA regulates most food products, but key sectors such as meat and poultry remain in the U.S. Department of Agriculture’s ambit, leading to the curious differential treatment of frozen pizzas, wherein cheese pizzas in a supermarket freezer are inspected and subject to regulation by the FDA, while their pepperoni or sausage neighbors are USDA-approved products.³³ This categorical thin-slicing of the FDA’s jurisdiction in other contexts worked to focus the legal analytical challenge for Kessler and his advisors—arguments based on a general, functional public health protection mandate were likely to meet counterarguments derived from this existing incremental structure. They therefore needed to find more specific textual authority for the FDA’s jurisdiction over cigarettes.

This project was made more difficult by the specific manifestation of this fragmentation of the FDA’s jurisdiction—the fact that prior FDA commissioners, and Kessler himself in the occasion mentioned above, had repeatedly expressed the view that

³² See *id.* at 35.

³³ See Timothy M. Hammonds, *It Is Time to Designate a Single Food Safety Agency*, 59 Food & Drug L. J. 427, 430 (2004).

the FDA did not have existing statutory authority to regulate cigarettes. For example, in a 1977 Senate hearing on saccharin in foods, then-Commissioner Donald Kennedy was asked why his agency had not tried to regulate instead a more dangerous product, namely cigarettes. Kennedy told the committee that he would “be glad to work on the cigarette ban as soon as you give me the legislative authority to do so.”³⁴ On at least half a dozen other instances, other FDA commissioners or top policy officials with the agency made similar disavowals of regulatory power before either Congress or the federal courts.³⁵

TOWARD A NEW THEORY OF JURISDICTION

These prior disclaimers of jurisdiction were a formidable obstacle for Kessler and his team as they grew more convinced of the public health imperative to move forward with meaningful tobacco regulation. To circumvent this hurdle required both a novel legal theory of jurisdiction, and a new foundation of factual predicates on which to build the jurisdictional case. Both were suggested in the early 1990s by developing evidence that indicated tobacco manufacturers consciously controlled, and perhaps even increased or “spiked,” the nicotine content of cigarettes to maintain their addictive potential. This led agency lawyers including Kessler to return to the basic statutory definition of “drug” contained in the FDCA. The statute defines drugs as “articles (other than food) intended to affect the structure or any function of the body.”³⁶ There was no question that nicotine has a marked pharmacological effect on the human body. The emerging industry evidence pointed Kessler and his advisors to a new theory of intent to bring cigarettes within the agency’s orbit: Tobacco company manipulation of nicotine levels satisfied the intent prong of the FDCA’s definition. This legal theory embodied a key conceptual shift in the agency’s thinking that Kessler attributes to career FDA attorney David Adams. In 1992 Adams suggested that the FDA turn away from cigarettes as the object of regulation and toward nicotine itself.³⁷ In the eyes of FDA regulators, nicotine became the drug of interest, and the cigarette merely the delivery device.

This new agency theory had three clear advantages going forward. First, it mapped closely onto the text of the FDCA’s definition of drug, a consideration that would prove persuasive to the first federal judge to adjudicate an industry challenge to the FDA’s ultimate regulatory effort, as well as to four justices on the Supreme Court in 2000. Second, it fit well with new factual revelations emerging from tobacco industry lawsuits and the FDA’s own investigations about manufacturer manipulation of nicotine content. Finally, the fact that the bulk of the evidence of manipulation was discovered by the government and the public only in the mid-1990s provided David Kessler with a principled rationale for distancing himself from his own and prior commissioners’ disclaimers of FDA authority. The newfound evidence of nicotine manipulation, and

³⁴ See Kessler, *supra* note 1, at 27.

³⁵ See, e.g., Cigarette Labeling and Advertising—1965: Hearings on H. R. 2248 before the House Committee on Interstate and Foreign Commerce, 89th Cong., 1st Sess., 193 (statement of FDA Deputy Commissioner Rankin that “[t]he Food and Drug Administration has no jurisdiction under the Food, Drug, and Cosmetic Act over tobacco, unless it bears drug claims.”); see generally *FDA v. Brown & Williamson*, 529 U.S. 120, 144-55 (2000) (collecting examples).

³⁶ 21 U.S.C. § 321(g)(1)(c).

³⁷ See Kessler, *supra* note 1, at 62-63.

therefore “intent,” was the trigger to bring nicotine within the FDCA’s ambit, the theory went. Knowledge of that factual predicate did not exist until after 1992.

THE ROAD TO REGULATION

To extend this legal theory of intentional nicotine manipulation by the industry into binding federal regulation supported by substantial evidence, the FDA needed significantly more hard evidence of such an industrial phenomenon than it possessed in 1992. Kessler and his advisors thus assembled a multidisciplinary team, including attorneys, investigators, and epidemiologists, to conduct an ongoing investigation into the nicotine content of cigarettes and the industry’s role in maintaining and increasing nicotine content. The fact-gathering enterprise was wide-ranging and eclectic, and took the FDA far beyond its established methodology of scientific analysis. Kessler and his aides made site visits to each of the major cigarette makers in the United States, asking pointed questions about industrial processes and nicotine content. More fruitfully, from the perspective of evidentiary payoff, the agency identified and interviewed a network of current or former industry scientists and executives about the industry’s practices with respect to nicotine content.³⁸

Many of the informants talked only upon promises of anonymity, and the FDA’s relationship with some of them bore the hallmarks of a Hollywood thriller, replete with secret meetings and code names. One top informant—a former R.J. Reynolds employee who told the FDA about that company’s method of “reconstituting” tobacco to increase nicotine content—was assigned the moniker “Deep Cough.”³⁹ Another top company employee who had extensive discussions with the agency (as well as CBS News and plaintiffs’ attorneys) was Jeffrey Wigand, whose story actually did become fodder for a major motion picture, *The Insider*, in which Wigand was played by Russell Crowe.⁴⁰

These interviews also yielded intelligence about the genetically engineered high-nicotine tobacco varieties “Y-1” and “Y-2,” described at the beginning of this story and that led FDA investigators to various reaches of rural North Carolina. Working on a different front relevant to Y-1, an FDA researcher named Carol Knoth enjoyed an ingenious breakthrough after searching for, and failing to find, any U.S. patent filed by a company claiming intellectual property rights in these newer high-nicotine strains of tobacco. Recognizing that the failure to file an American patent in the public record might reflect the industry’s strong preference for secrecy, but suspecting that it would be unwilling to go without intellectual property protection altogether, Knoth looked for and discovered a patent for the plant filed with the government of Brazil. Once the Portuguese terms were translated, the import of the document was clear: Industry scientists had patented a variety of tobacco that possessed, in their words, a nicotine content “significantly higher than any normal variety of tobacco grown commercially.”⁴¹

³⁸ See *id.* at 78-244.

