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ARTICLES

Smoking Out the Impact of Tobacco-Related Decisions on Public Health Law

Micah L. Berman[†]

Tobacco is a product—and public health problem—unlike any other. No other legal consumable product is nearly as addictive or as deadly as the cigarette, which kills approximately 440,000 Americans every year.¹ Moreover, tobacco products have exerted an unparalleled influence over American society and culture. As Allan Brandt wrote in *The Cigarette Century*, cigarettes have “deeply penetrated American culture,” leaving “few, if any, central aspects of American society that are truly smoke-free.”² These and other characteristics make tobacco use a highly unusual public health issue, and therefore courts have often distorted precedents and shaped their decisions to accommodate the unique exigencies of tobacco-related cases. In turn, these decisions have significantly reshaped public health law doctrine, affecting a wide variety of health-related concerns outside the tobacco context.

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¹ Rob Crane, *The Most Addictive Drug, the Most Deadly Substance: Smoking Cessation Tactics for the Busy Clinician*, 34 PRIMARY CARE CLINICAL OFF. PRAC. 117, 117 (2007) (“By several measures, nicotine is the world’s most highly addictive drug, and tobacco is its most deadly substance.”).

² ALLAN M. BRANDT, *THE CIGARETTE CENTURY* 3 (2007).

This Article seeks to uncover and analyze the role that tobacco-related litigation has played in the evolution of public health law doctrine. “Public health law” can be described as the application of administrative and tort law to the field of public health, subject to the limitations imposed by constitutional law.³ The past twenty-five years have seen substantial shifts in both the administrative and tort law aspects of public health law. In administrative law, the Supreme Court has “gradually erod[ed] the deference accorded to administrative agencies,” including public health entities.⁴ This retreat from the highly deferential rule announced in *Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc.*⁵ has had profound implications for the ability of regulatory agencies to proactively address public health challenges. At the same time, federal court decisions in personal injury and products liability cases have made it substantially more difficult for public health advocates to use tort law in ways that “influence and develop . . . policies directly affecting the public’s health.”⁶

What role have tobacco-related cases played in these developments? Have these cases pushed public health law in particular directions? Or have tobacco-related decisions merely reflected broader cross-cutting trends? This Article suggests that while there have certainly been other factors concurrently driving the development of public health law, a broader perspective reveals that tobacco cases have had a considerable influence that has been generally unrecognized. In several different areas, doctrines developed or extended in tobacco-related cases have engrained an anti-regulatory bias into

³ See generally Edward P. Richards, *Public Health Law as Administrative Law: Example Lessons*, 10 J. HEALTH CARE L. & POL’Y 61 (2007); Elizabeth A. Weeks, *Beyond Compensation: Using Torts to Promote Public Health*, 10 J. HEALTH CARE L. & POL’Y 27 (2007); Wendy E. Parmet, *Public Health and Constitutional Law: Recognizing the Relationship*, 10 J. HEALTH CARE L. & POL’Y 13 (2007). This Article will not explore the constitutional law aspects of public health law, though tobacco-related cases have played a substantial role in that field as well. See, e.g., *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525, 532 (2001) (exploring First Amendment limitations on the regulation of commercial speech).

⁴ Stephen M. Johnson, *Bringing Deference Back (But for How Long?): Justice Alito, Chevron, Auer, and Chenery in the Supreme Court’s 2006 Term*, 57 CATH. U. L. REV. 1, 1, 42-43 (2007) (suggesting that Justice Alito’s elevation to the Supreme Court created a modest shift back towards a more deferential view of agency decisions in the 2006 Term).

⁵ 467 U.S. 837 (1984).

⁶ Wendy E. Parmet, *Tobacco, HIV, and the Courtroom: The Role of Affirmative Litigation in the Formation of Public Health Policy*, 36 HOUS. L. REV. 1663, 1669 (1999).

public health law, and this has made it more difficult for plaintiffs seeking redress for other types of health-related injuries to have their cases heard in court. Overall, if it had not been for tobacco-related cases, today's health-related litigation would likely encounter a markedly different legal landscape. Reconsidering the history of tobacco-related cases is important for understanding the dynamics of public health law's evolution and the ways in which public health goals can (or cannot) be pursued through regulation and litigation. This, in turn, raises questions for legal scholars, judges, and public health experts alike as to how tobacco-related cases *should* be treated by the courts.

Part I of this Article discusses whether tobacco cases are "exceptional," and suggests several reasons why courts have approached smoking-related litigation differently from other public health cases. Part II reviews the impact of tobacco cases in the regulatory context, focusing on the wide-ranging impact of the Supreme Court's decision in *FDA v. Brown & Williamson Tobacco Corp.*⁷ There, the Court rejected the FDA's jurisdiction over tobacco products, after struggling with what it termed tobacco's "unique place in American history and society."⁸ In the process of reaching this conclusion, the Court collapsed the two-part *Chevron* test into a one-step process that provided far less deference for administrative action. The impact of this decision has reached far beyond tobacco cases, limiting the ability of other regulatory agencies to address emerging public health concerns. Part III assesses the influence of tobacco cases on personal injury litigation and products liability lawsuits. This Part covers three primary subjects: preemption, class certification, and punitive damages. Part IV concludes the Article by raising the normative question of how the courts should have approached tobacco-related cases, and suggests that the courts' failure to directly confront this question has allowed tobacco litigation to have a distorting impact on the rest of public health law.

I. IS TOBACCO EXCEPTIONAL?

As an initial matter, it may be necessary to explore the concept of uniqueness and disentangle two meanings of the

⁷ 529 U.S. 120 (2000).

⁸ *Id.* at 159-60.

word “exceptionalism.” In various fields of law, scholars have argued that if a particular subject is “exceptional,” it must be subjected to a unique set of legal rules because the existing legal framework cannot accommodate it. For example, claims have been made that distinct legal structures (whether statutory or judicially developed) are needed to address modern phenomena such as the Internet, genomics, and nanotechnology.⁹ In the context of public health, Ronald Bayer argued in 1991 that despite the existence of a legal framework for combating communicable diseases, “HIV exceptionalism” had produced a unique set of laws to deal with the AIDS epidemic.¹⁰

This Article will not explore that type of exceptionalism, i.e., whether a different legal framework is necessary to address the issue of tobacco. Tobacco products do have their own regulatory regime, which is clearly “exceptional” in the world of food and drug law.¹¹ Though warning labels are required on cigarette packages by the Federal Cigarette Labeling and Advertising Act (FCLAA), “[c]igarettes have been specifically exempted from coverage under the Fair Labeling and Packaging Act of 1966, the Controlled Substances Act of

⁹ See generally Lawrence Lessig, *The Law of the Horse: What Cyberlaw Might Teach*, 113 HARV. L. REV. 501 (1999) (arguing that the “law of cyberspace” should be considered a distinct and specialized area of law); Lainie Friedman Ross, *Genetic Exceptionalism vs. Paradigm Shift: Lessons from HIV*, 29 J.L. MED. & ETHICS 141 (2001) (considering, but ultimately rejecting, the arguments in favor of “genetic exceptionalism”); Frederick A. Fielder & Glenn H. Reynolds, *Legal Problems of Nanotechnology: An Overview*, 3 S. CAL. INTERDISC. L.J. 593 (1994) (“Some of the problems posed by nanotechnology may be sui generis . . . and may therefore be addressable only through the creation of entirely new rules.”).

¹⁰ Ronald Bayer, *Public Health Policy and the AIDS Epidemic: An End to HIV Exceptionalism?*, 324 NEW ENG. J. MED. 1500, 1501 (1991) (“[I]n the end, it was those who called for ‘HIV exceptionalism’ who came to dominate the public discourse.”). Scott Burris later responded that the response to HIV was better viewed as a typical response to a new public health threat. Scott Burris, *Public Health, “AIDS Exceptionalism,” and the Law*, 27 J. MARSHALL L. REV. 251, 261 (1994) (“in other words, unique but not exceptional”).

¹¹ After years of inaction, Congress recently passed the Family Smoking Prevention and Tobacco Control Act, which for the first time grants the FDA limited authority to regulate cigarettes. See Pub. L. No. 111-31, 123 Stat. 1776 (2009); see also Jeff Zeleny, *Occasional Smoker, 47, Signs Tobacco Bill*, N.Y. TIMES, June 23, 2009, at A15. This 83-page law sets out an intricate and unique set of regulatory provisions that will govern the tobacco industry. The FDA’s authority over tobacco products is limited in several respects. Most notably, the FDA is prohibited from “(A) banning all cigarettes, all smokeless tobacco products, all little cigars, all cigars other than little cigars, all pipe tobacco, or all roll-your-own tobacco products; or (B) requiring the reduction of nicotine yields of a tobacco product to zero.” H.R. 1256, 111th Cong. § 907(d)(3) (2009). The law also specifically states that it should not be read to “establish a precedent with regard to any other industry.” *Id.* § 4(a)(1).

1970, the Consumer Product Safety Act of 1972 (establishing the Consumer Product Safety Commission), and the Toxic Substances Act of 1976.”¹² That Congress has chosen to regulate (or not regulate) tobacco differently from other public health concerns has certainly had implications for tobacco-related litigation, as discussed below. But whether such unique treatment by Congress is itself warranted or unwarranted is a policy debate beyond the scope of this Article.

Rather, this Article suggests that tobacco cases are treated in an “exceptional” manner by the courts, and that such treatment has had a distorting effect on judicial decision-making in the field of public health. Courts purport to apply the same legal doctrine to tobacco cases that they apply to all other public health issues, and they do so in a facially neutral way. In actuality, however, courts tend to be unusually skeptical of attempts to regulate tobacco and of plaintiffs’ claims against the tobacco industry. Because tobacco-related cases then stand as precedent for other public health cases, this legal “exceptionalism” exerts a significant influence on the overall direction of public health law.

By analogy, scholars have noted a similar phenomenon in the field of criminal procedure, where courts purport to apply the Fourth Amendment in a facially neutral way, but seem to operate with less concern for privacy interests when illegal drugs are involved.¹³ Limiting Fourth Amendment rights in drug cases then has a distorting impact on Fourth Amendment jurisprudence more generally, leading to weakened privacy protections for defendants even when illegal drugs are not involved. Although there are surely other factors beyond the “war on drugs” that have led the Supreme Court towards a more pro-prosecution posture in Fourth Amendment cases, scholars have persuasively argued that the unique exigencies of drug cases have played a significant role in shaping the law.

¹² Peter D. Jacobson & Kenneth E. Warner, *Litigation and Public Health Policy Making: The Case of Tobacco Control*, 24 J. HEALTH POL., POL’Y & L. 769, 774 (1999).

¹³ Erik Luna, *Drug Exceptionalism*, 47 VILL. L. REV. 753, 766-72 (2002) (suggesting as possible explanations for this phenomenon the “sheer magnitude of drug crime and enforcement activities” and the “substantial personal and professional pressures of any given judge” to support the government’s efforts to combat illegal drugs); see also Steven Wisotsky, *Crackdown: The Emerging “Drug Exception” to the Bill of Rights*, 38 HASTINGS L.J. 889, 926 (1987) (predicting that dangerous precedents developed in drug prosecutions would inevitably “spill over to other areas of law”).

Similarly, as discussed below, courts purport to apply existing legal doctrine to tobacco cases, but the results in key cases have departed from prior precedent in significant ways. Just as illegal drug cases have played a prominent role in reshaping Fourth Amendment doctrine, tobacco cases have facilitated or furthered broader changes in the contours of public health law doctrine for all future cases—even when tobacco is not involved.

But what is it about tobacco cases that causes courts to approach these cases differently? Though this is by no means an exhaustive list, tobacco's unique history, the volume of tobacco litigation, and the saliency of the cultural and economic issues involved have all been significant factors.

A. *History and Entrenchment in Society*

Although many people assume that cigarettes have been popular for centuries, it was not until the early Twentieth Century that the cigarette rolling machine was invented, allowing tobacco companies to mass produce and mass market cigarettes. Cigarettes soon became hugely popular, helped in part by the distribution of free cigarettes to U.S. soldiers in World War II.¹⁴ By the early 1950s, when the first credible reports of the link between smoking and cancer were published in medical journals, “[n]early one out of two Americans could be counted as a regular smoker.”¹⁵

The rapid growth of the industry was impressive, but it was the industry's response to revelations of the cigarette's dangers that set its history on a unique course. Instead of removing the product from the market or providing explicit warnings to consumers, the tobacco companies chose a third option—a cover-up. With the help of a public relations firm, Hill & Knowlton, the industry began its fifty-year campaign to deceive the public about the health effects of smoking.¹⁶ As

¹⁴ Deb Reichmann, *Military Encounters Resistance to Proposed Ban on Smoking*, BOSTON GLOBE, Aug. 30, 2009, at 4 (“Soldiers got cigarettes in their C-rations during World War II.”).

¹⁵ Robert L. Rabin, *A Sociolegal History of the Tobacco Tort Litigation*, 44 STAN. L. REV. 853, 855 (1992) [hereinafter Rabin, *Sociolegal History*].

¹⁶ Jon D. Hanson & Douglas A. Kysar, *Taking Behavioralism Seriously: Some Evidence of Market Manipulation*, 112 HARV. L. REV. 1420, 1483-87 (1999) (summarizing Hill & Knowlton's involvement in the “extraordinary decades-long campaign of the [cigarette] industry, acting in concert, to foster and perpetuate ‘controversy’ over whether cigarettes cause disease”).

Judge Kessler summarized in *United States v. Philip Morris USA, Inc.*:

From at least 1953 until at least 2000, [the cigarette manufacturers] repeatedly, consistently, vigorously—and falsely—denied the existence of any adverse health effects from smoking. Moreover, they mounted a coordinated, well-financed, sophisticated public relations campaign to attack and distort the scientific evidence demonstrating the relationship between smoking and disease, claiming that the link between the two was still an “open question.” Finally, in doing so, they ignored the massive documentation in their internal corporate files from their own scientists, executives, and public relations people that, as Philip Morris’s Vice President of Research and Development, Helmut Wakeham, admitted, there was “little basis for disputing the findings [of the 1964 Surgeon General’s Report concluding that smoking causes lung cancer].”¹⁷

Although manufacturers of other products have delayed reporting known dangers of their products, the scope and duration of the tobacco industry’s campaign of deception stands alone. The success of this fraudulent campaign had substantial legal implications, as the tobacco companies were able to successfully argue in court for decades that cigarettes did not cause cancer (or, in each specific case, that cigarettes had not caused the plaintiff’s cancer).¹⁸ By the time that defense was no longer tenable, the tobacco companies were able to pivot—amazingly, without conceding the connection between smoking and disease—to the defense that the plaintiff’s own decision to smoke (in light of the “common knowledge” that smoking causes disease) should absolve the companies of any responsibility.¹⁹

The tobacco companies, however, were not able to fully escape legal liability. Most notably, the tobacco companies signed the Master Settlement Agreement (MSA) in 1998, committing themselves to paying more than \$200 billion to state governments.²⁰ Although the MSA (and the avalanche of document disclosures that both preceded and followed the

¹⁷ *United States v. Philip Morris USA, Inc.*, 449 F. Supp. 2d 1, 208 (D.D.C. 2006), *aff’d in part, vacated in part*, 566 F.3d 1096 (D.C. Cir. 2009).

¹⁸ *See infra* Part III.B.

¹⁹ At times, the industry attempted to assert these two arguments simultaneously: “Its lawyers and executives would deny that there was any proof that cigarettes caused cancer. At the same time, they maintained that anyone . . . who chose to smoke assumed the risk of getting such a disease.” MICHAEL OREY, *ASSUMING THE RISK* 49 (1999).