³⁹ See *id.* at 80.

⁴⁰ See Janet Maslin, *Mournful Echoes of a Whistle-blower*, N.Y. Times, Nov. 5, 1999, at E1.

⁴¹ See Kessler, *supra* note 1, at 191-92.

The FDA later discovered customs invoices indicating that substantial quantities of the Y-1 high-nicotine variant had been imported into the United States from Brazil.⁴²

In its fact-gathering endeavors from 1992 to 1995, the FDA benefited from developments spurred by other large institutional players who were showing newfound willingness to go after Big Tobacco. The national media began to investigate and broadcast the addictive potential of nicotine, and FDA staff closely monitored the information that appeared. In a February 1994 broadcast entitled “Day One,” ABC News purported to reveal “the tobacco industry’s last, best secret—how it artificially adds nicotine to cigarettes to keep people smoking and boost profits.”⁴³ The show also publicly aired for the first time the news that “the Food and Drug Administration ... is now considering whether to regulate cigarettes as drugs.” Although the FDA did not act in concert with ABC News on the broadcast, and agency officials declined requests to be interviewed on camera, Kessler and his team followed the disclosures with great interest.

A SHIFTING JUDICIAL CLIMATE

More important for producing hard documentary evidence that the FDA could use in defense of its regulations were several private and quasi-public lawsuits being pressed by plaintiffs’ attorneys and state attorneys general in the 1990s. Some key lawsuits that produced troves of documents were individual causes of action, which faced the typical barriers to proving causation and achieving ultimate recovery that earlier lung cancer plaintiffs had. But despite vigorous attempts by industry attorneys to keep materials secret, such lawsuits did succeed in persuading various judges around the country to force discovery of previously confidential industry documents. Many of these documents found their way into the hands of the FDA or congressional committee investigators, and then ultimately into the public domain. Another major contemporaneous legal development was the innovative coordinated lawsuits brought by state attorneys general seeking reimbursement for the public’s health care costs from smoking-related illnesses. This litigation would ultimately produce a key settlement described later in this chapter.⁴⁴ Beyond the generalized pressure that such lawsuits put on the industry, the FDA’s rulemaking process benefited specifically from the documentary and testimonial leads that such litigation produced and, in many instances, the FDA relied and expanded upon the factual clues that emerged from the ongoing litigation in multiple jurisdictions.

A few examples illustrate the explosive potential of the industry’s previously secret documents, and their clear connection to the FDA’s legal theory of jurisdiction that rested on proof of manufacturer intent over nicotine content. A long-hidden R.J. Reynolds document emerged that contained the 1972 statement of a research scientist that neatly supported the FDA’s theory of nicotine manipulation. The scientist wrote that “a tobacco product is, in essence, a vehicle for the delivery of nicotine.” Continuing the analogy to pharmaceuticals, the scientist wrote that therefore the tobacco “industry is ...

⁴² See *id.* at 240-41.

⁴³ See Walter Goodman, *Television View: Life Lessons From ABC’s Nicotine Expose on ‘Day One’*, N.Y. Times, May 8, 1994, at sec. 2.

⁴⁴ See *infra* at text accompanying notes 69-74.

based on the design, manufacture, and sales of attractive dosage forms of nicotine.”⁴⁵ In a New Jersey product liability case, the plaintiff’s attorneys unearthed internal Philip Morris documents with a similar theme; company researchers described cigarette packs as “a storage container for a day’s supply of nicotine” and a “puff of smoke” as a “vehicle of nicotine.”⁴⁶ A different set of documents produced in a South Carolina case and obtained by the FDA were even more pointed. “In a sense,” one decades-old company research report stated, “the tobacco industry may be thought of as being a specialized, highly ritualized and stylized segment of the pharmaceutical industry.”⁴⁷

If David Kessler and his colleagues were heartened by the revelation of this important new evidence about industry intent and its conceptual fit with their theory of statutory jurisdiction, they were likewise encouraged by the strong rhetoric of the various federal judges who ordered production of such documents over heated company objections. Given the long track record of industry success in federal and state litigation, and the certainty that any new FDA regulations affecting tobacco would be challenged in court, the emerging judicial skepticism of the industry’s factual defenses and legal arguments was a significant institutional signal to the FDA. For instance, Judge Harold Greene of the U.S. District Court for the District of Columbia recognized that his discovery ruling in a particular case had much broader implications. In ruling against Brown & Williamson on a discovery matter involving sensitive documents, he wrote:

This is a seemingly arcane dispute over subpoenas and motions to quash them. But what is involved at bottom is not arcane at all; it is a dispute over documents which may reveal the Brown and Williamson tobacco company concealed for decades that it knew its products to be both hazardous and addictive.⁴⁸

Judge Greene went on to more sharply rebuke the company, concluding that “[t]here are several rules, even constitutional doctrines, that stand in the way of so high-handed a course of conduct, and one so patently crafted to harass those who would reveal facts.”⁴⁹ Judge Lee Sarokin of the U.S. District Court in New Jersey went further a few years earlier in denying Liggett & Myers’ motion for summary judgment in a different individual tort action, stating that the evidence presented at trial would permit a reasonable jury “to find a tobacco industry conspiracy, vast in its scope, devious in its purpose and devastating in its results.”⁵⁰

CONGRESSIONAL INACTION AND THE REGULATORY IMPERATIVE

All of these developments on multiple fronts provided the FDA with the raw material it required to empirically substantiate its own regulations and suggested a newly favorable legal-political atmosphere in which its theory of jurisdictional authority would be tested. Even so, David Kessler later recounted that, as late as the end of 1994, he and his agency colleagues hoped that Congress would act to explicitly grant regulatory

⁴⁵ See Brandt, *supra* note 13, at 318.

⁴⁶ See *id.* at 340.

⁴⁷ See *id.* at 341.

⁴⁸ See Maddox v. Williams, 855 F. Supp. 406, 415-16 (D.D.C. 1994).

⁴⁹ See *id.* at 416.

⁵⁰ See Cipollone v. Liggett Group, Inc., 683 F. Supp. 1487, 1493 (D.N.J. 1988).

authority to the FDA and thus avoid the need for unilateral agency action. In February 1994 Kessler floated a trial balloon with a pointed invitation for congressional involvement, in the body of a public letter to the Coalition on Smoking and Health.⁵¹ In the letter he made the legal case for FDA jurisdiction based on the plain text of the FDCA's definition of drug, claiming that "a strict application of these provisions" would legitimate FDA action. But he was opaque about the agency's regulatory intentions, stating that it was "vital" that "Congress provide clear direction to the agency" on these questions, and pledging to "work with Congress to resolve ... the regulatory status of cigarettes under the [FDCA]."

Kessler tried again with Congress in person in March 1994, testifying before Rep. Henry Waxman's (D-Calif.) Subcommittee on Health and the Environment. Waxman was a clear ally in the fight to regulate tobacco; his committee was independently subpoenaing industry documents and key witnesses during 1994.⁵² Fifteen years later, in 2009, Waxman would be the key sponsor of the bill that ultimately did change the FDCA to give the FDA jurisdiction over tobacco products. Before Waxman's committee in 1994, Kessler described the results of the agency's fact gathering and told the subcommittee that "[t]he research undertaken by the cigarette industry is more and more resembling drug development." Yet he remained tentative, stating that he was "seeking guidance" from Congress on how to proceed, and that the prospect of potential FDA jurisdiction over cigarettes "raises many broader social issues for Congress to contemplate."⁵³

As the FDA awaited a congressional response during 1994, a different episode of committee testimony took place that produced the most memorable single image of the tobacco battles of the 1990s. In April 1994 Representative Waxman subpoenaed the chief executive officers of the nation's seven largest tobacco companies to testify about tobacco's addictive properties in a hearing widely covered in the print and broadcast media. They stood together in the hearing room and swore to testify truthfully. Then, to a man (and they were all men), the seven CEOs flatly denied the addictive properties of nicotine and any industry efforts to manipulate nicotine levels in cigarettes. Lorillard's Andrew Tisch was particularly strident; he not only denied that nicotine was addictive but even expressed disbelief that cigarettes could cause lung cancer.⁵⁴ Most observers expressed complete incredulity at the CEOs' claims, with one editorialist expressing characteristically that it was a "[g]ood thing no one asked those tobacco executives whether they think the world is round or flat."⁵⁵ *The New York Times*, more soberly, called the spectacle a "shameful day for American business."⁵⁶

⁵¹ See Brandt, *supra* note 13, at 361-62.

⁵² See *Maddox v. Williams*, 855 F. Supp. at 415 (discussing Waxman's efforts to obtain sensitive industry documents).

⁵³ See Brandt, *supra* note 13, at 214 (testimony of David Kessler).

⁵⁴ See Justin Catanoso, *Tobacco Execs Plead Their Case in Testimony Before Congress*, Greensboro News & Rec., Apr. 16, 1994, at A1.

⁵⁵ *Blowing Smoke* (op-ed), Balt. Sun, Apr. 16, 1994, at 8A.

⁵⁶ *Blowing Smoke at Congress* (op-ed), N.Y. Times, Apr. 17, 1994, at 4-16.

Despite general disbelief of the industry's factual denial about nicotine, any hopes that David Kessler and his FDA colleagues had of congressional action evaporated with the large Republican gains in the midterm elections of November 1994. The new Congress was characterized by a general deregulatory bent, and several committee chairs were closely tied to tobacco states and tobacco companies. Once the election results were clear, Kessler and his team set about crafting a set of regulations with an eye toward official promulgation through the Administrative Procedures Act's notice-and-comment rulemaking procedure. Although the agency was secure in its basic jurisdictional theory that was grounded in manufacturer intent about nicotine content, the regulations required one more conceptual legal innovation to stand a chance of success in subsequent litigation. The FDA is required to approve all "drugs" as both "safe" and "effective," a standard that nicotine would never meet and thus could result in a regulatory ban of cigarettes. Everyone understood that a ban on cigarettes was both politically impossible and legally suspect.

The solution was to use nicotine as the jurisdictional hook but then regulate cigarettes as "drug-delivery systems" that were medical devices, a category that gave the agency a greater range of regulatory flexibility. Rather than prohibit cigarettes, the draft regulations sought to impose a variety of restrictions and requirements on their marketing, package design, and retail sale. For both sound public health and shrewd political reasons, the regulations centered on preventing children under 18 from becoming addicted; thus, most of the restrictions concerned youth smoking, with the ambitious goal of "reducing roughly by half children's and adolescents' use of tobacco products" within seven years of the rules taking effect.⁵⁷

With the substance of the policy in place by early 1995, the FDA required final executive branch authorization to move ahead with official publication of the draft regulations in the Federal Register. The agency's initiative received only lukewarm support in the halls of the Department of Health and Human Services, to the extent that David Kessler felt compelled to take the draft regulations directly to the White House. He met with Abner Mikva, the White House counsel and a former federal circuit judge and member of Congress (and author of a legal casebook on legislation⁵⁸), who gave his opinion that the rules were a valid exercise of FDA authority.