²⁰ Master Settlement Agreement 1-2, 44-45 (1998), *available at* <http://www.naag.org/backpages/naag/tobacco/msa/msa-pdf/>.

agreement) wounded the tobacco industry's reputation, it permitted the industry to continue operating and it provided a measure of immunity from state-initiated lawsuits. It also provided some amount of protection from private lawsuits, as the industry was later able to argue in court that the MSA had forced it to fully account for its past misdeeds and reform its conduct.²¹

Looking at this history as a whole, the continued existence of tobacco in the marketplace can be seen as a historical accident. As Thomas Merrill has written, "If cigarettes were introduced today, knowing what we know about them as a product, there is little doubt that they would be banned."²² (This is in contrast to other public health concerns such as firearms and alcohol, where the risk/benefit trade-off has been more or less apparent for centuries.) However, because the cigarette became so deeply engrained in American society before its dangers were acknowledged—and because roughly 45 million Americans remain addicted to cigarettes—prohibition is not seen as an attractive or realistic policy option.²³ Thus, tobacco remains a legal product, but one that poses unique challenges for the courts and public health regulators because of its entrenchment in society and the massive number of people addicted to this highly dangerous product.

B. *Volume of Litigation*

Both the scope of the devastation caused by tobacco products and the profitability of the industry made it a uniquely appealing target for plaintiffs' attorneys. In addition, the fact that tobacco products, despite their enormous death

²¹ See, e.g., *Brown & Williamson Tobacco Corp. v. Gault*, 627 S.E.2d 549, 550-51, 553-54 (Ga. 2006) (holding that private plaintiffs could not seek punitive damages from Brown & Williamson because the MSA had vindicated the state's interest in punishing the tobacco companies). Provisions which would have explicitly limited the tobacco companies' liability were included in earlier versions of the agreement, but not the final draft of the MSA.

²² Thomas W. Merrill, *The Constitution and the Cathedral: Prohibiting, Purchasing, and Possibly Condemning Tobacco Advertising*, 93 NW. U. L. REV. 1143, 1203 (1999).

²³ See, e.g., Jonathan Turley, *A Crisis of Faith: Tobacco and the Madisonian Democracy*, 37 HARV. J. ON LEGIS. 433, 435 (2000) ("While various contemporary leaders . . . have denounced tobacco as a leading killer of Americans, there has been no call from the White House or Congress to ban the product."). For an argument in favor of gradually phasing out cigarettes, see Richard A. Daynard, *Doing the Unthinkable (and Saving Millions of Lives)*, 18 TOBACCO CONTROL 2 (2009).

toll, were uniquely unregulated, led public health advocates to turn to the courts as an alternative channel through which to impose limits on the industry.²⁴ In some cases, the goal was compensation for injured clients, while in others, plaintiffs' attorneys sought to use litigation to "get [the tobacco companies] out of business."²⁵

These efforts by plaintiffs' attorneys confronted a "scorched earth" litigation strategy by the tobacco industry that was "unique in the annals of tort litigation."²⁶ As Sara Guardino and Richard Daynard write, "The industry's success in the litigation [was] primarily because at the outset a decision was made to fight the lawsuits all out, never considering settlement in even the smallest sum."²⁷ This strategy set the industry apart from most other defendants:

[I]n mass tort litigation—that is, litigation involving a huge number of claims arising out of a single hazardous course of conduct or event, such as the asbestos, Dalkon Shield, and DES cases—there has always come a point when the beleaguered defense has decided that at least some of the persistently arising claims are worth settling. By contrast, over a period of thirty-five years, the tobacco industry never offered to settle a single case.²⁸

The collision of aggressive litigation against the tobacco industry and the no-compromise strategy adopted by the defendants has meant that more smoking-related cases have been (and will continue to be) brought to trial, in comparison to cases dealing with other public health concerns. This is especially true given the length of time that cigarettes have been on the market and the millions of Americans with potential legal claims. Compare, for example, the recent litigation over Merck's pain reliever Vioxx. When it became clear that there was a connection between Vioxx use and heart attacks, Merck was hit with a flood of thousands of lawsuits. After litigating fewer than twenty cases to trial, Merck agreed

²⁴ See BRANDT, *supra* note 2, at 439 ("Attempts to regulate the tobacco industry had usually—when they yielded any results at all—ended in legislation that protected the industry from regulation. The resort to litigation grew out of these long-standing failures of political and regulatory efforts.")

²⁵ See, e.g., *CBS This Morning: Florida Lawyer Launches Attack on Several Major Tobacco Companies* (CBS television broadcast Aug. 26, 1996) (interviewing plaintiffs' attorney Stanley Rosenblatt).

²⁶ Rabin, *Sociolegal History*, *supra* note 15, at 857.

²⁷ Sara D. Guardino & Richard Daynard, *Punishing Tobacco Industry Misconduct: The Case for Exceeding a Single Digit Ratio Between Punitive and Compensatory Damages*, 67 U. PITT. L. REV. 1, 39 (2005).

²⁸ Rabin, *Sociolegal History*, *supra* note 15, at 857-58.

to a massive \$4.85 billion settlement that resolved more than 26,000 claims at once.²⁹ As Merck no longer sells Vioxx, having withdrawn it from the market in 2004,³⁰ the settlement seems to have effectively ended litigation over the drug. The decision to settle was thus a logical business calculation, despite the existence of viable defenses. By contrast, Cliff Douglas et al. report that at least seventy-five smoking-related cases were tried to a verdict between 1995 and 2005, while nearly 3000 individual actions are still pending.³¹ Since cigarettes, unlike Vioxx, remain on the market, and since there are literally millions of plaintiffs who could have similar claims, the tobacco companies are strongly predisposed against settling or conceding liability in any of these cases (which is, similarly, a logical business decision). The trajectory of the Vioxx litigation—a short-term outburst of cases followed by settlement of most claims—appears to be the more common pattern for public-health related claims. Yet it is the steady flow of tobacco-related cases that continues to produce more trials, more appeals, and ultimately more case law.³²

This high volume of litigation is a direct result of the uniqueness of tobacco as a product. Whereas other dangerous products have been either banned by regulators (lead paint, DDT, thalidomide) or litigated out of business (asbestos),

²⁹ Vioxx Settlement Agreement 1-2 (2007), *available at* http://www.merck.com/newsroom/vioxx/pdf/Settlement_Agreement.pdf; Press Release, Merck & Co., Inc., Merck Agreement to Resolve U.S. VIOXX Product Liability Lawsuits (Nov. 9, 2007), *available at* http://www.merck.com/newsroom/press_releases/corporate/2007_1109_print.html.

³⁰ Marc Kaufman, *Merck Withdraws Arthritis Medication*, WASH. POST., Oct. 1, 2004, at A1.

³¹ Clifford E. Douglas et al., *Epidemiology of the Third Wave of Tobacco Litigation in the United States, 1994-2005*, 15 TOBACCO CONTROL (Supp. IV) iv9, iv11-12 (2006). Thousands more individual cases have since been filed in Florida, following the decertification of the *Engle v. Liggett Group, Inc.* class action. Stephen Hudak, *Smokers Crowd Court to Sue Big Tobacco*, ORLANDO SENTINEL, Jan. 11, 2008, at A1 (citing projections that as many as 10,000 individuals may file individual lawsuits). In *Engle*, the Florida Supreme Court decertified a massive smoking-related class action following a jury verdict for the plaintiff class. *Engle v. Liggett Group, Inc.*, 945 So. 2d 1256, 1268 (Fla. 2006); *see also infra* text accompanying note 194. In decertifying the class, the Florida Supreme Court held that factual findings made by the *Engle* jury would be given res judicata effect in future individual lawsuits. *Engle*, 945 So. 2d at 1269.

³² The tobacco industry's pattern of appealing each adverse verdict until it receives a more favorable ruling has resulted in more precedential law being established in the context of tobacco claims, with the vast majority of these cases leaning in industry's direction. Douglas et al. found that that of the thirty-one jury verdicts that plaintiffs won in litigation against tobacco companies between 1995 and 2005, all of them were appealed. In only three cases was the initial jury verdict upheld and the defendant ordered to pay the plaintiff. Douglas, *supra* note 31, at iv12 tbl. 2.

tobacco remains on the market despite its status as the leading cause of preventable death. With some dangerous products, such as firearms, Congress has made the policy decision to prohibit most litigation against the industry.³³ But with Congress unwilling to either ban tobacco litigation or ban the product, the steady drumbeat of tobacco litigation is set to continue indefinitely.³⁴

C. *Cultural & Economic Significance*

Although cultural and economic pressures frame the background in all legal proceedings, these pressures have been particularly acute in the case of tobacco litigation. At the time the first medical studies linking smoking to cancer emerged in the mid-1950s, “cigarette smoking rivaled baseball as America’s national pastime.”³⁵ “The cigarette was a cultural icon in Western society—tobacco smoking was viewed as chic, promoted ubiquitously, and portrayed by sports and movie stars as an accoutrement of the good life.”³⁶ Although the allure of smoking gradually declined as the health effects of smoking were revealed, the industry has worked hard to maintain the cigarette’s status as a cultural icon, spending more than \$15 billion a year in advertising in the U.S. alone.³⁷

Perhaps due in part to this unique history, tobacco litigation has sparked intense debate—both inside and outside the courtroom—about the role of government in regulating individual conduct. Tobacco lawsuits have become the stage for

³³ See, e.g., Protection of Lawful Commerce in Arms Act, 15 U.S.C. §§ 7901-7903 (2006) (prohibiting, with limited exceptions, “a civil action or proceeding or an administrative proceeding brought by any person against a manufacturer or seller of [firearms or ammunition], or a trade association, for damages, punitive damages, injunctive or declaratory relief, abatement, restitution, fines, or penalties, or other relief, resulting from the criminal or unlawful misuse of a [firearm or ammunition] by the person or a third party”).

³⁴ It has yet to be seen whether Congress’s recent enactment of the Family Smoking Prevention and Tobacco Control Act will at all alter this dynamic. The law does not ban tobacco products, see *supra* note 11, nor does it bar further litigation against the tobacco industry. See, e.g., H.R. 1256, 111th Cong. § 916(b) (2009) (“No provision of this chapter relating to a tobacco product shall be construed to modify or otherwise affect any action or the liability of any person under the product liability law of any State.”).

³⁵ Robert A. Kagan & William P. Nelson, *The Politics of Tobacco Regulation in the United States*, in REGULATING TOBACCO 11, 11 (Robert L. Rabin & Stephen D. Sugarman eds., 2001).

³⁶ Lawrence O. Gostin, *Global Regulatory Strategies for Tobacco Control*, 298 J. AM. MED. ASSN. 2057, 2057 (2007).

³⁷ JUDITH MACKAY ET AL., THE TOBACCO ATLAS 60 (2d ed. 2006).

“morality play[s], with judges and juries responsible for scripting which party is most deserving of blame.”³⁸ The tobacco industry has worked to “reframe[] tobacco from a public health problem to an issue of individual choice . . . tap[ping] into American ideals of individual freedom, and in turn portray[ing] public health advocates as extremists who support government intrusion into private decision making.”³⁹ These efforts have made tobacco litigation a socially contentious issue, as much about preserving “free choice and personal responsibility” as about the industry’s misconduct.⁴⁰

Although issues of personal choice and individual responsibility are central to many public health threats (drug addiction, sexually transmitted disease, etc.), only tobacco litigation has seen this subject intensely litigated in the courtroom.⁴¹ Some have suggested that food-related litigation, which clearly implicates the issue of personal responsibility, is “the next tobacco.”⁴² Obesity-related lawsuits, however, face numerous challenges and thus far have not been legally significant.⁴³

Economic pressures are also a significant—though somewhat less unique—feature of tobacco litigation. In *Barbarians at the Gate*, Warren Buffet was quoted as saying, “I’ll tell you why I like the cigarette business It costs a penny to make. Sell it for a dollar. It’s addictive. And there’s

³⁸ Richard L. Cupp, Jr., *A Morality Play’s Third Act: Revisiting Addiction, Fraud and Consumer Choice in “Third Wave” Tobacco Litigation*, 46 U. KAN. L. REV. 465, 465 (1998).

³⁹ P.A. McDaniel & R.E. Malone, *Understanding Philip Morris’s Pursuit of U.S. Government Regulation of Tobacco*, 14 TOBACCO CONTROL 193, 197 (2005). For a recent example, see Lorillard Tobacco Company’s efforts to prevent Congress from regulating menthol cigarettes. Menthol Choice, <http://www.mentholchoice.com/> (last visited Sept. 21, 2009) (“Freedom of choice isn’t a privilege. It’s a right. But unless you speak up, you may not have the right to choose menthol cigarettes for much longer. Legislators are being pushed by some self-appointed activists to ban all menthol cigarettes. . . . Speak now . . . [o]r run the risk of starting a trend that may end up with all of us having fewer rights to choose.”).

⁴⁰ See Kagan & Nelson, *supra* note 35, at 32 (“By appealing to values of free choice and personal responsibility, the tobacco industry has been largely able to deflect potentially devastating lawsuits and perhaps helped dampen public support for higher taxes.”).

⁴¹ In illegal drug cases, for example, there is no legal industry that can be sued.

⁴² See, e.g., Roger Parloff, *Is Fat the Next Tobacco?*, FORTUNE, Feb. 3, 2003, at 50.

⁴³ See Kyle Graham, *Why Torts Die*, 35 FLA. ST. U. L. REV. 359, 404 (2008) (“No plaintiff has ever prevailed at trial on an obesity claim alleging common law fraud or negligence, and it is uncertain whether anyone ever will in light of the problems of pleading and proof attendant to a suit pursued under those theories.”). For example, although causation can be a significant hurdle in tobacco cases, causation would be far more complex—if not impossible—to establish in an obesity-focused lawsuit.

fantastic brand loyalty.”⁴⁴ Although taxes and inflation have increased the price of cigarettes, that fundamental equation remains true. Despite having to pay billions in settlement payments to the states, the major tobacco companies remain extremely profitable. Altria (the parent company of Philip Morris) is by far the largest U.S. tobacco company, with \$70 billion in revenue and nearly \$10 billion in profits in 2007.⁴⁵ Other companies like R.J. Reynolds and Lorillard, though much smaller, are still multi-billion dollar businesses and substantial employers.⁴⁶ As tobacco companies are such an integral part of corporate America, both courts and legislatures have at times expressed their concerns that curtailing or eliminating the tobacco industry could have destabilizing effects on the entire national economy.⁴⁷

The cultural and economic prominence of tobacco has loomed over tobacco litigation, leading many judges to assume that any decision adverse to the tobacco industry defendant may have severe cultural and economic ramifications. Consequently, the safe, risk-averse path is the one that protects the industry from liability. For example, in *FDA v. Brown & Williamson* the Supreme Court referenced both tobacco’s “unique place in American history and society” and its status as a “significant portion of the American economy” in concluding that the Food and Drug Administration did not have the authority to regulate tobacco.⁴⁸ The Court repeatedly emphasized that tobacco is not just another product; it is a product of unparalleled cultural and economic significance.

These factors—the pervasiveness of tobacco in society, the sheer volume of tobacco litigation, and the cultural and

⁴⁴ BRYAN BURROUGH & JOHN HELYAR, *BARBARIANS AT THE GATE: THE FALL OF RJR NABISCO* 218 (1990) (internal quotation marks omitted).

⁴⁵ John Reid Blackwell, *Altria Moves Headquarters from N.Y. to Va. Today: Shift to Henrico Helps Area Keep Fortune 500/1000 Presence Here on an Even Keel*, RICHMOND TIMES-DISPATCH, Mar. 31, 2008, at A1; see also *The Fortune 500’s Biggest Winners: 15. Altria Group*, FORTUNE, http://money.cnn.com/galleries/2008/fortune/0804/gallery.most_profitable.fortune/15.html (last visited Sept. 27, 2009).

⁴⁶ See CNNMoney.com, Lorillard Inc. Company Profile, <http://money.cnn.com/quote/snapshot/snapshot.html?symb=LO> (last visited Sept. 21, 2009); CNNMoney.com, Reynolds American Inc. Company Profile, <http://money.cnn.com/quote/snapshot/snapshot.html?symb=RAI> (last visited Sept. 21, 2009).

⁴⁷ See *infra* note 77 and accompanying text; see also Yussuf Saloojee & Elif Dagli, *Tobacco Industry Tactics for Resisting Public Policy on Health*, 78 BULL. WORLD HEALTH ORG. 902, 905 (2000) (quoting a Philip Morris executive as stating that “[e]conomic contribution arguments form the cornerstone of tobacco industry public affairs”).

⁴⁸ *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 159 (2000).

economic significance of the industry—may explain why tobacco cases have seemingly diverged from prior case law.⁴⁹ Moreover, the intensity with which tobacco cases have been litigated helps account for why tobacco cases have been so influential in the subsequent development of public health law.

The following sections explore these developments, focusing on (1) the creation of new doctrine in the context of tobacco cases, and (2) the subsequent impact of these decisions on public health law doctrine. While the “exceptionalism” of tobacco has not been the sole factor causing these various areas of public health law to evolve, it is clearly significant that tobacco cases have played a prominent and consistent role in the development of several different doctrinal fields of public health law.

II. TOBACCO LITIGATION AND REGULATORY AUTHORITY

Much of public health law is administrative law. At the federal level, an alphabet soup of regulatory agencies and cabinet departments—the FDA, CDC, OSHA, EPA, USDA—have the primary responsibility for ensuring that we have safe workplaces, healthy (or at least nontoxic) food, rigorously-tested pharmaceuticals, and coordinated responses to chronic and infectious diseases. At the state level, local and state health departments do the day-to-day work of enforcing food and sanitation codes, conducting safety inspections, controlling infectious diseases, and, in many cases, providing preventive health services.

At both the federal and the state level, regulatory agencies derive their powers from the legislature, and their authority is limited by statute.⁵⁰ Delegations of power relating to public health, however, have tended to be quite broad and liberally construed.⁵¹ For example, the Massachusetts General

⁴⁹ This is not intended to be an exhaustive list; there may be other factors that account for the unique manner in which tobacco has received in the courts. For example, at the state court level, an additional factor may be campaign contributions by the tobacco companies to elected judges. *See, e.g.*, Kevin McDermott, *Donations Complicate Philip Morris Tobacco Suit*, ST. LOUIS POST-DISPATCH, Dec. 18, 2005, at D1.

⁵⁰ Peter D. Jacobson & Richard E. Hoffman, *Regulating Public Health: Principles and Applications of Administrative Law*, in LAW IN PUBLIC HEALTH PRACTICE 23, 25 (Richard A. Goodman et al. eds., 2002).

⁵¹ *See, e.g.*, *Columbia v. Bd. of Health & Env'tl. Control*, 355 S.E.2d 536, 538 (S.C. 1987) (“The delegation of authority to an administrative agency is construed

Laws provide that “[b]oards of health may make reasonable health regulations,”⁵² and this expansive provision has been interpreted to mean that “boards of health [have] plenary power to issue reasonable, general health regulations.”⁵³ Similarly, at the federal level, the Supreme Court has recognized that the FDA “has been delegated broad discretion by Congress in any number of areas” relating to the regulation of food and drugs.⁵⁴ Such broad delegations of power are deemed necessary because public health authorities may be called upon to respond to “unanticipated and rapidly emerging needs and threats.”⁵⁵

Indeed, because of changes in science, medicine, and society, the major public health concerns of today bear little resemblance to the primary public health concerns of a century ago. Broad delegations of power have allowed public health authorities to refocus their missions to address new and unexpected public health needs. The Massachusetts statute quoted above has remained more or less unchanged since 1816, despite the fact that the 1816 legislature could not possibly have imagined the issues boards of health confront today—West Nile Virus, lead paint exposure, childhood obesity, bioterrorism preparedness, and others.

In the 1990s, however, when the FDA and state regulatory agencies attempted to use their broadly-worded regulatory authority to address tobacco-related harms, the tobacco industry fought back in court. The resulting decisions set new precedents that undermined the ability of regulators to respond to emerging public health threats.

In *FDA v. Brown & Williamson*, the Supreme Court blocked the Food and Drug Administration (FDA) from exerting regulatory authority over the tobacco industry, and in the process restricted the amount of deference provided to public health authorities.⁵⁶ In that case, the Court developed new rules for statutory interpretation that gave future courts greater flexibility to strike down public health regulations in

liberally when the agency is concerned with the protection of the health and welfare of the public.”); *see also* 39 AM. JUR. 2D, *Health* § 39, n.81 (2008) (collecting cases).

⁵² MASS. GEN. LAWS ch. 111, § 31 (2008).

⁵³ *Tri-Nel Mgmt. v. Bd. of Health*, 741 N.E.2d 37, 42 (Mass. 2001).

⁵⁴ *See Young v. Cmty. Nutrition Inst.*, 476 U.S. 974, 981 (1986).

⁵⁵ Sara Rosenbaum et al., *New Models for Prevention Systems: Public Health Emergencies and the Public Health/Managed Care Challenge*, 30 J. L. MED. & ETHICS 63, 64 (2002).

⁵⁶ 529 U.S. 120 (2000).

non-tobacco settings. In particular, the Court collapsed the two-part *Chevron* test into one step by using the statute's "context" to conclude that the statute in question did not contain any ambiguity.⁵⁷ By addressing the issue this way, the Court was able to circumvent *Chevron*'s far more deferential second step. Although the Supreme Court's decision was likely driven by the cultural and economic importance of tobacco, this legal mechanism developed in *Brown & Williamson* was later used to strike down public health regulations in other fields.

A. FDA v. Brown & Williamson

In 1996, the FDA, for the first time in its history, promulgated rules "concerning tobacco products' promotion, labeling, and accessibility to children and adolescents."⁵⁸ The FDA based this departure from previous practice—the FDA had previously stated that it lacked authority to regulate tobacco products⁵⁹—on new revelations that the tobacco companies were fully aware of the addictive properties of nicotine and had in fact manipulated nicotine levels in tobacco products in order to create and sustain addiction.⁶⁰ The text of the Food, Drug, and Cosmetic Act (FDCA) provided the FDA with broad authority to regulate "drugs" and "devices" that were "intended to affect the structure or any function of the body."⁶¹ Following a year-long investigation, the FDA concluded that nicotine was a "drug" and that cigarettes and smokeless tobacco products were "drug delivery devices" subject to the FDA's jurisdiction.⁶² Several tobacco companies immediately filed suit in the U.S. District Court for the Middle District of North Carolina.

Given the plain language of the statute and the FDA's extensive investigative work, it appeared the FDA had a strong argument.⁶³ Its position was seemingly bolstered by the

⁵⁷ See *infra* notes 68-75 and accompanying text.

⁵⁸ *Brown & Williamson*, 529 U.S. at 128.

⁵⁹ *Id.* at 146-56 (quoting various statements from FDA officials that the FDA lacked authority to regulate tobacco products).

⁶⁰ See William B. Schultz, *The FDA's Decision to Regulate Tobacco Products*, 18 PACE L. REV. 27, 28-34 (1997).

⁶¹ *Brown & Williamson*, 529 U.S. at 126 (quoting 21 U.S.C. § 321(g)-(h) (1994) (internal quotation marks omitted)).

⁶² See generally DAVID KESSLER, A QUESTION OF INTENT (2001) (discussing the FDA's decision to assert authority to regulate tobacco products).

⁶³ See Cass R. Sunstein, *Is Tobacco a Drug? Administrative Agencies as Common Law Courts*, 47 DUKE L.J. 1013, 1028 (1998) ("[T]he natural reading of the

Chevron doctrine that the Supreme Court used (and still uses) to analyze an administrative agency's construction of its authorizing statute.⁶⁴ Pursuant to the *Chevron* doctrine, if Congress has "directly spoken to the precise question at issue," the agency must "give effect to the unambiguously expressed intent of Congress."⁶⁵ However, "if the statute is silent or ambiguous with respect to the specific issue, the question for the court is whether the agency's answer is based on a permissible construction of the statute."⁶⁶ This doctrine—also known as "*Chevron* deference"—was intended to give administrative agencies wide latitude in interpreting enabling statutes. The Court was clear in *Chevron* that "a court may not substitute its own construction of a statutory provision for a reasonable interpretation made by the administrator of an agency."⁶⁷

Despite the plain language of the statute and the *Chevron* doctrine's deference towards agency rulemaking, the Court concluded in a 5-4 ruling that the FDA lacked authority to regulate tobacco products.⁶⁸ Although the statute said nothing explicitly about whether tobacco could be characterized as a "drug delivery device" (in contrast to numerous other federal statutes that expressly exempted tobacco products from their scope), the Court nonetheless found that Congress had "directly spoken" to the issue and precluded FDA regulation.⁶⁹

Instead of reviewing whether the statute was "ambiguous" and, if so, whether the FDA's construction of the statute was "permissible," the Court collapsed these two steps into one and conducted its own investigation into the "contextual" meaning of the FDCA's terms. It first reviewed the structure of the FDCA and concluded that "if tobacco products were 'devices' under the FDCA, the FDA would be required to remove them from the market."⁷⁰ While perhaps a plausible

text appears to be strongly supportive of the FDA. It suggests not ambiguity but a relatively clear understanding like that of the current FDA.").

⁶⁴ See *Chevron U.S.A. Inc. v. Natural Res. Def. Council, Inc.* 467 U.S. 837, 842-44 (1984).

⁶⁵ *Id.* at 842-43.

⁶⁶ *Id.* at 843.

⁶⁷ *Id.* at 844. The *Chevron* test "appears to call for a large degree of judicial deference to agency interpretations." Thomas J. Miles & Cass R. Sunstein, *Do Judges Make Regulatory Policy? An Empirical Investigation of Chevron*, 73 U. CHI. L. REV. 823, 824 (2006).

⁶⁸ *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 133 (2000).

⁶⁹ *Id.* at 160-61.

⁷⁰ *Id.* at 135.

reading of the FDCA, the FDA had considered and rejected this interpretation of the FDCA during its rulemaking process. It had instead concluded that “the record does not establish that . . . a ban is the appropriate public health response under the [FDCA]” and that the FDCA allowed the agency to adopt regulatory restrictions short of an outright ban.⁷¹ Rather than view this provision of the statute as ambiguous and then consider whether the FDA’s interpretation of the statute was reasonable, the Court substituted its own interpretation of the statute for the FDA’s.⁷²

Although the FDA had not attempted to ban tobacco products, the Court then used its first conclusion (if the FDA had authority to regulate tobacco products, it would have to remove them from the market) as the starting point for its subsequent analysis. It then concluded that because Congress had made several statements in other statutes implicitly suggesting that tobacco products would remain available for sale, it could not have intended for the FDA to ban tobacco products. Thus, Congress had “spoken directly to the FDA’s authority to regulate tobacco” and denied it such authority.⁷³

Contextual clues—in this case, subsequent congressional actions regarding tobacco—would surely have been relevant for determining whether the FDA’s application of the FDCA was “reasonable.” The Court, however, used its questionable analysis of the statute’s context in order to conclude that the statute itself was unambiguous with respect to the FDA’s authority to regulate tobacco. In essence, it read the patent ambiguity out of the statute instead of deferentially reviewing whether the FDA’s application of the statute was “reasonable.”⁷⁴ Rather than employing the two-step *Chevron* test, the Court collapsed the *Chevron* analysis into a one-step

⁷¹ *Id.* at 139.

⁷² For a forceful argument that the FDCA did permit the FDA to take remedial action short of a complete ban of cigarettes, see *id.* at 174-81 (Breyer, J., dissenting).

⁷³ *Id.* at 143-44 (majority opinion).

⁷⁴ Beyond the Court’s problematic restructuring of the *Chevron* test, its decision ran contrary to the general scheme of public health law, which typically provides regulatory agencies with broad authority to address new public health threats. Writing in a different administrative law context, Justice Stevens wrote that the Court should be particularly deferential to agency interpretations “in a statutory regime so obviously meant to maximize administrative flexibility.” *MCI Telecom. Corp. v. AT&T Co.*, 512 U.S. 218, 244 (1994) (Stevens, J., dissenting).

“contextual” reading that allowed it to avoid a more deferential review of the agency’s action.⁷⁵

The Court’s sleight of hand was legally questionable, but it seems to have reflected the majority’s point of view that tobacco products were simply *different*. It is hardly unusual for regulatory agencies to assert jurisdiction over new products or activities when new facts warrant it, and prior to *Brown & Williamson* those extensions of regulatory oversight were generally upheld. For example, consider Cass Sunstein’s discussion of the regulation of DDT:

[I]t is generally agreed that the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizes the EPA to regulate DDT as a product raising “a substantial question” of human safety, but that this authority does not rest on a judgment that the Congress that enacted FIFRA believed that the EPA could regulate DDT. On the contrary, when introduced, DDT was thought to be unproblematic and entirely safe, and hence the enacting Congress did not contemplate that FIFRA would authorize EPA regulation of DDT. The EPA nevertheless possesses just such authority. Statutes regulating health and safety quite routinely contain broad language authorizing agencies to regulate articles or substances if the statutory criteria are met. Whether Congress believed that the statutory criteria were met when it enacted the relevant legislation is beside the point unless Congress embodied that belief in law.⁷⁶

In *Brown & Williamson*, however, the majority went out of its way to emphasize the uniqueness of tobacco. It wrote:

This is hardly an ordinary case. Contrary to its representations to Congress since 1914, the FDA has now asserted jurisdiction to regulate an industry constituting a significant portion of the American economy Owing to its unique place in American

⁷⁵ Matthew Stephenson and Adrian Vermeule argue that *Chevron’s* inquiry is really only one step and that the distinction between the two steps has always been artificial. See Matthew Stephenson & Adrian Vermeule, *Chevron Has Only One Step*, 95 VA. L. REV. 597, 597 (2009). They claim that “[t]he single question is whether the agency’s construction is permissible as a matter of statutory interpretation.” *Id.* at 599. Thus, while *Brown & Williamson* was decided under Step One, they write that “[i]t would have been equally easy . . . for the Court to find under Step One that the full scope of the FDA’s statutory jurisdiction is ambiguous . . . but to declare that the FDA’s assertion of jurisdiction over tobacco products was unreasonable under *Chevron* Step Two.” *Id.* at 599-600. In my view, this analysis misses the mark. While the question asked under the two steps may be similar, the deference with which the question is approached is not. If the Court construes the statute to have a narrow meaning under Step One, it need not provide deference to the agency’s interpretation. In *Brown & Williamson*, had the Court conceded that there was ambiguity in the statute, it would have been nearly impossibly to find that the FDA was not “reasonable” in concluding that tobacco met the statutory definition. That is why the Court labored so hard to force its analysis into Step One.

⁷⁶ Sunstein, *supra* note 63, at 1030-31.

history and society, tobacco has its own unique political history [W]e are confident that Congress could not have intended to delegate a decision of such economic and political significance to an agency in so cryptic a fashion.⁷⁷

Perhaps driven by the political salience of the tobacco issue, the *Brown & Williamson* case also caused several justices to depart from their typical approach to administrative cases. The Court's most ardent textualists—Justice Scalia and Justice Thomas—joined an opinion that avoided addressing the plain meaning of the text and instead looked carefully at post-enactment Congressional actions.⁷⁸ Meanwhile, the majority opinion made a point of noting that Justice Breyer—author of the dissenting opinion—had previously written a law review article suggesting that judges should be more hesitant to find a broad delegation of authority to an administrative agency when “the legal question is an important one.”⁷⁹

The majority was of course correct that tobacco presented a unique case. As discussed above, tobacco has certainly had its own “political history” and a powerful influence on American society.⁸⁰ The majority clearly felt that tobacco regulation was not just a new application of broad regulatory authority, but instead that tobacco (even if it were to be considered a “drug delivery device”) was somehow different, deserving of an implied exception to the statute's broad language.