The political landscape was more complicated. Bruised by the Republican gains in November 1994, some advisors to President Clinton feared new rules on tobacco could cost the president key Southern states in his 1996 re-election bid. "Is this worth doing if it costs us Kentucky and Tennessee?" Kessler recalls one political advisor asking. Ultimately the internal political stalemate was broken by pressure on the president from Vice President Al Gore, a strong supporter of expanded jurisdiction, and by political advisor Dick Morris, who predicted (correctly) based on his own polling data that FDA regulation of tobacco was one area where Americans welcomed greater government intervention.⁵⁹ President Clinton announced the proposed regulations in a ceremony in

⁵⁷ See 60 Fed. Reg. 41314, 41314 (1995).

⁵⁸ See Abner J. Mikva and Eric Lane, *Legislative Process* (3d ed. 2009).

⁵⁹ See generally Kessler, *supra* note 1, at 321-25, 331-33.

August 1995, and they predictably attracted the largest rulemaking record in FDA history, a total of more than 710,000 comments. After a frenetic year of reviewing and responding to this administrative record, the FDA issued its final regulations on tobacco, only slightly revised from their original form, in August 1996, to take effect exactly one year later.

THE INDUSTRY'S CHALLENGE

The tobacco companies' challenge to the new FDA rules was swift, strategic, and well-coordinated. Soon after the issuance of final rules in August 1996, the industry filed suit. Under a federal statute governing the location of suits against federal agencies, the companies had a choice of suing in the district where the FDA was headquartered or where any of the company plaintiffs were based.⁶⁰ They chose the latter option and filed their challenge in what appeared to be a favorable venue: the U.S. District Court in the Middle District of North Carolina, based in Greensboro, the heart of tobacco-growing country. Even better for industry hopes was the judge assigned to the case, William Osteen, a Bush appointee whose family owned a tobacco farm and who had represented tobacco growers in lawsuits against the federal government prior to taking his seat on the bench.⁶¹ Judge Osteen shocked both litigants and observers of the trial when he ruled in April 1997 that the FDA's basic assertion of jurisdiction over cigarettes was valid, although he struck down some of the advertising restrictions contained in the new rules. The decision sent tobacco stock prices reeling to a one-day drop of 5% of aggregate value, translating to a loss of about six billion dollars in market capitalization.⁶²

Even more potentially damaging to the industry's litigation hopes were Judge Osteen's rationales for his ruling, in which he accepted two legal arguments pressed by government attorneys.⁶³ First, Judge Osteen accepted the plain language argument on which the FDA rested its basic jurisdictional claim, finding that "tobacco products fit within the FDCA's definitions of 'drug' and 'device.'"⁶⁴ Moreover, he applied a significant amount of *Chevron* deference⁶⁵ in dismissing the industry's arguments about past congressional understandings and agency disclaimers of authority over tobacco.⁶⁶

The government's victory in district court was short lived. The Fourth Circuit Court of Appeals agreed to hear the case on an expedited basis, and oral arguments took place in August of 1997. The importance of the case to the government was reflected in the fact that acting Solicitor General Walter Dellinger made a rare circuit court appearance to argue in favor of the FDA's authority. The case was reargued in June 1998 after original panel member Judge Donald Russell died abruptly before a decision had

⁶⁰ See 28 U.S.C. § 1391(e).

⁶¹ See Jeffrey R. Lax & Mathew McCubbins, *Courts, Congress and Public Policy, Part I: The FDA, the Courts, and the Regulation of Tobacco*, 15 J. Contemp. Legal Issues 163 (2006).

⁶² See *id.* at 170.

⁶³ See *Coyne Beahm Inc. v. FDA*, 966 F. Supp. 1374 (M.D. N.C. 1997).

⁶⁴ See *id.* at 1380.

⁶⁵ See *Chevron, U.S.A., Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 867 (1984) (holding that federal courts must defer to "reasonable" or "permissible" executive branch constructions of statutes).

⁶⁶ See *Coyne Beahm*, 966 F. Supp. at 1397.

issued. Finally, the reconstituted panel ruled 2-1 in favor of the tobacco companies. Unlike the lower court, the Fourth Circuit majority placed great weight on the long history of Congress's incremental regulation of tobacco in statutes other than the FDCA, and also the repeated representations by prior FDA officials to Congress that the agency lacked authority over tobacco.⁶⁷ The majority judges also held that tobacco fit poorly within the overall structure of the FDCA, given that it could never be found "safe" and "effective."⁶⁸

THE BATTLE AGAINST TOBACCO ON OTHER FRONTS

The stage was now set for briefing and argument before the U.S. Supreme Court, and arguments were set for December 1999. The issue of tobacco regulation was not playing out in a vacuum, however. In the two years between oral arguments in the Fourth Circuit and those in the Supreme Court, dramatic developments unfolded on other fronts in the tobacco wars, and one of these almost mooted the *Brown & Williamson* case. Beginning in early 1994, some entrepreneurial state attorneys general had partnered with private attorneys to bring a set of massive lawsuits against tobacco companies grounded in an innovative theory of recovery. Smoking-related illnesses caused billions of dollars in health care expenditures each year, and a large fraction of these costs was borne by state governments through their funding of Medicaid and related public health insurance programs. The states were thus able to argue that the costs of smoking harmed the public fisc, not just individual smokers, and they sought recovery of the public health expenditures that had been spent on smoking-related illnesses. These lawsuits, typically grounded in theories of unjust enrichment and restitution, were path-breaking in that they circumvented the problems of proving individual causation that had traditionally been the industry's greatest shield to ordinary tort liability.⁶⁹

This doctrinal innovation was a powerful threat to the tobacco industry, and a popular mechanism for states to exert pressure on the companies. By 1997 forty states had filed health care reimbursement suits; some labor unions, cities, and counties had also joined the coordinated effort.⁷⁰ In July 1997 the tobacco companies and the state plaintiffs inked a draft "global settlement" agreement for presentation to Congress that would have resulted in a statute settling the cases with striking concessions by both sides.⁷¹ The industry's fear of unbridled liability was such that companies were willing to acknowledge FDA jurisdiction over nicotine and accept many of the restrictions on youth advertising contained in the new FDA rules. In return, the states offered blanket immunity from Medicaid restitution and individual tort suits that they contemplated entrenching in a pre-emptive federal statute.⁷² If ratified by Congress, this sweeping agreement would have mooted the *Brown & Williamson* case pending before the Supreme Court.

⁶⁷ See *Brown & Williamson v. FDA*, 153 F.3d 155, 164-65 (4th Cir. 1998).

⁶⁸ See *id.* at 168-70.

⁶⁹ See generally Robert L. Rabin, *The Tobacco Litigation: A Tentative Assessment*, 51 DePaul L. Rev. 331 (2001).

⁷⁰ See *id.* at 338.

⁷¹ See *id.*

⁷² See *id.* at 338-39.

Congress, however, rejected the terms of the proposed settlement agreement, largely on the grounds that the broad immunity provisions were too protective of the industry going forward. Senator John McCain (R-Ariz.) was particularly critical of what he called an overly generous deal for the industry.⁷³ Without a supervening federal statute, the industry negotiated a scaled-down overall settlement agreement with the states in 1998, agreeing to pay almost \$250 billion in return for permanent relief from the state health care reimbursement claims.⁷⁴ Consent to FDA jurisdiction dropped out of this renegotiated deal, and the case proceeded to the Supreme Court. Whether this settlement, and the hefty sums the tobacco companies agreed to pay the states, affected the ultimate *Brown & Williamson* opinion is unclear. At least some justices in the majority might have been more comfortable thwarting FDA regulation of tobacco in a new world where tobacco companies were facing regulatory pressure from other institutional actors to an extent unheard of just a few years before.

ONWARD TO THE SUPREME COURT

In any event, at oral argument in December 1999, the high burden the government faced in defending the FDA regulations became clear. Seth Waxman, who had replaced Walter Dellinger as solicitor general, argued the case for the FDA and confronted pointed questions that in many respects previewed rationales that appeared in the majority opinion.⁷⁵ In a line of reasoning that would feature in that opinion, Justice Sandra Day O'Connor pressed Waxman on how tobacco fit uneasily within the FDA's ordinary regulatory portfolio, asking "[i]s it the position of the Government that the use of tobacco is safe and effective?"⁷⁶ (The FDA is required to assess all new drugs as both "safe" and "effective" in order to grant regulatory approval.⁷⁷) Before Waxman could answer, Justice O'Connor cut him off and answered her own query: "I take it not. So ... it just doesn't fit."⁷⁸ Later in his argument, Waxman sought to distance David Kessler's FDA from the agency's prior disclaimers of authority by noting that the evidence about nicotine's addictive potential had only recently come to light. He chose a poor example, however, when he cited the tobacco chief executives' infamous joint denial of nicotine's addictive character before Congress as hard evidence of scientific uncertainty as late as 1994. Chief Justice William Rehnquist interrupted with the quip "nobody believed them," and the courtroom erupted in laughter.⁷⁹

THE COURT'S DECISION AND ITS JURISPRUDENTIAL AND LEGISLATIVE AFTERMATH

The Supreme Court decided *FDA v. Brown & Williamson* in March 2000, and by a narrow 5-4 majority ruled against the FDA's authority to regulate tobacco. Justice O'Connor authored the majority opinion, joined by the chief justice and by Justices Antonin Scalia, Anthony Kennedy, and Clarence Thomas. The rationales in Justice

⁷³ See *id.* at 339-40.

⁷⁴ See *id.* at 340.

⁷⁵ See Transcript of Oral Argument, *FDA v. Brown & Williamson*, 1999 WL 1134652 (Dec. 1, 1999).

⁷⁶ See *id.* at 5.

⁷⁷ See 21 U.S.C. §393(b)(2).

⁷⁸ See Tr. Oral Arg., *supra* note 75, at 5.

⁷⁹ See *id.* at 13.

O'Connor's opinion tracked the themes of oral argument and rested on two central analytical frames, neither of which was closely concerned with the plain language of the key components of the FDCA.

First, the majority opinion stressed the uneasy overall statutory fit of tobacco with the FDCA's drug-regulatory framework. Perhaps ironically, here tobacco's very dangerousness worked against its regulation. Justice O'Connor began by stating the proposition that "one of the Act's core objectives is to ensure that any product regulated by the FDA is "safe" and "effective," a purpose that she found "pervades the FDCA."⁸⁰ Her opinion then cited the agency's own data on the severe health effects of smoking against it, holding that the health findings "logically imply that, if tobacco products were 'devices' under the FDCA, the FDA would be required to remove them from the market."⁸¹ Once the Court had adopted this reading of the statute, coupled with its consequentialist prediction about a total ban, the finding against jurisdiction became a foregone conclusion, because no one, including the government, maintained that Congress had authorized the FDA to ban cigarettes. The Court's conclusion on this structural point is sound as to the FDA's regulatory mandate as to drugs, but it is overbroad to say, as Justice O'Connor does, that the mandate to ensure safety and efficacy "pervades the FDCA" or embodies the FDA's complete regulatory role. The FDA incrementally regulates the labeling, marketing, and manufacturing of many products other than drugs—such as foods and some classes of medical devices—without demanding proof of comprehensive safety and effectiveness.

Although this element of the Court's opinion is linked tightly to the structure of the FDCA, the Court's second main support for its holding came from a more general methodological choice. The majority opinion broadly canvassed the longitudinal statutory history of the FDCA and other statutes, as well as prior agency declarations about tobacco jurisdiction. The FDCA, amended frequently throughout the second half of the twentieth century, remained silent as to tobacco, although there is a strong case that nicotine fit well within the plain language of the act's general definition of "drug." The Court's opinion, however, shifted the legislative history analysis to a bevy of other statutes, including "six separate statutes since 1965 addressing the problem of tobacco use and human health"⁸² that the Court read as excluding tobacco from the FDA's jurisdiction. Focusing in particular on the Federal Cigarette Labeling and Advertising Act of 1965 (FCLAA), Justice O'Connor concluded that Congress intended to keep tobacco regulation separate from the FDA and more generally to "preclude any administrative agency from exercising significant policymaking authority on the subject of smoking and health."⁸³ This is an accurate characterization of the FCLAA, which then and now has been pilloried as congressional capitulation to the power of the tobacco industry. But to extend that 1965 statute's deregulatory impulse through time and regulatory space to preclude a different agency decades later from addressing one of the nation's greatest public health problems is a serious diminution of administrative discretion.