The majority's conclusion can also be seen as an example of inter-branch communication that addressed unstated political tensions. According to Jonathan Turley, the Court's decision is better read as a response to the FDA's attempt to circumvent Congress. Turley writes:

⁷⁷ *Brown & Williamson*, 529 U.S. at 159-60. As detailed in the Court's decision, previous FDA commissioners had expressed the view that the FDA did not have the authority to regulate tobacco. *Id.* at 145. The FDA, led by Commissioner David Kessler, changed its position after its investigation indicated that the tobacco companies were aware of nicotine's addictive properties and had engineered their tobacco products in order to create and maintain addiction. Previous FDA commissioners had not been aware of such facts. See KESSLER, *supra* note 62, at 381 (“[The Supreme Court justices] were unable to recognize how much had changed, how much more we understood, not only about the effects of nicotine, but about the extent of the industry's knowledge. We finally had evidence of intent.”).

⁷⁸ See John F. Manning, *The Nondelegation Doctrine as a Canon of Avoidance*, 2000 SUP. CT. REV. 223, 226 (2000).

⁷⁹ *Brown & Williamson*, 529 U.S. at 159 (quoting Stephen Breyer, *Judicial Review of Questions of Law and Policy*, 38 ADMIN. L. REV. 363, 370 (1986) (internal quotation marks omitted)).

⁸⁰ See *supra* Part I.C.

The circumvention of Congress in the FDA case was open and notorious. Not only did the FDA break from its long-held position that it lacked the authority to regulate tobacco, but prior to seeking this authority through the courts, the Clinton administration was rebuffed in an attempt to secure a legislative mandate.⁸¹

In this view, the Court was trying to strike down an end-run around Congress and simply restore tobacco regulation to the *status quo ante*. Since this reasoning was not made explicit, however, the Court's facially neutral application of the *Chevron* test—which Turley characterizes as “a strikingly contextual view”⁸²—was established as precedent for future plaintiffs to utilize in challenging other regulatory actions.⁸³

B. Subsequent Applications of Chevron and FDA v. Brown & Williamson

Even without the tobacco-focused *Brown & Williamson* decision, perhaps the Supreme Court would have moved towards a less deferential application of the *Chevron* test in any event. Other notable decisions preceding *Brown & Williamson*—in particular, *MCI Telecommunications Corp. v. AT&T*⁸⁴—have been similarly described as “discretion-denying” decisions that evaded the requirements of *Chevron*.⁸⁵ Moreover, later cases that did not cite or reference *Brown & Williamson* also imposed further limitations on the reach of *Chevron* deference.⁸⁶ In general, this long-term effort by the Court to undermine or limit *Chevron* deference has been attributed to

⁸¹ Turley, *supra* note 23, at 457.

⁸² *Id.* at 456.

⁸³ As previously noted, nine years after the *Brown & Williamson* decision, the U.S. Congress did grant the FDA limited regulatory authority over the tobacco industry. *See supra* note 11. Congress's decision to belatedly revisit the issue does nothing to limit the ability of future litigants to use *Brown & Williamson* as a precedent when seeking to strike down administrative actions.

⁸⁴ 512 U.S. 218 (1994).

⁸⁵ Cass R. Sunstein, *Chevron Step Zero*, 92 VA. L. REV. 187, 243, 244 (2006). In *MCI*, the Supreme Court held that the FCC had exceeded its authority in ruling that long-distance carriers other than AT&T would no longer have to file their rates with the FCC. 521 U.S. at 218; *see also* Thomas W. Merrill, *Judicial Deference to Executive Precedent*, 101 YALE L.J. 969, 970 (1992) (“[I]n recent Terms the application of *Chevron* has resulted in *less* deference to executive interpretations than was the case in the pre-*Chevron* era. Thus, instead of functioning as a ‘counter-*Marbury*,’ there are signs that *Chevron* is being transformed by the Court into a new judicial mandate ‘to say what the law is.’”).

⁸⁶ *See, e.g.*, *United States v. Mead Corp.*, 533 U.S. 218 (2001) (suggesting that less formal administrative rulemaking processes were not entitled to full *Chevron* deference).

the Court's desire to assert its own authority and retain some oversight over administrative decisions, a desire obviously in tension with the dictates of *Chevron*.⁸⁷ One could read *Brown & Williamson* as one example among many of the Court asserting its right to restrict agency discretion, and thus its uniqueness should not be overstated. Nonetheless, subsequent applications of the precedent established in *Brown & Williamson* show that the case was particularly influential in the field of public health, where, as discussed above, a significant degree of agency flexibility is needed to protect against emerging public health threats.⁸⁸

1. *Nutritional Health Alliance v. FDA* (2003)

It did not take long for the ruling of *Brown & Williamson* to start impacting public health cases outside the tobacco control arena. Even before *Brown & Williamson* was decided, a group of diet supplement manufacturers filed a lawsuit challenging the FDA's regulatory authority in another area.⁸⁹ To deal with the problem of iron poisoning—a leading cause of death among young children—the FDA had issued regulations requiring dietary supplements containing high doses of iron to be distributed in unit-dose packages.⁹⁰ In

⁸⁷ See, e.g., Merrill, *supra* note 85, at 998 (“[*Chevron*] reduc[es] the role of the courts to a point that threatens to undermine the principal constitutional constraint on agency misbehavior. Given these failings, it is small wonder that the Court often seems wary of the *Chevron* doctrine, applying it inconsistently at best.”); Eric R. Womack, *Into the Third Era of Administrative Law: An Empirical Study of the Supreme Court’s Retreat from Chevron Principles in United States v. Mead*, 107 DICK. L. REV. 289, 291 (2002) (“[T]he Supreme Court has chosen to limit the scope of *Chevron* and refocus the inquiry into congressional intent in order to limit unprincipled deference and delegation to agencies that can exercise such power without sufficient procedural protections.”); cf. William N. Eskridge, Jr. & Lauren E. Baer, *The Continuum of Deference: Supreme Court Treatment of Agency Statutory Interpretations from Chevron to Hamdan*, 96 GEO. L.J. 1083, 1202 (2008) (suggesting that the Supreme Court applies a “continuum of deference” and is less deferential when agency decisions involve “larger normative concerns”).

⁸⁸ See, e.g., Linda Jellum, *Chevron’s Demise: A Survey of Chevron from Infancy to Senescence*, 59 ADMIN. L. REV. 725, 779-80 (2007) (“In *Chevron*, one of the Court’s rationales for deferring to the agency’s interpretation was that by enacting gaps and creating ambiguities, Congress intended to delegate implicitly to the agency. But in a series of cases, starting with *FDA v. Brown & Williamson Tobacco Corp.*, the Court rejected, or at least limited, this rationale.”); James T. O’Reilly, *Losing Deference in the FDA’s Second Century: Judicial Review, Politics, and a Diminished Legacy of Expertise*, 93 CORNELL L. REV. 939, 976 (2008) (“[*Brown & Williamson*] was a dramatic decision that has had ripple effects on the law of deference to administrative rules.”).

⁸⁹ *Nutritional Health Alliance v. FDA (Nutritional I)*, 2000 U.S. Dist. LEXIS 22330 (E.D.N.Y. Nov. 1, 2000), *rev’d*, 318 F.3d 92 (2d Cir. 2003).

⁹⁰ *Id.* at *3-5.

Nutritional Health Alliance v. FDA, an association of manufacturers challenged the rule, asserting that the FDA had exceeded its authority in promulgating the regulations. They argued that the FDCA did cover issues of poison prevention and that such concerns could only be addressed by the Consumer Products Safety Commission (CPSC).⁹¹

As the case was pending, the Supreme Court issued its decision in *FDA v. Brown & Williamson*, and the plaintiffs immediately brought it to the attention of Judge Sterling Johnson, Jr. Presumably relying on the Supreme Court's statement that *FDA v. Brown & Williamson* was a "unique" case, Judge Johnson wrote that "the nature of the tobacco-specific legislation makes the case inapplicable here," and that he would instead follow the dictates of *Chevron*.⁹² Judge Johnson went on to conclude that the FDA rule was authorized under either prong of the *Chevron* test; by its plain meaning, the FDCA authorized the FDA's exercise of authority, and even assuming *arguendo* that there was some ambiguity in the statute, the FDA's construction of the statute was a permissible one.⁹³

Saying nothing about the uniqueness of tobacco, the Second Circuit relied heavily on the "instructive guidance" from *FDA v. Brown & Williamson* in reversing the district court's opinion.⁹⁴ Using *Brown & Williamson* as precedent, it concluded the language of a statute must be read in light of subsequent congressional action. The court wrote:

Following [*United States v. Estate of*] *Romani* and *Brown & Williamson*, we would not defer to the FDA regarding its interpretation of ambiguous language in the [FDCA] where doing so would allow the FDA to circumvent the detailed regulatory scheme . . . set forth by Congress in the [Poison Prevention Packaging Act (which granted limited authority for poison control to the CPSC)].⁹⁵

As the FDA had argued, however, the Poison Prevention Act did not in any way directly limit the FDA's authority (though Congress certainly could have included such a provision).⁹⁶

⁹¹ *Nutritional Health Alliance v. FDA (Nutritional II)*, 318 F.3d 92, 94 (2d Cir. 2003).

⁹² *Nutritional I*, 2000 U.S. Dist. LEXIS 22330 at *9 n.3.

⁹³ *Id.* at *11-12.

⁹⁴ *Nutritional II*, 318 F.3d at 102.

⁹⁵ *Id.* at 104.

⁹⁶ *Nutritional I*, 2000 U.S. Dist. LEXIS 22330 at *7-8.

Although the court purported to apply step two of the *Chevron* test, it was clear that the Second Circuit was, like the Supreme Court in *Brown & Williamson*, using a “contextual” reading of the FDCA as the basis for substituting its own judgment for that of the FDA.

2. *Supreme Beef Processors* (2000) and *Association of American Physicians and Surgeons, Inc.* (2002)

FDA v. Brown & Williamson has also been used as authority by several district courts that have struck down health-related regulations. In these cases, *FDA v. Brown & Williamson* seems to have tipped the scales, providing these courts with legal support for overturning a regulation where a more deferential posture would have led to the opposite result.

For example, in *Supreme Beef Processors v. United States Department of Agriculture*, the regulation at issue involved the testing of processed beef for salmonella.⁹⁷ Under the relevant statute, the USDA was authorized to bar the sale or transport of meat if “it has been prepared, packed or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health.”⁹⁸ Since salmonella results from unsanitary conditions and is the leading cause of food-borne illness, USDA developed a salmonella test to measure compliance with this provision.⁹⁹ Supreme Beef Processors—which had failed the salmonella test three different times—argued that the USDA had exceeded its authority in testing for salmonella, because the salmonella could have resulted from contaminated beef *entering* the assembly line, and not (or not solely) from unsanitary conditions in the plant itself.¹⁰⁰ The court agreed with this reasoning, concluding that the USDA could not block the sale of Supreme Beef Processor’s meat because “the agency—in effect—never found the *conditions* of Supreme Beef’s plant insanitary”—only the meat itself.¹⁰¹ This exercise in semantic nitpicking, which produced a result quite unsettling to anyone who eats meat, runs contrary to the deferential approach of *Chevron*. The court, however, based its approach

⁹⁷ 113 F. Supp. 2d 1048, 1048 (N.D. Tx. 2000), *aff’d*, 275 F.3d 432 (5th Cir. 2001).

⁹⁸ *Id.* at 1052 (citing 21 U.S.C. § 601(m)(4)).

⁹⁹ *Id.*

¹⁰⁰ *Id.* at 1052-53.

¹⁰¹ *Id.* at 1054 (emphasis added).

on *Brown & Williamson*, quoting its language that “[t]he meaning—or ambiguity—of certain words or phrases may only become evident when placed in context.”¹⁰² Like the Supreme Court in *Brown & Williamson*, the district court then proceeded to read the ambiguity out of the statute by finding a “contextual meaning” (in this case, based on the court’s analysis of the overall structure of the Federal Meat Inspection Act) that limited the USDA’s authority.¹⁰³ Nowhere in the decision was there a mention of the “uniqueness” of tobacco (or, for that matter, any discussion of the facts of *Brown & Williamson*).

In dealing with a somewhat more complex issue, the D.C. District Court in *Association of American Physicians and Surgeons, Inc. v. FDA* struck down an FDA regulation requiring most new pharmaceuticals to be tested for efficacy in pediatric populations.¹⁰⁴ The FDA had claimed authority to act under broad enabling provisions of the FDCA.¹⁰⁵ The plaintiffs, citing a later statute that addressed pediatric testing more specifically (though without directly limiting the broader provisions of the FDCA), argued that the FDA had exceeded its authority.¹⁰⁶ In ruling for the plaintiffs, the court directly rejected the conception that the tobacco issue addressed in *Brown & Williamson* was a unique or unusual case. Instead, the court wrote:

This situation is therefore analogous to the one faced by the Supreme Court in *Brown & Williamson*; the FDA and Congress have both spoken and have taken two different approaches to respond to the same public health issue. *Brown & Williamson* suggests that by enacting a “distinct regulatory scheme” to address a given issue . . . Congress demonstrates its intention to occupy the field, and any attempt by the FDA to intervene with an inconsistent regime shall be deemed in excess of its authority. This militates strongly in favor of concluding that the FDA exceeded its authority when it enacted the [rule requiring pediatric tests].¹⁰⁷

Again, other congressional action in a similar field may have been relevant to whether the FDA’s interpretation of the scope of its authority was “reasonable.” But instead of deferentially

¹⁰² *Id.* at 1051 (alteration in original) (internal quotation marks omitted) (quoting *FDA v. Brown & Williamson*, 529 U.S. 120, 132 (2000)).

¹⁰³ *Id.*

¹⁰⁴ 226 F. Supp. 2d 204, 205 (D.D.C. 2002).

¹⁰⁵ *Id.* at 212-13.

¹⁰⁶ *Id.* at 205, 219.

¹⁰⁷ *Id.* at 219 (citations omitted).

asking whether the FDA had acted reasonably in applying an ambiguous statute, the court avoided the question by ignoring the statute's patent ambiguity and collapsing the *Chevron* analysis into one step. Indeed, the court's analysis—building on *Brown & Williamson*—suggests that anytime Congress has passed a law addressing a public health issue, it has intended to preclude any further regulatory action on the subject. Such a doctrine is a drastic departure from *Chevron's* deferential approach to agency regulations and would severely tie the hands of public health agencies.

In sum, *Brown & Williamson* “embed[s] an unhealthy status quo bias into administrative law,” making agencies wary of using their existing authority to tackle new challenges, even when the broad language of their authorizing statutes could justify such action.¹⁰⁸ This “status quo bias” is particularly dangerous in the field of public health, where the next public health challenge is always an unknown, and agency flexibility is therefore crucial.¹⁰⁹ Ironically, in dealing with the issue of tobacco—a public health challenge with a very long history—the Supreme Court may have weakened the government's ability to adequately prepare for and address future public health challenges. Although the Supreme Court stated in *Brown & Williamson* that tobacco was a “unique case,” the discussion above demonstrates that *Brown & Williamson* was quickly seized upon by those seeking to challenge government regulations in a variety of other contexts.

C. State Analogues

The problem of attempted tobacco regulation leading to new constraints on agency authority is not limited to the federal government. The same dynamic plays out at the state level, and given that state public health authorities are often the first line of defense in dealing with public health challenges and crises, this is potentially even more dangerous.

¹⁰⁸ See Sunstein, *supra* note 85, at 246.

¹⁰⁹ Of course, a deferential posture towards agency decisions can be problematic from a public health perspective if agencies are interpreting their own authorizing statutes narrowly or using their discretion *not* to regulate public health concerns. From a long-term perspective, however, this is less troubling. An agency's decision not to act can be easily reversed (by a subsequent administrator or administration). A Supreme Court ruling explicitly limiting the scope of agency discretion cannot be so easily undone.

Although the legal reasoning has differed from the federal cases, state courts have been similarly reluctant to allow public health entities to apply their broad regulatory authority to the issue of tobacco. In some cases, state courts have relied on the absence of an explicit delegation to strike down tobacco-related regulations, even when the same courts had never insisted on such express delegation in the past.

For example, in *D.A.B.E. v. Toledo-Lucas County*, the Ohio Supreme Court addressed the question of whether a local board of health had the authority to limit smoking in public places.¹¹⁰ As in *Brown & Williamson*, at issue was a novel application of extremely broad statutory authority. In that case, the relevant Ohio law, Ohio Revised Code § 3709.21, stated that “[t]he board of health of a general health district may make such orders and regulations as are necessary for its own government, for the public health, the prevention or restriction of disease, and the prevention, abatement, or suppression of nuisances.”¹¹¹ The plain language seemed to provide authority for the secondhand smoke regulations at issue, particularly since the Surgeon General of the United States had found that “nonsmokers are placed at increased risk for developing disease as the result of exposure to [secondhand] smoke” and that “measures to protect the public health are required now.”¹¹² Nonetheless, the court went out of its way to avoid directly addressing the plain meaning of the text.

Echoing *Brown & Williamson*, the court wrote:

[T]he natural meaning of words is not always conclusive as to the construction of statutes. While it is a long-recognized canon of statutory construction that the words and phrases used by the General Assembly will be construed in their usual, ordinary meaning, that is not so when a contrary intention of the legislature clearly appears. Accordingly and for the following reasons, we find that the General Assembly has not indicated any intent through [Ohio Rev. Code § 3709.21], or otherwise, to vest local boards of health with unlimited authority to adopt regulations addressing all public-health concerns.¹¹³

The court went on to conclude—for the first time in the long history of the statute—that § 3709.21 was “a rules-enabling

¹¹⁰ 773 N.E.2d 536, 539 (Ohio 2002).

¹¹¹ *Id.* at 541.

¹¹² U.S. DEP’T OF HEALTH & HUMAN SERV., THE HEALTH CONSEQUENCES OF INVOLUNTARY SMOKING: A REPORT OF THE SURGEON GENERAL, at xi-xii (1986), available at <http://profiles.nlm.nih.gov/NN/B/C/P/M/> (follow “PDF” hyperlink).

¹¹³ *D.A.B.E.*, 773 N.E.2d at 542 (citations omitted).

statute, not a provision granting substantive regulatory authority.”¹¹⁴ It explained that in order for public health authorities to address a particular public health issue, they would need to point to *another* statute providing explicit authority for such an action, in addition to the general rulemaking powers provided in § 3709.21.¹¹⁵ In order to reach this conclusion, the court had to ignore or reinterpret several Ohio Supreme Court cases that had upheld health authority regulations based solely on the authority provided by § 3709.21 or its predecessor statute.¹¹⁶ Indeed, in previous cases the court had emphasized the need for regulatory flexibility in addressing public health challenges, writing (when referring to the predecessor of § 3709.21): “Where a law relates to a police regulation for the protection of public health, and it is impossible or impractical to provide specific standards, and to do so would defeat the legislative object sought to be accomplished, such law is valid and constitutional without providing such standards.”¹¹⁷

How had the Ohio Supreme Court reached a conclusion that seemed to reject its own precedents? The Court semi-apologetically wrote that “[o]ur disposition of this matter turns on issues of law and not on the deleterious effect of environmental tobacco smoke, more commonly known as secondhand smoke.”¹¹⁸ Nonetheless, it seems virtually certain that the unique political salience of the issue at hand—the regulation of smoking in public places—was the driving force behind the Court’s decision.

As in *Brown & Williamson*, the Court likely viewed the Board of Health’s action as an end run around the legislature on a controversial political issue. In a brief aside, the Court wrote:

Administrative regulations cannot dictate public policy but rather can only develop and administer policy already established by the General Assembly. In promulgating the Clean Indoor Air

¹¹⁴ *Id.* at 547.

¹¹⁵ *Id.* at 547-49.

¹¹⁶ See, e.g., *Johnson’s Markets, Inc. v. New Carlisle Dep’t of Health*, 567 N.E.2d 1018, 1027 (Ohio 1991); *Schlenker v. Bd. of Health*, 167 N.E.2d 920, 922 (Ohio 1960). For a persuasive discussion of this issue reaching the opposite conclusion from the Ohio Supreme Court (though striking down the regulation at issue on other grounds), see *Cookie’s Diner v. Columbus Bd. of Health*, 640 N.E.2d 1231, 1235-37 (Ohio Mun. Ct. 1994).

¹¹⁷ *Weber v. Bd. of Health*, 74 N.E.2d 331, 332 (Ohio 1947).

¹¹⁸ *D.A.B.E.*, 773 N.E.2d at 547.

Regulation, petitioners engaged in policy-making requiring a balancing of social, political, economic, and privacy concerns. Such concerns are legislative in nature, and by engaging in such actions, petitioners have gone beyond administrative rule-making and usurped power delegated to the General Assembly.¹¹⁹

In short, the Court felt that tobacco regulation was a contentious public issue most properly resolved by the legislative branch, and not an unelected Board of Health. Courts rarely view administrative rulemaking as a problem when non-tobacco regulations are at issue, despite the fact that *every* public health regulation is a policy-making exercise “requiring a balancing of social, political, economic, and privacy concerns.”¹²⁰ When tobacco is at issue, however, judges are often sympathetic to the argument that decisions about such a weighty issue—with its powerful historical, social, cultural, and political baggage—cannot be left to public health authorities.¹²¹

Ultimately, the *D.A.B.E.* decision did not derail progress towards smoke-free regulations in Ohio—it merely rechanneled the effort away from health departments and into the political arena. In 2006, Ohio voters passed a ballot measure prohibiting smoking in nearly all indoor public places.¹²² Like *Brown & Williamson*, however, *D.A.B.E.* still stands as a precedent that may hamper regulatory efforts in other areas of public health. In essence, the *D.A.B.E.* holding means that boards of public health in Ohio can only be reactive; they are prohibited from

¹¹⁹ *Id.* at 546 (citations omitted). At the time of this decision, there were some state laws addressing smoking in public places. Unlike *Brown & Williamson*, however, the court did not suggest that these other statutes implicitly limited the authority boards of public health to regulate in this area. *See, e.g.*, OHIO REV. CODE ANN. § 3791.031 (LexisNexis 2009) (providing for nonsmoking sections in various “place[s] of public assembly”).

¹²⁰ *D.A.B.E.*, 773 N.E.2d at 546. For example, food safety regulations—regulations that can be enforced with intrusive inspections—certainly implicate all of these concerns. It would be significantly cheaper to run a restaurant without complying with food safety regulations and the accompanying paperwork requirements. Public health departments, however, must balance economic efficiency against the concern for the health and safety of the diners. Rarely are public health authorities accused of “lawmaking” when they promulgate new food safety regulations. (Such charges have been leveled against health departments that have recently banned trans-fats. To date however, legal challenges to such bans have not succeeded.)

¹²¹ *See, e.g.*, *Boreali v. Axelrod*, 71 N.Y.2d 1, 12, 517 N.E.2d 1350, 1355 (1987) (striking down secondhand smoke regulation promulgated by the New York Public Health Counsel, and writing that “[s]triking the proper balance among health concerns, cost and privacy interests . . . is a uniquely legislative function”).

¹²² The ballot measure is codified at OHIO REV. CODE ANN. §§ 3794.01-09 (West 2009). For general information on the law, see Ohio Dep’t of Health, Smoke-free Workplace Program, <http://www.ohionosmokelaw.gov> (last visited Sept. 21, 2009).

proactively addressing public health threats that have not yet received the sustained public attention needed to produce legislative action.¹²³ The public health implications of such a ruling are impossible to measure, but they will be all too real when public health authorities are unable to address future public health concerns in a timely manner.¹²⁴

III. TOBACCO LITIGATION AND PERSONAL INJURY/PRODUCTS LIABILITY CLAIMS

As discussed in Part I, tobacco litigation has been, in the words of Robert Rabin, “unique in the annals of tort litigation.”¹²⁵ This section addresses the legal impact of tobacco-related personal injury lawsuits on the field of public health litigation. Tobacco litigation has led to pro-defendant rulings in the areas of preemption, class action certification, and punitive damages that have, in turn, significantly limited the potential impact of public health litigation in other areas. Before exploring the degree to which tobacco cases have influenced personal injury law, two detours are in order: a discussion of the role of personal injury litigation in promoting public health, and a very brief history of early tobacco litigation.

A. *Public Health Litigation: Pro and Con*

Whether lawsuits brought by private citizens can effectively promote public health goals is a question that has been debated for years. Jon Vernick, et al, present the general argument in favor of public health litigation as follows:

As a society, we make decisions about how to balance the risks and benefits of consumer products. One way we strike that balance is by allowing litigation against product makers when risks become too great. In this way, litigation can act as a public health feedback mechanism to affect manufacturers’ safety practices. If a product is considered unsafe (or society is less willing to accept certain risks),

¹²³ *D.A.B.E.*, 773 N.E.2d at 549.

¹²⁴ The *D.A.B.E.* decision has not been the basis for court challenges to health-related regulations, but that is likely because the bright line rule laid down by *D.A.B.E.* has provided clear guidance to regulatory agencies regarding the limits of their authority (though it muddled Ohio’s rules of statutory construction for everyone else). At least one Ohio Attorney General opinion has used *D.A.B.E.* as its authority for concluding that regulations being contemplated by a health department were outside the scope of its authority. See Ohio Op. Att’y Gen. 2007-005, at 5, 6-10 (2007), 2007 WL 1173766 (regarding burial of bodies on private lands).

¹²⁵ Rabin, *Sociolegal History*, *supra* note 15, at 857.

more litigation may follow. As manufacturers respond, products can become safer, the likelihood of successful litigation is reduced, and fewer lawsuits (and injuries) will result.¹²⁶

Although this is a standard argument in favor of health-related litigation, it is easy to see how tobacco—a product that cannot be made safe—does not fit easily into this paradigm.

In addition to prompting changes in product design and serving the traditional tort litigation goal of compensating injured victims, others have argued that public health litigation can also (a) increase costs for dangerous products (thereby decreasing demand and/or forcing the industry to internalize costs imposed on others), (b) bring health risks to the attention of regulators and legislators, (c) heighten public awareness of public health risks (potentially leading to social change), (d) uncover industry misconduct, and (e) deter future misconduct.¹²⁷ They point to a list of public health improvements credited to personal injury and products liability litigation: cars with airbags and shoulder restraints, the removal of dangerous products (such as asbestos and the Dalkon Shield intrauterine device) from the marketplace, and the clean-up of environmental toxins.¹²⁸

On the other hand, some scholars have argued that public health litigation constitutes public policy advocacy by other means (often by parties who have been unable to convince the legislature to adopt their position), and as such, it is an anti-democratic “misuse of the courts.”¹²⁹ Furthermore, some public health specialists have argued that courts are not the proper venue for addressing public health concerns because courts have limited remedies at their disposal (typically monetary damages that may unfairly single out particular defendants) and flexible regulatory bodies are better equipped

¹²⁶ Jon S. Vernick, Lainie Rutkow & Daniel A. Salmon, *Availability of Litigation as a Public Health Tool for Firearm Injury Prevention: Comparison of Guns, Vaccines, and Motor Vehicles*, 97 AM. J. PUB. HEALTH 1991, 1995 (2007).

¹²⁷ See R. Daynard, *Why Tobacco Litigation?*, 12 TOBACCO CONTROL 1, 1-2 (2003); Timothy D. Lytton, *Using Litigation to Make Public Health Policy: Theoretical and Empirical Challenges in Assessing Product Liability, Tobacco, and Gun Litigation*, 32 J.L. MED. & ETHICS 556, 558 (2004); Michelle M. Mello, Eric B. Rimm & David M. Studdert, *The McLawsuit: The Fast-Food Industry and Legal Accountability for Obesity*, 22 HEALTH AFF. 207, 212-14 (2003). For an optimistic view of the potential impact of litigation on public health, see generally Parmet, *supra* note 6.

¹²⁸ See Peter D. Jacobson & Soheil Soliman, *Litigation as Public Health Policy: Theory or Reality?*, 30 J.L. MED. & ETHICS 224, 225 (2002); Wendy Wagner, *When All Else Fails: Regulating Risky Products Through Tort Litigation*, 95 GEO. L.J. 693, 711-713 (2007).

¹²⁹ Lytton, *supra* note 127, at 559.

to deal with public health concerns.¹³⁰ Finally, some have argued that lawsuits are simply an ineffective means of promoting public health.¹³¹

It is unnecessary (and would be futile) to try to resolve this longstanding dispute here. Regardless, it seems clear that the ability of personal injury lawsuits to serve public health ends has been significantly eroded by judicial decisions over the past several decades. It is also clear that tobacco-related decisions have played a prominent role in this erosion. These developments are particularly troubling if one agrees with the premise that private litigation “does play a vital and indispensable role in ensuring the safety and accountability of product manufacturers and industrial polluters.”¹³² Even if one rejects the social significance of public health litigation, however, it is still important for those involved in health-related litigation to understand the ways in which relevant legal doctrines have been influenced by tobacco litigation.

B. *Early Tobacco Litigation and Cipollone*

Tobacco litigation has occurred in three distinct “waves.”¹³³ The first and longest wave began soon after the initial revelations about the connection between smoking and lung cancer in the 1950s, and lasted until the 1980s. The plaintiffs were almost all lung cancer victims or their families, and their claims were “grounded in varying theories of negligence, misrepresentation and breach of warranty.”¹³⁴ Due to the tobacco industry’s early adoption of an aggressive, “scorched earth” strategy, few of these cases made it to trial. Of those that did, the industry’s argument that the connection

¹³⁰ See Jacobson & Soliman, *supra* note 128, at 226-28 (summarizing arguments against using litigation to make public health policy). They note the concern that “[p]ublic policy might well be distorted by an attempt to extract financial concessions at the expense of public health objectives.” *Id.* at 227.

¹³¹ See, e.g., *id.* at 233 (reviewing cases and finding that “gun litigation has not succeeded at all”). For an extremely critical assessment of public health litigation, see Joe Nocera, *Forget Fair; It’s Litigation as Usual*, N.Y. TIMES, Nov. 17, 2007, at C1 (“Mass torts have become a rogue form of regulation, and not necessarily in the public interest.”).

¹³² Wagner, *supra* note 128, at 731-32.

¹³³ See generally Robert L. Rabin, *The Third Wave of Tobacco Tort Litigation*, in REGULATING TOBACCO 176 (Robert L. Rabin & Stephen D. Sugarman eds., 2001) [hereinafter Rabin, *Third Wave*] (discussing the “waves” of tobacco litigation).

¹³⁴ D. DOUGLAS BLANKE, WORLD HEALTH ORG., TOWARDS HEALTH WITH JUSTICE: LITIGATION AND PUBLIC INQUIRIES AS TOOLS FOR TOBACCO CONTROL 16 (2002), available at <http://www.emro.who.int/TFI/Litigation.pdf>.

between smoking and lung cancer had not been conclusively established successfully defeated all claims of liability.

When the causation defense became untenable in the 1980s, the tobacco industry deftly shifted its argument to defend against the “second wave” of tobacco litigation:

For years they had denied their products were unsafe. Now they insisted instead that the hazards they had indignantly denied for so long were no longer preposterous, but were suddenly, in fact, “common knowledge” — so much so that smokers were fully aware of them and had, in fact, “assumed the risk” of death and disease. So well known were these risks, manufacturers argued, that smokers could not claim to have “relied” on the industry’s own denials. Perhaps most audaciously, manufacturers were able to invoke these defenses without so much as acknowledging the inconsistencies of their positions, and without ever conceding that tobacco causes disease.¹³⁵

As with all of the first wave cases, the hundreds of second wave plaintiffs were similarly unable to win a case against the tobacco industry—until *Cipollone v. Liggett Group, Inc.*, which ushered in the “third wave” of tobacco litigation.¹³⁶

Cipollone was the first case in which the tobacco industry lost a jury verdict—a \$400,000 award to the plaintiff. The breakthrough of *Cipollone* was driven by the plaintiff’s attorney’s ability to

gain access to internal industry documents and testimony of former industry employees to an extent then unprecedented in the forty-year history of litigation against the industry—documents and testimony indicating the industry had discouraged internal efforts to take cognizance of the health risks of smoking and to develop a safer cigarette.¹³⁷

This verdict demonstrated that the tobacco industry was not invincible in court, and it seemed to presage an onslaught of litigation that would bury the tobacco industry under the weight of its own documents.