⁸⁰ See *FDA v. Brown & Williamson*, 529 U.S. 120, 133.

⁸¹ See *id.* at 135.

⁸² See *id.* at 143.

⁸³ See *id.* at 149.

A related component of the Court's broad use of legislative history beyond the FDCA also sharply constrains administrative discretion, here by directly binding the FDA to its prior statements about tobacco jurisdiction. The Court correctly noted that over the past four decades FDA officials had disavowed jurisdiction on numerous occasions before Congress and the federal courts. The Court stressed that "Congress has acted against the backdrop of the FDA's consistent and repeated statements that it lacked authority under the FDCA to regulate tobacco."⁸⁴ More than that, the Court characterized prior FDA administrators, not Congress, as dictating policy on the issue. For the Court, it was "evident that Congress' tobacco-specific statutes have effectively ratified the FDA's long-held position"⁸⁵ on tobacco. In so reasoning the Court cast Congress as "relying" on the prior representations of the FDA, and enforced a rule holding Kessler's FDA (and by implication all future FDAs) to the testimonial statements of prior officials, who spoke when a different scientific understanding of nicotine's role in cigarettes prevailed. To understand Congress as acquiescing over time in background legal interpretations from other institutional actors was not unprecedented.⁸⁶ However, the Congressional reliance rationale that Justice O'Connor stressed in her *Brown & Williamson* majority was pointedly driven by statements by political agency officials as opposed to judicial decisions. Justice O'Connor did not fully explain why the weight given to statutory precedents rendered by the judiciary should be extended to statements made by agency bureaucrats, who might be more likely than courts to shift their views over time.

It is worth pausing to note that both of these primary arguments in the majority opinion—the one resting on the structure of the FDCA and its prime directive that drugs be "safe" and "effective," and the other grounded in the long legislative history and institutional interactions with respect to the FDCA—give little controlling weight to the plain language of the most relevant section of that statute. The majority did not seriously dispute that tobacco fell literally within the statute's definition of a drug as "as substance ... intended to affect the substance or function of the body," even as the opinion shifted the analysis to broader modes of reasoning grounded in overall structure and history. As Professors Jody Freeman and Adrian Vermeule have noted, nicotine "surely met" the "clear text" of this definition; the Court's analysis to the contrary "overrode" this plain language only "through a grab-bag of interpretive techniques" that went beyond the text.⁸⁷

This contra-textual reading is arguably anomalous on both an institutional and individual level. The Rehnquist Court is generally regarded by scholars as giving relatively more weight to statutory text than the Court in prior decades,⁸⁸ but there was scant evidence of this "new textualism" in the majority opinion in *Brown & Williamson*. Moreover, Justice O'Connor's opinion was joined by colleagues such as Justices Scalia and Thomas, and Chief Justice Rehnquist, all of whom are associated with the Court's

⁸⁴ See *id.* at 144.

⁸⁵ *Id.*

⁸⁶ See, e.g., *Flood v. Kuhn*, 407 U.S. 258 (1972).

⁸⁷ See Jody Freeman and Adrian Vermeule, *From Politics to Expertise*, 2007 Sup. Ct. Rev. 51, 73.

⁸⁸ See, e.g., William Eskridge, Jr., *The New Textualism*, 37 U.C.L.A. L. Rev. 621 (1990); Philip Frickey, *From the Big Sleep to the Big Heat: The Revival of Theory in Statutory Interpretation*, 77 Minn. L. Rev. 241 (1992).

textualist turn. Justice Scalia's adherence to the majority's sweeping use of legislative history beyond the text of the FDCA is particularly surprising given his frequent statements in other cases about the unreliability of such extrinsic evidence.⁸⁹

By a similar token, it is perhaps unusual that Justice Stephen Breyer, who wrote the dissent for himself and three other justices (Ruth Bader Ginsberg, John Paul Stevens, and David Souter) in *Brown & Williamson* focused first and foremost on the statutory text. Ordinarily no strong textualist, Justice Breyer recognized the strength of a plain language argument for the FDA's asserted jurisdictional argument, and his opinion led with the FDCA's definition of "drug" and with his conclusion that "tobacco products (including cigarettes) fall within the scope of this statutory definition, read literally."⁹⁰ A literal reading of the text was also important for Justice Breyer in his effort to counter the majority's argument that tobacco did not fit within the FDCA's regulatory regime with its emphasis on safety and efficacy of regulated products, and the majority's related conclusion that for the FDA to regulate tobacco would require a total ban. For Justice Breyer, the fact that the statute did not expressly mandate a ban was important, and given the overall purpose of public health protection that undergirded the FDCA, the fact that "the statute's language ... permit[ted] the agency to choose" more incremental remedies for tobacco regulation were persuasive.⁹¹

Despite this opportunistic use of favorable statutory text, Justice Breyer's dissent in *Brown & Williamson* was essentially motivated by, and gave voice to, a profoundly different view of the legitimacy of major policy change by expert agencies in the American democracy. Whereas Justice O'Connor's majority read the FDCA and related statutes to "preclude any administrative agency from exercising significant policymaking authority on the subject of smoking and health,"⁹² Justice Breyer found such authority to update and change policy implicit in both the statute and the structure of the modern administrative state. The rationale for such updating could be driven by both political change and new scientific understandings. Supporting the political impulse for changed regulation, he quoted Chief Justice Rehnquist's language from an earlier landmark administrative deference case for the proposition that "a change in administration brought about by the people casting their votes is a perfectly reasonable basis for an executive agency's reappraisal of the costs and benefits of its programs and regulations."⁹³ However, the technocratic expertise that the FDA brought to bear in framing its new tobacco regulations was also important to Justice Breyer's conception of their legitimacy, and this reasoning fit with his prior extrajudicial writings on administrative policymaking.⁹⁴ Breyer repeatedly mentioned the new "scientific evidence" that the FDA had mustered about nicotine's addictive potential and this "emerging scientific consensus" as legitimating the FDA's assertion of jurisdiction.

⁸⁹ See, e.g., *Wis. Pub. Intervenor v. Mortier*, 501 U.S. 597 (1991).

⁹⁰ See *Brown & Williamson*, 529 U.S. 120, 154 (Breyer, J., dissenting).

⁹¹ See *id.* at 156.

⁹² See *id.* at 149.

⁹³ See *id.* at 164 (quoting *Motor Vehicles Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 59 (1983)).

⁹⁴ See, e.g., Stephen Breyer, *Breaking the Vicious Circle: Toward Effective Risk Regulation* (1993).

ECHOES IN THE COURT'S TWENTY-FIRST CENTURY JURISPRUDENCE

As described briefly below, a 2009 Congressional amendment to the FDCA has given the FDA the jurisdiction over tobacco that it sought in the *Brown & Williamson* litigation, and thus the case has been effectively overruled as a jurisdictional precedent. What remains contested, however, are the profoundly different judicial outlooks toward bureaucratic policy change expressed in the majority and dissenting opinions. Such disagreement is one with high stakes given the major issues on which Congress has been either silent or conflicted in its statutes, and one that is bound to recur given the broad range of topics left unresolved by statutory text. How much latitude do, and ought, executive branch agencies have to shift policy in response to new political conditions and scientific understandings? Relatedly, will such administrative discretion be cabined—as it was in *Brown & Williamson*—if the agency has repeatedly gone on record with a previous position?

It is possible to discern in jurisprudence since *Brown & Williamson* a style of reasoning that echoes the majority's emphasis on dampening dramatic policy change from agency actors absent congressional modification of the statute. The *Brown & Williamson* majority opinion enforced a broad norm that encourages continuity in agency policymaking and in the ongoing relationship between executive branch agencies and Congress. Though critiqued at the time as result-oriented jurisprudence, it is a style of reasoning that has resurfaced in other cases in the past decades where agencies have shifted their positions on key regulatory topics. Important justices at the center of the Supreme Court's voting array, namely Justices O'Connor and Kennedy, have in these cases enshrined a norm of administrative consistency on large public policy questions. Where agencies have articulated views on a given topic in the past, the Court had made it more difficult for new administrations to alter those policy positions absent statutory change. This continuity norm significantly intensifies the Court's supervisory relationship over agencies acting in the face of congressional silence, and it is in profound tension with the rationale of *Chevron*⁹⁵ and related precedents that are more deferential to agency policy entrepreneurship.

The most closely analogous recent case reflecting this policy continuity norm is *Wyeth v. Levine*,⁹⁶ which involved another FDA attempt to reverse a longstanding policy, a rule that met with a similar end result as David Kessler's tobacco regulations. *Wyeth* bears a close resemblance to the *Brown & Williamson* story on many dimensions, although it came to the Court with an opposite political valence. The case presented the question of whether the FDA's bureaucratic approval of a drug's labeling—replete with extensive language on risks, benefits, and contraindications—pre-empted a state tort lawsuit for “failure to warn” that alleged that the label should have included additional information beyond what the FDA scientists had required. The FDA supported the drug manufacturer's claims of implied pre-emption in *Wyeth*, and had issued a regulatory statement in favor of pre-emption a few years before the Supreme Court's consideration

⁹⁵ See *Chevron, U.S.A., Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 867 (1984) (holding that federal courts must defer to “reasonable” or “permissible” executive branch constructions of statutes).

⁹⁶ 129 S. Ct. 1187 (2009).

of the case. In its regulation and in the *Wyeth* lawsuit itself, the FDA plausibly argued that state tort suits could decrease the effectiveness of a label by inducing drug makers to clutter the label with even trivial risks.⁹⁷

There was more to the institutional story, however, and this longer history mattered greatly to the Supreme Court majority, which rejected the agency's arguments for pre-emption in an opinion that tracked some of *Brown & Williamson's* most important themes. For the Supreme Court majority, authored by Justice Stevens, it was important that the FDA's pro-pre-emption position was brand new. Like the *Brown & Williamson* Court, the *Wyeth* majority opinion made much of the long "70-year history" of the FDCA, and of Congress' "certain awareness of the prevalence of state tort litigation" during that period, when it otherwise amended the FDCA numerous times.⁹⁸ More pointed was the Court's refusal to defer to the Bush FDA's policy position given the agency's "dramatic change in position" on pre-emption. The Court noted that the FDA had "long maintained" the view that tort law and regulatory approval could coexist, and the new rule "reverse[d] the FDA's own longstanding position without providing reasoned explanation." The agency's "newfound" and "recently adopted" position was entitled to "no weight" in construing the statute.⁹⁹

Echoes of the *Brown & Williamson* continuity norm are also present in the majority opinion in *Gonzales v. Oregon*,¹⁰⁰ but they are more muted in light of the other substantive interpretive values important to the Court there. That case involved the Court's invalidation of Attorney General John Ashcroft's interpretive directive prohibiting the use of federally controlled pharmaceuticals by physicians in Oregon's assisted-suicide regime. (State law made it legal for doctors to assist terminally ill patients in ending their lives under highly regulated circumstances.) Ashcroft's interpretation of the federal Controlled Substances Act¹⁰¹ was arguably a plausible one, and had the Court applied ordinary deference to this episode of executive branch interpretation, it might well have upheld the policy.

The Court's opinion by Justice Kennedy, however, gave no deference to Ashcroft's interpretation, in large part because he had dramatically departed from the views of his predecessor on the specific question of the federal role in banning assisted suicide.¹⁰² More generally, the attorney general's interpretation diverged from the statements of prior federal officials who had consistently disclaimed federal authority to regulate medical practice. Against this decades-long backdrop, Ashcroft's policy initiative was "a radical shift," and one the Court did not permit him to make without express statutory authorization.¹⁰³

⁹⁷ See *id.* at 1192-95.

⁹⁸ See *id.* at 1200.

⁹⁹ See *id.* at 1203-04.

¹⁰⁰ 546 U.S. 243 (2006).

¹⁰¹ See 21 U.S.C. § 801 *et. seq.*

¹⁰² See 546 U.S. at 273-75.

¹⁰³ See *id.* at 275.