But the tobacco industry survived this “third wave” of litigation intact, and in some ways emerged even stronger than before. Its success was built in large part on its ability to persuade the court to adopt new legal doctrines limiting its liability, including an expansive notion of federal preemption, a narrow view of class action certification, and Due Process

¹³⁵ *Id.* at 17.

¹³⁶ *Id.*

¹³⁷ Rabin, *Third Wave*, *supra* note 133, at 178 (citations omitted).

limitations on punitive damages. These doctrines not only helped the tobacco industry to endure the “third wave” of tobacco litigation; they also dramatically reshaped the legal landscape for other types of public health litigation.

C. *Preemption*

1. *Cipollone v. Liggett Group Inc.*

After decades of frustration, the jury verdict in *Cipollone* provided the first glimmer of hope for those hoping to defeat the tobacco industry in court. These hopes were quickly dashed, however, when the Supreme Court agreed to hear the *Cipollone* appeal and ultimately ruled that the common law failure to warn claims against Liggett were preempted by the Federal Cigarette Labeling and Advertising Act (FCLAA).¹³⁸ The FCLAA is the statute that requires warning labels to be placed on cigarette packs, and the primary purpose of its preemption provision had been to prevent “diverse, nonuniform, and confusing cigarette labeling and advertising regulations.”¹³⁹ Though the Court interpreted the authorizing clause in *FDA v. Brown & Williamson* narrowly in order to preclude FDA regulation of tobacco, it took the opposite approach (though with a similar substantive result) in *Cipollone*, reading the preemption clause of the FCLAA broadly in order to preempt tort suits against the tobacco industry.

The Supreme Court’s opinion did not directly suggest that preemption principles should operate differently in the context of tobacco, but its decision was a striking departure from past precedent. At issue was § 5 of the FCLAA (titled “Preemption”), which read in part:

(b) . . . No requirement or prohibition based on smoking and health shall be imposed under State law with respect to the advertising or promotion of any cigarettes the packages of which are labeled in conformity with the provisions of this chapter.¹⁴⁰

Every circuit court that had addressed the issue had concluded that the preemption provision of § 5(b) did not expressly

¹³⁸ *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 524 (1992).

¹³⁹ 15 U.S.C. § 1331 (2006) (expressing congressional intent in the preamble to the FCLAA).

¹⁴⁰ *Id.* § 1334(b).

preclude common law tort claims.¹⁴¹ Courts assumed that the preemption provision applied only to affirmative regulatory action by state legislatures and regulators, not to common law litigation. For example, the Third Circuit (from which the *Cipollone* appeal originated) had noted that Congress could have easily included a provision in the FCLAA preempting common law tort claims—as it had done in other statutes—but it had not.¹⁴²

The plurality opinion, authored by Justice Stevens, gave lip service to the presumption that “the historic police powers of the States [are] not to be superseded by . . . Federal Act unless that [is] the clear and manifest purpose of Congress,”¹⁴³ but then proceeded to blithely ignore the intent of Congress in finding that “[t]he phrase ‘no requirement or prohibition’ sweeps broadly and suggests no distinction between positive enactments and common law.”¹⁴⁴ Justice Stevens wrote that “[a]lthough portions of the legislative history of the 1969 Act suggest that Congress was primarily concerned with positive enactments by states and localities, the language of the Act plainly reaches beyond such enactments.”¹⁴⁵ In other words, the plurality opinion held that since the language of the statute was so abundantly clear, there was no need to consider evidence regarding Congress’s intent. Given that the circuit courts had not found any such clarity in Congress’s words—and given that there was considerable evidence of a different congressional intent—this was an astounding conclusion.¹⁴⁶ In a partial dissent, Justice Blackmun wrote that “[u]nlike the plurality, I am unwilling to believe that Congress, without any

¹⁴¹ *Cipollone*, 505 U.S. at 542 n.6 (Blackmun, J., concurring in part and dissenting in part) (citing cases).

¹⁴² *Cipollone v. Liggett Group, Inc.*, 789 F.2d 181, 185 (3d Cir. 1986), *rev’d*, 505 U.S. 504 (1992). Likewise, the Fifth Circuit wrote: “It is clear, however, that [the FCLAA preemption provision] does not make any reference to a state tort claim, even indirectly, which relates to the effects of smoking upon health. We must conclude that the Act does not expressly preempt [the plaintiff’s] products liability claims.” *Pennington v. Vistrion Corp.*, 876 F.2d 414, 418 (5th Cir. 1989).

¹⁴³ *Cipollone*, 505 U.S. at 516 (alterations in original) (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)).

¹⁴⁴ *Id.* at 521 (plurality opinion).

¹⁴⁵ *Id.* (citations omitted).

¹⁴⁶ Notably, “[l]ess than a decade earlier, in *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238 (1984), all nine members of the Court had agreed that actions to recover compensatory damages survived sweeping federal pre-emption in the nuclear safety field.” Lars Noah, *The Preemption Morass: Medtronic Leaves Muddled the Question of Whether or When Federal Law Preempts Tort Law Claims Against Defective Medical Devices*, LEGAL TIMES, July 29, 1996, at S37.

mention of state common-law damages actions or its intention dramatically to expand the scope of federal pre-emption, would have eliminated the only means of judicial recourse for those injured by the cigarette manufacturers' unlawful conduct."¹⁴⁷

Although the methodology differed, the Court's approach in *Cipollone* presaged the later *Brown & Williamson* decision. In both cases, the Court was faced with a legal rule instructing it to use a highly deferential approach in interpreting statutory language, yet it refused to recognize any ambiguity in the statutes. In *Brown & Williamson*, the Court looked at the context of subsequent congressional actions in order to find the statute's "clear meaning," whereas *Cipollone* ignored contrary congressional intent and redefined the relevant terms for itself. In both instances, the Court supported the tobacco companies' position, applying its own reading of the statute instead of deferring to the administrative agency (in *Brown & Williamson*) or the states (in *Cipollone*).

As in *Brown & Williamson*, it seems likely that unspoken policy concerns and questions of institutional competency lay behind the Court's decision in *Cipollone*. Allan Brandt writes:

Tobacco litigation became a lightning rod for a larger public debate about the role of tort litigation in American society. For critics of the liability revolution, suits against tobacco companies epitomized the excesses of tort claims, if not the ultimate perversion of the courts. According to such arguments—encouraged by the industry—tobacco litigation was an abuse of the legal system in several ways. First, it was a veiled attempt to secure through the courts regulatory legislation that Congress had never enacted. This marked a constitutionally inappropriate breach in the separation of powers. Second, the litigation created a radical expansion of torts that threatened to flood all industries with costly and spurious claims from consumers. Finally, tobacco liability was seen as a cultural failure: the refusal of individuals to take responsibility for their own willful actions.¹⁴⁸

Awareness of these concerns likely influenced the Supreme Court's decision to limit—but not entirely eliminate—avenues for tobacco-related litigation.¹⁴⁹ The Supreme Court was

¹⁴⁷ *Cipollone*, 505 U.S. at 542 (Blackmun, J., concurring in part and dissenting in part).

¹⁴⁸ BRANDT, *supra* note 2, at 353.

¹⁴⁹ Though the *Cipollone* case barred failure to warn claims, the plurality opinion held that state law fraud claims were not preempted by the FCLAA. This part of the opinion was recently reaffirmed by a five-to-four margin in *Altria Group, Inc. v. Good*, 129 S. Ct. 538 (2008). The four dissenting Justices would have held that the

understandably reluctant to place the courts at the center of a broader cultural and political battle, and it sought to protect the lower courts from the flood of litigation that would have inevitably followed a ruling for the plaintiff in *Cipollone*.¹⁵⁰

It is of course possible that the Supreme Court would have built towards an aggressive preemption doctrine anyway. Preemption is the subject of the “fiercest battle in products liability litigation today,” with a variety of industries—supported by a well-organized and well-funded tort reform movement—pushing courts to declare that state tort law claims against them are preempted by federal law.¹⁵¹ Although the Supreme Court might have inevitably moved towards the same position as a more conservative court took the bench, reading a preemption clause broadly in cigarette context—which was perhaps less controversial because of general skepticism about the merits of tobacco litigation—clearly opened the door for the Court to build upon *Cipollone* in subsequent decisions unrelated to tobacco. Furthermore, as discussed below, the *Cipollone* decision immediately opened the door for similar preemption arguments in state courts and lower federal courts, providing for rapid expansion of the preemption doctrine.

2. Post-*Cipollone* Decisions

“Almost immediately after *Cipollone* was decided, the preemption theory permeated tort-claim cases in the lower courts, which began to read *Cipollone* as compelling preemption in a wide variety of circumstances.”¹⁵² Unlike in *Brown & Williamson*, the Supreme Court had not suggested that its analysis was in any way limited to tobacco cases, and the lower courts did not imply any such limitation. Lower courts read *Cipollone* broadly for the proposition that the term “requirement,” when used in a preemption clause, now

FCLAA also preempted all fraud-related claims against tobacco companies, which would have granted the companies virtual immunity from all health-related tort suits. *Id.* at 552 (Thomas, J., dissenting).

¹⁵⁰ See Richard A. Daynard, *Regulating Tobacco: The Need for a Public Health Judicial Decision-Making Cannon*, 30 J.L. MED. & ETHICS 281, 286 (2002) (writing that fear of an overwhelming surge in tobacco-related cases led circuit courts to conclude that the FCLAA preempted tort law claims).

¹⁵¹ Catherine M. Sharkey, *Products Liability Preemption: An Institutional Approach*, 76 GEO. WASH. L. REV. 449, 450 (2008).

¹⁵² Robert J. Katerberg, *Patching the “Crazy Quilt” of Cipollone: A Divided Court Rethinks Federal Preemption of Products Liability in Medtronic, Inc. v. Lohr*, 75 N.C. L. REV. 1440, 1478 (1997).

included all common law tort claims. Courts used this proposition to bar tort claims involving defective medical devices,¹⁵³ herbicides and insecticides,¹⁵⁴ and auto safety.¹⁵⁵

Justice Stevens, the author of the plurality decision in *Cipollone*, later retreated from the position he articulated in that case, finding himself on this short side of several subsequent preemption decisions that either reaffirmed or extended *Cipollone*.¹⁵⁶ In *Buckman v. Plaintiff's Legal Committee*, which extended *Cipollone* by taking a similarly broad view of *implied* preemption of common law claims, Justice Stevens expressed his concern:

Under the preemption analysis the Court offers today . . . parties injured by fraudulent representations to federal agencies would have no remedy even if recognizing such a remedy would have no adverse consequences upon the operation or integrity of the regulatory process. I do not believe the reasons advanced in the Court's opinion support the conclusion that Congress intended such a harsh result. Cf. *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 251 (1984) (declining to infer that a federal statutory scheme that affords to alternative means of seeking redress pre-empted traditional state-law remedies).¹⁵⁷

¹⁵³ See, e.g., *Gile v. Optical Radiation Corp.*, 22 F.3d 540, 542 (3d Cir. 1994) (finding state tort law claims under the Medical Device Act preempted because "the Supreme Court has clearly stated that the word 'requirement,' in the context of an express preemption provision, includes state law claims"); *Stamps v. Collagen Corp.*, 984 F.2d 1416, 1418 (5th Cir. 1993) (rejecting claim that collagen injection had caused autoimmune disease on same grounds).

¹⁵⁴ See, e.g., *King v. E.I. du Pont de Nemours & Co.*, 996 F.2d 1346, 1349 (1st Cir. 1993) ("The FIFRA [Federal Insecticide, Fungicide and Rodenticide Act] language prohibiting the states from 'impos[ing] or continu[ing] in effect any requirements,' 7 U.S.C. § 136v(b), is virtually indistinguishable from the state-imposed 'requirement' language that *Cipollone* held preempted the state common law tort claims based on inadequate warning. FIFRA's language, too, preempts the state law lack-of-warning claims involved in this case." (alterations in original)); *Levesque v. Miles, Inc.*, 816 F. Supp. 61, 70 (D.N.H. 1993) (finding that plaintiff's claim based on insecticide that ignited without warning in his pocket was preempted by FIFRA).

¹⁵⁵ See, e.g., *Estate of Montag v. Honda Motor Co.*, 856 F. Supp. 574, 576-77 (D. Colo. 1994) (finding that after *Cipollone*, claims relating to the lack of an airbag are expressly preempted by the National Traffic and Motor Vehicle Safety Act, despite a savings clause in the statute stating that "[c]ompliance with any Federal motor vehicle safety standard issued under this subchapter does not exempt any person from any liability under common law"), *aff'd on related grounds*, 75 F.3d 1414, 1421 (10th Cir. 1996).

¹⁵⁶ See *Buckman v. Plaintiff's Legal Comm.*, 531 U.S. 341, 353-355 (2001) (Stevens, J., concurring); *Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 886 (2000) (Stevens, J., dissenting).

¹⁵⁷ *Buckman*, 531 U.S. at 355 (Stevens, J., concurring). In *Buckman*, the Court held that plaintiffs' state law claims based on injuries caused by orthopedic bone screws were preempted because the screws had been approved by the FDA—even

Of course, by citing all the way back to *Silkwood*, Justice Stevens conveniently overlooked *Cipollone*. His own plurality decision in *Cipollone*, essentially holding that the statutory scheme in the FCLAA had “put a ceiling, as well as a floor, on the common law obligations of manufacturers to communicate the true dangers of their products to consumers,” had laid the groundwork for the majority’s decision in *Buckman* and similar cases.¹⁵⁸ The gravamen of the *Cipollone* decision, after all, was that the tobacco companies could not be required to warn customers of known dangers, even if those dangers were much more severe than those recognized on the FCLAA-required warning labels. Justice Stevens has never directly argued that *Cipollone* should be limited to its facts because it involved cigarettes, but his retreat from its holding suggests a belief on his part that tobacco products somehow present a unique case.

Justice Stevens’ reconsideration of his opinion, however, has not stopped the Supreme Court from building on the foundation of *Cipollone*. The most recent—and perhaps most troubling—example is *Riegel v Medtronic*,¹⁵⁹ where the Court held that the Medical Device Amendments (MDA) to the FDCA expressly preempted common law tort claims for medical devices that had been approved by the FDA. At issue was a coronary balloon catheter that had ruptured during its use in angioplasty. Noting that the preemption clause included in the MDA precluded contrary “requirements” from being applied under state law, Justice Scalia wrote for the majority: “Absent other indication, reference to a State’s ‘requirements’ includes its common-law duties. As the plurality opinion said in *Cipollone*, common-law liability is ‘premised on the existence of a legal duty,’ and a tort judgment therefore establishes that the defendant has violated a state-law obligation.”¹⁶⁰

The absurdity of *Riegel* was that it read the preemption provision in the MDA in a way that was clearly not intended by its authors. Senator Ted Kennedy, the sole sponsor of the MDA in the Senate, filed an *amicus* brief strenuously arguing that no one in Congress ever considered that the preemption provision in the MDA would preempt state tort claims. He wrote that the term “requirements” was understood to apply only to state

though plaintiffs alleged that the manufacturer had misled the FDA in its application for approval. *Id.* at 343.

¹⁵⁸ Daynard, *supra* note 150, at 286.

¹⁵⁹ 128 S. Ct. 999 (2008).

¹⁶⁰ *Riegel*, 128 S. Ct. at 1008.

regulations, and Congress did not even consider that the term might apply to lawsuits until the *Cipollone* decision in 1992 (the MDA was passed in 1976). Senator Kennedy wrote (along with Congressman Henry Waxman):

Congress was fully aware of widespread tort law suits over medical devices, yet there is nothing in the legislative history to suggest an intent [to] preempt such suits. At the time the MDA was enacted, Congress did not understand the term “requirement” to include state tort law verdicts. . . . If Congress had intended to preempt state tort law suits, it would have explicitly done so. Taking into account the plain language of the MDA preemption provision, the absence of any indication in the legislative history that Congress even considered the possibility that the provision would preempt state tort suits, the presumption against preemption, and the legislative purpose of the MDA, it is plain that the “requirements” preempted under the statute do not include state tort law suits.¹⁶¹

The majority neatly dismissed this argument, writing that the preemption of state tort claims “is exactly what [the MDA preemption clause] does by its terms.”¹⁶² Therefore, because the meaning of the statute was so clear, the intent of Congress need not even be considered. Though this reasoning is spectacularly circular—because we read the term “requirements” to include tort claims, the term is not ambiguous—it is surely consistent with *Cipollone*.

3. Public Health Impact

Immunity from tort litigation—which is effectively what federal preemption provides—removes a major incentive for manufacturers to make their products as safe as possible or to alert consumers to newly-discovered dangers. The public health implications of this doctrine are likely to be significant. Consider, for example, the *Riegel* case itself and the regulation of medical devices. As David Vladeck has explained, the MDA approval process, while important, does not provide manufacturers with any meaningful incentives to alert consumers of new dangers that are discovered *after* the product is on the market. Vladeck writes:

¹⁶¹ Brief of Senator Edward M. Kennedy et al. as Amici Curiae in Support of Petitioners at 21, *Riegel*, 128 S. Ct. 999 (No. 06-179).

¹⁶² *Riegel*, 128 S. Ct. at 1008-09. Legislation has been introduced in both houses of Congress to overrule *Riegel*. Thus far, the legislation has not been brought up for a vote. See Gregory D. Curfman et al., *The Medical Device Safety Act of 2009*, 360 NEW ENG. J. MED. 1550, 1551 (2009).

[P]remarket approval is a one-time licensing decision that is based on whether the device's sponsor has shown a "reasonable assurance" of safety. There is no provision in the MDA for devices to be periodically re-certified by the FDA. Medical devices are often approved on the basis of a single clinical trial, often involving very small numbers of patients Once on the market, the FDA engages in only limited surveillance

The FDA's track record demonstrates the agency's woeful inability to single-handedly protect the American people against defective and dangerous medical devices. Just in the past few years, we have seen massive recalls of defibrillators, pacemakers, heart valves, hip and knee prostheses, and heart pumps — all of which have exacted a terrible toll on the patients who have had them implanted in their bodies, and who often face the daunting prospect of explanation and replacement surgery. [If premarket approval preempts tort claims] . . . all of these people would be left without any remedy at all. Premarket approval is an important process intended to put an end to the marketing of devices without meaningful testing and with no assurance of safety. *But while the [premarket approval] process provides minimum safeguards, it cannot replace the continuous and comprehensive safety incentives, information disclosure, and victim compensation that tort law has traditionally provided.*¹⁶³

This is especially troublesome when one considers that "the data supporting a [premarket approval] application are compiled by the device manufacturer and are often unreliable."¹⁶⁴

Beyond medical devices, *Cipollone*, as suggested above, led to federal court decisions preempting state tort law claims in a variety of other contexts. The public health implications of these decisions are exceedingly difficult to track, and in some instances the Supreme Court later held that lower courts had extended *Cipollone* too far.¹⁶⁵ It is clear, however, that even if the *Cipollone* decision was based in part on the unique context and pressures of tobacco litigation, it armed defendants in a variety of other industries with a powerful (and often

¹⁶³ DAVID C. VLADECK, AMERICAN CONSTITUTION SOCIETY FOR LAW & POLICY, *THE EMERGING THREAT OF REGULATORY PREEMPTION* 6-8 (2008) (emphasis added) (citations omitted); see also David C. Vladeck, *Preemption and Regulatory Failure*, 33 PEPP. L. REV. 95, 126-30 (2005). Another concern is that "agency capture" may limit the effectiveness of regulatory oversight. See, e.g., VLADECK, *THE EMERGING THREAT OF REGULATORY PREEMPTION*, *supra*, at 16.

¹⁶⁴ Brief for the States of New York et al. as Amici Curiae in Support of Petitioners at 17-18, *Riegel*, 128 S. Ct. 999 (No. 06-179) (citing an FDA Inspector General report revealing "serious deficiencies . . . in the clinical data submitted as part of pre-market applications") (alteration in original).

¹⁶⁵ See, e.g., *Bates v. Dow Agrosciences, LLC*, 544 U.S. 431, 444 (2005) (holding that state law claims regarding negligent manufacturing and breach of warranty with respect to pesticides were not preempted by FIFRA).

successful) new weapon to use in defeating products liability actions and other state tort law claims. Justice Ginsburg, the sole dissenter in *Riegel*, was likely correct when she wrote: “[R]egardless of the strength of a plaintiff’s case, suits will be barred *ab initio*. The constriction of state authority ordered today was not mandated by Congress and is at odds with the MDA’s central purpose: to protect consumer safety.”¹⁶⁶ The same can be said of the other cases that followed in *Cipollone*’s wake.¹⁶⁷

D. Class Certification

Cipollone weakened tobacco litigation, but it did not end it. *Cipollone* held that post-1965 failure to warn cases were preempted, but the plurality decision left a window open for fraud and misrepresentation claims, as well as pre-1965 failure to warn actions. Moreover, the documents exposed in *Cipollone* and in the subsequent investigations of the tobacco industry by state attorneys general provided the means by which to establish the industry’s fraud. Individual litigation, however, remained extraordinarily expensive and risky, due to the industry’s aggressive litigation tactics. In the mid-1990s, the use of class action litigation appeared to be a promising avenue by which to neutralize the industry’s financial advantages and aggregate “individual claims for harm into one massive tort challenge to the industry.”¹⁶⁸ Cases in the 1980s had shown the class action to be a powerful tool that could address serious

¹⁶⁶ 128 S. Ct. at 1020 (Ginsburg, J., dissenting).

¹⁶⁷ In an important recent case, the Supreme Court in *Wyeth v. Levine* found that tort claims against the pharmaceutical industry were not preempted by federal law. 129 S.Ct. 1187 (2009). Unlike *Cipollone* and *Reigel*, *Wyeth* did not involve an issue of *express* preemption. The plaintiffs had argued that preemption should be implied because state tort law interfered with the ability of the FDA to exercise its control over the pharmaceutical industry. This argument was rejected six-to-three by the court. *Id.* at 1200 (“If Congress thought state-law suits posed an obstacle to its objectives, it surely would have enacted an express pre-emption provision at some point during the FDCA’s 70-year history. But despite its 1976 enactment of an express pre-emption provision for medical devices, Congress has not enacted such a provision for prescription drugs.” (citation omitted)). Thus, *Wyeth* did not in any way overrule or limit *Cipollone* and its progeny, though it did put some limits on the doctrine of *implied* preemption.

¹⁶⁸ Rabin, *Third Wave*, *supra* note 133, at 179. Class actions also had the potential to “reduce the focus on individual behavior and diagnosis.” BRANDT, *supra* note 2, at 405.

public health threats such as DES, the Dalkon Shield intrauterine contraceptive, Agent Orange, and asbestos.¹⁶⁹

Despite the promise of class action litigation, tobacco-related class actions ultimately failed, and it is now generally agreed that “class action litigation has largely fallen by the wayside as a means of determining collective liability for victims of mass products torts.”¹⁷⁰ Although the collapse of the class action is not solely due to the impact of tobacco litigation, tobacco cases appear to have sealed the fate of the mass tort class action. At least when it comes to health-related cases, the consensus is that “the mass tort class action is as dead as a doornail.”¹⁷¹

Two different issues have made it difficult for plaintiffs in tobacco-related cases to achieve class certification. The first is the question of “commonality.”¹⁷² In tobacco cases—as in other health-related cases—individual issues play a significant role. Questions about whether the plaintiffs relied on the tobacco companies’ misstatements or whether their injuries were caused by smoking are fact-specific inquiries where the answers likely vary from person to person. For such questions, class action certification may not be appropriate. This problem can be mitigated, however, by seeking issue certification on

¹⁶⁹ Myriam Gilles, *Opting Out of Liability: The Forthcoming, Near-Total Demise of the Modern Class Action*, 104 MICH. L. REV. 373, 382 (2005). If most injured individuals lack either the impetus (due to widely dispersed harm) or the resources to bring individual lawsuits, defendants will be “under-deterred.” The class action held the promise of remedying this problem while also promoting greater efficiency in the court system:

[T]he class action deters defendants from externalizing the costs of their actions by causing widespread, but individually minimal harm. Potential defendants know that they will be held accountable for such harm in both monetary and reputational terms, and they therefore have a greater incentive to avoid engaging in harmful activities. This deterrence function ultimately benefits consumers and courts alike, as greater deterrence leads to fewer future injuries and future lawsuits.

Developments in the Law: The Paths of Civil Litigation, 113 HARV. L. REV. 1752, 1809-10 (2000) (citation omitted).

¹⁷⁰ Donald G. Gifford, *The Challenge to the Individual Causation Requirement in Mass Products Torts*, 62 WASH. & LEE L. REV. 873, 895 (2005).

¹⁷¹ Gilles, *supra* note 169, at 388.

¹⁷² Under Federal Rule of Civil Procedure 23(b)(3), class action certification is appropriate only when “the court finds that the questions of law or fact common to class members predominate over any questions affecting only individual members.” FED. R. CIV. P. 23(b)(3).

questions shared by the entire class, while leaving individual issues to be resolved later.¹⁷³

The second issue is one of magnitude. Courts have been reluctant to allow certification for extremely large classes, particularly in situations where a verdict for the plaintiff class could potentially bankrupt the defendants. Given the number of current and former smokers, tobacco-related class actions inevitably present this issue. The concern about magnitude was famously outlined by Judge Richard Posner in *In re Rhone-Poulenc Rorer, Inc.*¹⁷⁴ In *Rhone-Poulenc*, a case involving a plaintiff class of hemophiliacs who had been exposed to the AIDS virus, Judge Posner advanced the novel argument (indeed, one that the defendant had not raised until oral argument) that high-stakes class actions unfairly pressure defendants to either settle or “stake their companies on the outcome of a single jury trial.”¹⁷⁵ He argued that class action treatment might be appropriate where “individual suits are infeasible because the claim of each class member is tiny relative to the expense of litigation,” but he found that “[t]hat plainly is not the situation here.”¹⁷⁶

Courts have not always distinguished between these two concerns when denying class certification in tobacco-related cases, but the concern about class size and potential unfairness to the defendants has likely played the more

¹⁷³ Federal Rule of Civil Procedure 23(c)(4) provides that “[w]hen appropriate, an action may be maintained as a class action with respect to particular issues.” FED. R. CIV. P. 23(c)(4).

¹⁷⁴ 51 F.3d 1293, 1297-98 (7th Cir. 1995); cf. Elizabeth J. Cabraser, *The Class Action Counterreformation*, 57 STAN. L. REV. 1475, 1481 (2005) (“The *Rhone-Poulenc* decision has been vastly influential in all aspects of class action jurisprudence. Its ‘free market’ attitude toward the maturation of mass torts through repetitive trials in multiple jurisdictions has held sway across the country” (citations omitted)).

¹⁷⁵ 51 F.3d. at 1299. Although Judge Posner advanced other reasons for decertifying the class, this concern appeared to be his “core reason.” Gilles, *supra* note 169, at 386.

¹⁷⁶ *Rhone-Poulenc*, 51 F.3d at 1299. This reasoning leads to the odd result that in life-and-death cases, where a group of plaintiffs have been killed or seriously injured by the defendant, class action treatment is almost never appropriate. On the other hand, class actions can be used for cases with trivial damages such as lawsuits involving overpriced cosmetics or “junk faxes.” See, e.g., *Azizian v. Federated Dep’t Stores, Inc.*, 243 Fed. Appx. 311, 312 (9th Cir. 2007) (affirming certification of class action and approval of final settlement in cosmetics-related antitrust case); *CE Design v. Beaty Constr., Inc.*, 2009 U.S. Dist. LEXIS 5842 (N.D. Ill. Jan. 26, 2009) (certifying class action in “junk faxes” case). This is a perverse result given that, as several commentators have noted, it is attorneys who are most likely to benefit from class action settlements where the plaintiffs have little stake in the matter. By contrast, in health-related cases, class actions present the opportunity for meaningful redress for plaintiffs.

significant (though often unrecognized) role. In *Castano v. American Tobacco Co.*, a class action brought on behalf of addicted smokers, this concern was clearly central to the court's decision.¹⁷⁷ Basing their case on newly revealed evidence that tobacco companies had been manipulating nicotine levels in cigarettes in order to create and sustain addiction, the plaintiffs focused their lawsuit on the tobacco companies' fraud, rather than on the health effects of smoking.¹⁷⁸ In this way, they hoped to avoid some of the "commonality" questions that had doomed previous attempts at class actions. Although the district court certified the class (with respect to whether the industry had defrauded the plaintiffs and whether punitive damages were warranted), the Fifth Circuit reversed, relying heavily on *Rhone-Poulenc*.¹⁷⁹ Characterizing the plaintiffs' claim as a "novel and wholly untested theory," the Fifth Circuit wrote that the case presented unique concerns:

[C]lass [action] certification creates insurmountable pressure on defendants to settle, whereas individual trials would not These settlements have been referred to as judicial blackmail.

The traditional concern over the rights of defendants in mass tort class actions is magnified in the instant case. . . . This is because certification of an immature tort results in a higher than normal risk that the class action may not be superior to individual adjudication.¹⁸⁰

This deference for "the rights of defendants" does not appear anywhere in Rule 23. Nonetheless, there is no reason not to take the Fifth Circuit's statements at face value when it expressed its concern that class action certification might unfairly force the tobacco industry to either settle (regardless of meritorious defenses it might have) or "roll the dice" on one massive trial. The stakes involved were indeed huge.¹⁸¹ The plaintiffs were a class of roughly 40 million people in what was

¹⁷⁷ See 84 F.3d 734, 746 (5th Cir. 1996).

¹⁷⁸ See Robert L. Rabin, *The Tobacco Litigation: A Tentative Assessment*, 51 DEPAUL L. REV. 331, 333 (2001) [hereinafter Rabin, *Tentative Assessment*].

¹⁷⁹ *Castano*, 84 F.3d at 746, 748.

¹⁸⁰ *Id.* at 737, 746-47 (footnote omitted). For a rebuttal to the charge of "judicial blackmail," see Charles Silver, "We're Scared to Death": *Class Certification and Blackmail*, 78 N.Y.U. L. REV. 1357 (2003).

¹⁸¹ See Richard L. Marcus, *Reassessing the Magnetic Pull of Megacases on Procedure*, 51 DEPAUL L. REV. 457, 484 (2001) ("Had the plaintiffs succeeded in preserving class certification in *Castano* . . . the availability of the class device itself would have been a generating factor behind litigation of almost unimaginable dimensions.").

quite possibly “the largest class action ever attempted in federal court.”¹⁸² Even without seeking health-related damages, the economic damages and punitive damages could plausibly have bankrupted the tobacco industry. Given the circumstances, it is not at all surprising that the Fifth Circuit was reluctant to allow a “winner-takes-all shootout at the OK Corral.”¹⁸³

Judge Posner, as noted above, had suggested in *Rhone-Poulenc* that individual treatment might be appropriate where “individual suits are infeasible because the claim of each class member is tiny relative to the expense of litigation.”¹⁸⁴ The Fifth Circuit determined that *Castano* was not such a case, but its conclusion that “individual suits are feasible” proved to be mistaken.¹⁸⁵ In fact, individual plaintiffs have not been able to afford lawsuits based on *Castano*’s addiction-focused theory. The *Castano* plaintiffs’ attorneys’ threat that they would “inundate the courts with individual claims if class certification is denied” was revealed to be idle bluster.¹⁸⁶ Thus, in retrospect, *Castano*’s reliance on *Rhone-Poulenc* was arguably misplaced. Nonetheless, by loosening the conditions under which *Rhone-Poulenc*’s “blackmail” theory would be applied, the Fifth Circuit made it easier for subsequent cases to further unmoor *Rhone-Poulenc*’s holding from Judge Posner’s articulated limitations.