In both *Wyeth v. Levine* and *Gonzales v. Oregon*, then, it is possible to discern a continuing judicial impulse to dampen unilateral administrative policy change on important questions, particularly where the agency at issue has publicly expressed a different position from other institutional actors. The practical effect of this continuity norm is to tightly constrain dramatic agency-driven policy change on controversial questions. What results is a kind of administrative incrementalism: Agencies receive greater discretion when they regulate more modestly, or moderately. Given that the key jurisprudential architects of this continuity norm are the centrist “minimalists”¹⁰⁴ Anthony Kennedy and Sandra Day O’Connor, it appears that the Court is imposing on agency actors a similar incremental style that it has displayed in many of its key constitutional rulings.

Judicial enforcement of this norm of institutional policy minimalism has two further implications. First, it is a clear theoretical repudiation of *Chevron’s* central political theory about agency legitimacy—that executive branch actors are relatively politically accountable, and thus political change in the White House might produce real change in agency policies, in which case the federal courts should presumptively defer. In *Chevron*, authored by Justice Stevens, the Court found it “entirely appropriate for [the] political branch[es] 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.”¹⁰⁵ The continuity norm on display in *Brown & Williamson* and *Wyeth* and related cases inverts this presumption, particularly given the talismanic role of prior agency statements in calcifying agency positions. It is possible, perhaps, to reconcile *Chevron’s* statement about political policy discretion with the Court’s rejection of John Ashcroft’s directive in *Gonzales v. Oregon*, if one regards that directive as a democratically illegitimate fiat.¹⁰⁶ But the two FDA cases of *Wyeth v. Levine* and *Brown & Williamson* provoke greater conceptual tension, because the decision to regulate smoking and the decision to reduce the tort costs for pharmaceuticals through pre-emption were clearly supported by major elements in the governing coalitions of Presidents Clinton and Bush, respectively.

Given the substantial constraint on agency flexibility that it represents, this continuity norm is justifiable, if at all, only when used sparingly. The Court appears sensitive to this consideration, and has reserved the norm’s application only to some of the most significant policy questions: tobacco jurisdiction, pre-emption of drug products liability lawsuits, and the permissibility of assisted suicide. Agencies are not permitted to combine statutory silence with scientific expertise and a newfound political mandate to shift to new policies once a stable norm has become entrenched. In the view of key members of the Supreme Court, significant and influential policy change ought to emerge from Congress, not the bureaucracy.

¹⁰⁴ See Sunstein, *supra* note 9.

¹⁰⁵ 467 U.S. at 864-65.

¹⁰⁶ See Theodore W. Ruger, *Gonzales v. Oregon and the Supreme Court’s (Re)Turn to Constitutional Theory*, 34 J.L.M.E. 817 (2006).

CONCLUSION

If *Brown & Williamson* and related cases are best understood as articulating a kind of non-delegation rule that forces Congress rather than agencies to effectuate key policy shifts, a more recent coda to the story of the FDA and tobacco ought to hearten the Court's majority. Congress did finally explicitly act on the question of the FDA and tobacco in 2009. In enacting The Family Smoking Prevention and Tobacco Control Act of 2009,¹⁰⁷ which was signed by President Barack Obama in June 2009, Congress created a new title of the FDCA and expressly granted the FDA jurisdiction over tobacco products. Like the 1996 FDA regulations, the new statutory amendments focus heavily on reducing and controlling youth smoking; they also contain a host of marketing and advertising restrictions. Two components of the new statute speak directly to the Court's 2000 ruling. First, Congress in the statute directs the FDA to reissue the 1996 regulations that the Supreme Court struck down in *Brown & Williamson*. Second, Congress expressly forbids the FDA from banning tobacco products or reducing their nicotine content to zero, thus foreclosing directly the structural conclusion that Justice O'Connor thought predictable.

That Congress responded directly to the *Brown & Williamson* issue, but only after a decade of inactivity, serves as a kind of Rorschach test through which to assess the Court's continuity norm that foreclosed dramatic policy change on the agency's own initiative. On one hand, the Court's insistence that Congress speak on the precise issue did indeed produce a more democratically legitimate statute, and one that altered the structural balance of the FDCA to ensure against an outright agency ban of tobacco products. On the other hand, the fact that it took a decade to do so (and similar bills were introduced every year after 2000) illustrates the difficulty in enacting even popular policies into statutes given entrenched oppositional interests, particularly when representatives of those interests occupy powerful positions in the legislature. When the subject of legislation is itself a major public health killer, the costs of delay are poignantly borne by members of the public.

Still, on the specific issue of smoking reduction, the Court's decision was not as cataclysmic from a public health perspective as it might have seemed at the time. Smoking rates, already in decline in 1999, have continued downward to the lowest ebb in over half a century. Even youth smoking, the major object of the FDA's invalidated regulations, has declined precipitously due to other regulatory and behavior-changing interventions. When it promulgated its tobacco rules in 1996, the FDA announced a bold desire to cut youth smoking in half within seven years. This goal was almost met even without the binding force of the federal rules; CDC data shows that the prevalence of current cigarette use among high school students fell from 36.4% in 1997 to 21.9% in 2003.¹⁰⁸

¹⁰⁷ Pub. L. No. 111-131, §§2(3), 2(5), 2(31) and 2(49), 123 Stat. 1776, 1777-1781 (2009).

¹⁰⁸ See Centers for Disease Control, *Cigarette Use Among High School Students—United States, 1999-2007*, 57 M.M.W.R. 689-91 (June 27, 2008)

In the absence of FDA regulation, smoking's decline in the United States was caused by a range of strategies and governmental interventions, including public information campaigns, aggressive counter-marketing, state lawsuits, local bans in restaurants and other public places, and continued Federal Trade Commission supervision of marketing practices. Health care institutions such as hospitals and insurers—now collectively the nation's largest private industry—took a strong pecuniary interest in avoiding the substantial costs associated with smoking. Ultimately, given the multiple institutional players lining up against tobacco, the Supreme Court's decision was simply one setback in a larger struggle. At least in the United States, tobacco has been partially tamed, though with no help from the Supreme Court.