Myriam Gilles writes:

The *Castano* decertification was followed, in quick succession, by the Sixth Circuit’s decertification of a class involving penile implants, the Ninth Circuit’s decertification of medical products liability classes, and the Third Circuit’s decertification of an asbestos class. Finally, the Supreme Court got into the act [in *Amchem Prods. v. Windsor*, 521 U.S. 591 (1997)], rejecting a prepackaged settlement deal in which plaintiffs and defendants agreed to certify an asbestos class for settlement purposes only. Once again, the refusal to certify

¹⁸² *Castano*, 84 F.3d at 737; Rabin, *Tentative Assessment*, *supra* note 178, at 333.

¹⁸³ Gilles, *supra* note 169, at 387.

¹⁸⁴ *In re Rhone-Poulenc Rorer, Inc.*, 51 F.3d 1293, 1299 (7th Cir. 1995).

¹⁸⁵ *Castano*, 84 F.3d at 748. Thus, *Castano* may have been the unusual case where the individual damages were not significant enough to support individual lawsuits, but class certification created a case so large it could have destroyed the industry.

¹⁸⁶ *Id.* Following the decertification of *Castano*, some individual lawsuits against the tobacco industry have succeeded, but the successful claims have not been based upon the addiction-based theory put forward in *Castano*. See Robert L. Rabin, *Tobacco Control Strategies: Past Efficacy and Future Promise*, 41 LOY. L.A. L. REV. 1721, 1742-44 (2008) (surveying recent individual lawsuits against the tobacco industry).

was driven, in part, by concerns with “fairness” to the defendants, given the coercive settlement power of a certified class proceeding.¹⁸⁷

More recent cases have similarly relied on *Castano* to deny class certification in lawsuits involving allegedly defective pharmaceuticals,¹⁸⁸ exposure to radiation,¹⁸⁹ welding fumes,¹⁹⁰ and toxic chemical leaks.¹⁹¹ In most of these cases (with the exception of the asbestos cases), the discrepancy in power between the parties and/or the stakes involved would not have exerted undue pressure on the defendants to either settle the case or risk bankruptcy. Thus, the reasoning behind *Rhone-Poulenc* and *Castano* was inapplicable. Nonetheless, cases following *Castano* have ignored the context of the case and focused instead on its holding or its ancillary concerns about commonality.

Several subsequent tobacco cases have followed *Castano*, thus setting additional precedents making class action certification more difficult in health-related cases. Overreaching by plaintiffs’ attorneys—as in the recent case of *McLaughlin v. American Tobacco Co.*, which sought \$800 billion in damages for a massive class consisting of all “light” cigarette smokers since 1971—has not helped.¹⁹² In the notable *Engle* case in Florida, a Miami jury awarded a class of Florida smokers \$145 billion in punitive damages against the tobacco industry.¹⁹³ Though the Florida Supreme Court later decertified the class on “commonality” grounds,¹⁹⁴ it is likely that the court’s decision was also due in part to astonishment at the size of the jury verdict and concern about unfairness to the tobacco

¹⁸⁷ Gilles, *supra* note 169, at 387-88 (citations omitted).

¹⁸⁸ Blain v. Smithkline Beecham Corp., 240 F.R.D. 179, 190-91 (E.D. Pa. 2007).

¹⁸⁹ Norwood v. Raytheon Co., 237 F.R.D. 581, 602-05 (W.D. Tex. 2006).

¹⁹⁰ *In re Welding Fume Prods. Liab. Litig.*, 245 F.R.D. 279, 306 (N.D. Ohio 2007).

¹⁹¹ *Steering Comm. v. Exxon Mobil Corp.*, 461 F.3d 598, 604-05 (5th Cir. 2006). In all, *Castano* has been cited by more than 600 cases. Some of these have focused on *Castano*’s remarkably broad statement that “a fraud class action cannot be certified when individual reliance will be an issue.” *Castano*, 84 F.3d at 745.

¹⁹² See 522 F.3d 215, 221 (2d Cir. 2008). In *McLaughlin*, District Judge Jack Weinstein, who had helped originate the mass tort class action with his decision in *In re “Agent Orange” Product Liability Litigation*, 597 F. Supp. 740, 857-58 (E.D.N.Y. 1984), granted class certification before being reversed by the Second Circuit. *Schwab v. Philip Morris USA*, 449 F. Supp. 2d 992 (E.D.N.Y. 2006).

¹⁹³ *Engle v. Liggett Group, Inc.*, 945 So. 2d 1246, 1254 (Fla. 2006).

¹⁹⁴ *Id.* at 1268 (writing that “individualized issues such as legal causation, comparative fault, and damages predominate”).

companies.¹⁹⁵ The suspicion that the Florida Supreme Court was more troubled by the outcome than the procedure is heightened by the fact that the court had previously refused the defendants' request to decertify the class before the trial.

In leading the decline of the class action in health-related cases, tobacco cases have been joined by asbestos cases. With respect to class action certification, asbestos cases share the salient characteristics of tobacco litigation: extremely large numbers of potential plaintiffs who present widely varied medical conditions and histories of exposure. In *Amchem*, the Supreme Court decertified a settlement class action in an asbestos case, noting the same problems highlighted in *Castano*. It highlighted the massive size of the proposed class, and it emphasized that courts must exercise caution when "individual stakes are high and disparities among class members great."¹⁹⁶ This was followed by the rejection of an asbestos-related class action settlement two years later in *Ortiz v. Fibreboard Corp.*, where the Court again signaled its distaste for the use of class action settlements to resolve mass tort cases.¹⁹⁷

Thus, it was perhaps not the "tobacco-ness" of the tobacco cases that led to their decertification, but rather a set of characteristics common to both tobacco and asbestos litigation. Together, these two types of cases have created precedents in nearly every circuit that can be seized upon to decertify mass tort class actions. These cases have precipitated the collapse of the class action as a public health tool, even though the unusual features of tobacco and asbestos litigation are absent in many other public health contexts.

E. Punitive Damages

Because tobacco companies have historically been so successful in defending against liability, tobacco-related cases contributed nothing to the law of punitive damages until recently. Indeed, it was not until 2005, in *Henley v. Philip Morris*, that a tobacco industry defendant actually made a payment of punitive damages to a plaintiff in a personal injury

¹⁹⁵ *Id.* at 1265 n.8 ("We also conclude that the punitive damages award was clearly excessive [T]he award would result in an unlawful crippling of the defendant companies.").

¹⁹⁶ *Amchem Prods., Inc. v. Windsor*, 521 U.S. 591, 624-25 (1997).

¹⁹⁷ 527 U.S. 815, 864 (1999).

lawsuit.¹⁹⁸ Over the last ten years, however, the tobacco companies have begun to face more adverse judgments that have included awards of punitive damages. In keeping with their reputation as tenacious litigators, the tobacco companies have consistently pursued every possible avenue to appeal these verdicts and delay paying claims.¹⁹⁹ This strategy—though not always successful in vacating damages awards—has often worked (as it did in *Henley*) to significantly reduce the amount of punitive damages.²⁰⁰ It has also meant that tobacco cases are more frequently the subject of precedent-making decisions involving punitive damages awards—particularly in cases interpreting the Supreme Court’s rapidly-shifting Due Process jurisprudence on the topic.

The use of tobacco-related cases to set new precedents can have unintended consequences that severely limit the availability of punitive damages for subsequent litigants. For example, in *Boerner v. Brown & Williamson Tobacco Co.*, the Eighth Circuit slashed an Arkansas jury’s award of punitive damages by two-thirds, finding that a 1:1 ratio between compensatory and punitive damages was appropriate.²⁰¹ The court, astoundingly, concluded that despite clear evidence that American Tobacco (a predecessor company to Brown & Williamson) “actively misled consumers about the health risks associated with smoking,” there was “no evidence that anyone at American Tobacco intended to victimize its customers.”²⁰² It is easy to see how all sorts of defendants—in other public health contexts and beyond—could subsequently argue that punitive damages greater than a 1:1 ratio were not warranted

¹⁹⁸ *Henley v. Philip Morris, Inc.*, 9 Cal. Rptr. 3d 29, 38-39 (Ct. App. 2004), *appeal dismissed*, 97 P.3d 814 (Cal. 2004), *cert. denied*, 544 U.S. 920 (2005).

¹⁹⁹ The *Henley* case demonstrates the resources the tobacco industry has been willing to invest in appealing adverse verdicts. In 1999, a San Francisco jury awarded Patricia Henley \$1.5 million in compensatory damages and \$50 million in punitive damages. It was not until six years later that Philip Morris exhausted its appeals and was forced to pay. By that time, the case had made two trips to the California Supreme Court and the punitive damages awards had been slashed from \$50 million to \$9 million. See Myron Levin, *High Court Turns Away Philip Morris*, L.A. TIMES, March 22, 2005, at C1.

²⁰⁰ See, e.g., *Bullock v. Philip Morris USA, Inc.*, 71 Cal. Rptr. 3d 775 (Ct. App. 2008) (overturning award of \$28 billion in punitive damages); *Boeken v. Philip Morris, Inc.*, 26 Cal. Rptr. 3d 638 (Ct. App. 2005) (reducing punitive damages award from \$3 billion to \$50 million); *Philip Morris, Inc. v. French*, 897 So. 2d 480, 487 (Fla. Dist. Ct. App. 2004) (noting that in response to Philip Morris’ motion, the trial judge had reduced the award of damages from \$5.5 million to \$500,000).

²⁰¹ 394 F.3d 594, 603 (8th Cir. 2005).

²⁰² *Id.*

because their conduct, however egregious, paled in comparison to the actions of the tobacco companies.²⁰³

Though *Boerner* and cases like it can be characterized as (perhaps dubious) applications of the Supreme Court's Due Process jurisprudence, the Supreme Court's decision in *Philip Morris USA v. Williams* unquestionably broke new ground.²⁰⁴ This decision—which has been roundly criticized by commentators as unintelligible²⁰⁵—is likely to have a significant impact on future public health litigation.

1. *Philip Morris USA v. Williams*

Williams involved a suit by the estate of Oregon resident Jesse Williams, a longtime smoker of Marlboro cigarettes who began smoking in the 1950s and died of smoking-related lung cancer in 1997. The jury found for the plaintiff on claims of negligence and fraud. On the fraud claim, the jury awarded compensatory damages of \$821,000 and punitive damages of \$79.5 million.²⁰⁶ After the award was affirmed for a second time by the Oregon Supreme Court,²⁰⁷ Philip Morris appealed to the U.S. Supreme Court. The tobacco company was optimistic that the Supreme Court would apply its holdings in *State Farm Mutual Automobile Insurance Co. v.*

²⁰³ See Anna Van Duzer, *Boerner v. Brown & Williamson Tobacco Co.: The Eighth Circuit Misapplied the Second Gore Guidepost to Erroneously Decide a Punitive Damages Award Was Excessive*, 39 CREIGHTON L. REV. 387, 416, 440 (2006) (writing that the *Boerner* decision was a misapplication of both Supreme Court and Eighth Circuit precedent, and that “by imposing a ratio of approximately 1:1 in *Boerner* without identifying particular facts from the case that supported doing so, the court essentially locked in a 1:1 ratio for all future cases involving large compensatory awards”).

²⁰⁴ 549 U.S. 346, 349 (2007).

²⁰⁵ See, e.g., Michael P. Allen, *Of Remedy, Juries, and State Regulation of Punitive Damages: The Significance of Philip Morris v. Williams*, 63 N.Y.U. ANN. SURV. AM. L. 343, 359 (2008) (“I have read this passage scores of times. I have also taught it to hundreds of students in Remedies courses so far. I confess, however, to being truly perplexed as to how the Court envisions the jury complying with this requirement.”); Keith N. Hylton, *Reflections on Remedies and Philip Morris v. Williams*, 27 REV. LITIG. 9, 30 (2007) (“*Philip Morris* instructs courts that it is permissible to consider harm to other victims in determining reprehensibility, but impermissible to actually increase an award in an effort to punish the defendant for the harms inflicted on others. It is a distinction that many will find confusing, as the dissenting opinions noted.”).

²⁰⁶ *Williams v. Philip Morris, Inc.*, 48 P.3d 824, 828 (Or. Ct. App. 2002). The jury awarded no punitive damages on the negligence claim (finding that Williams was fifty percent at fault); the \$79.5 million in punitive damages was awarded on the fraud claim. The compensatory damages were later reduced by the trial judge. *Id.*

²⁰⁷ *Williams v. Philip Morris Inc.*, 127 P.3d 1165 (Or. 2006).

*Campbell*²⁰⁸ and *BMW of North America v. Gore*²⁰⁹ to find that a nearly 100:1 ratio between punitive damages and compensatory damages (on the fraud claim) was unconstitutionally excessive. Instead, in a 5-4 decision written by Justice Breyer, the Supreme Court avoided the question of excessiveness, finding alternate grounds on which to remand the case to the Oregon Supreme Court.²¹⁰

The Court held that “the Constitution’s *Due Process Clause* forbids a State to use a punitive damages award to punish a defendant for [an] injury that it inflicts upon nonparties . . . those who are, essentially, strangers to the litigation.”²¹¹ This holding, as Justice Breyer acknowledged, was a new interpretation of the Due Process Clause.²¹² It was also an interpretation likely to confuse state courts, as Justice Breyer’s opinion further explained that evidence of harm to nonparties *could* be introduced in order to show that the defendant’s conduct was sufficiently “reprehensible” to justify an award of punitive damages. In dissent, Justice Stevens outlined the problem:

[T]he majority relies on a distinction between taking third-party harm into account in order to assess the reprehensibility of the defendant’s conduct—which is permitted—and doing so in order to

²⁰⁸ 538 U.S. 408 (2003).

²⁰⁹ 517 U.S. 559 (1996).

²¹⁰ See *Philip Morris USA v. Williams*, 549 U.S. 346, 357-58 (2007). On remand, the Oregon Supreme Court declined to reduce or reconsider the damages award, finding that there had been independent state law grounds for rejecting the jury instruction requested by Philip Morris. *Williams v. Philip Morris, Inc.*, 176 P.3d 1255, 1260 (Or. 2008), *cert. granted*, 128 S. Ct. 2904 (2008). This decision, arguably a “provocation to the United States Supreme Court,” led the Supreme Court to grant certiorari again, and in December 2008, the Supreme Court heard arguments in the case for the third time. Anthony J. Sebok, *The Unusual Story of Williams v. Philip Morris, and Its Third Trip to the Supreme Court—Including Some Predictions About What the Court Will Do This Time*, FINDLAW, Dec. 16, 2008, available at <http://writ.news.findlaw.com/sebok/20081216.html>. However, on March 31, 2009, the Supreme Court unexpectedly dismissed the writ of certiorari as improvidently granted. *Philip Morris USA, Inc. v. Williams*, 129 S. Ct. 1436 (2009).

²¹¹ *Williams*, 549 U.S. at 353 (emphasis added).

²¹² *Id.* at 356-57 (“We did not previously hold explicitly that a jury may not punish for the harm caused by others. But we do so hold now.”). As Michael Rustad notes, the conclusion of *Williams* appears to run contrary to the Court’s previous statement in *BMW v. Gore* that “evidence that a defendant has repeatedly engaged in prohibited conduct while knowing or suspecting that it was unlawful would provide relevant support for an argument that strong medicine is required to cure the defendant’s disrespect for the law.” Michael L. Rustad, *The Supreme Court and Me: Trapped in Time with Punitive Damages*, 17 WIDENER L. J. 783, 820 (2008) (quoting *BMW of N. Am., Inc. v. Gore*, 517 U.S. 559, 576-77 (1996)).

punish the defendant “directly”—which is forbidden. This nuance eludes me.²¹³

The *Williams* decision has been characterized as just another step in the Supreme Court’s recent efforts to use the Due Process Clause to place both procedural and substantive limits on awards of punitive damages. To some extent, that is unquestionably true. Previous cases had suggested that the Court’s conception of damages was based on a model of “one-on-one torts” that discounted broader social or deterrence-based goals that of punitive damages could serve. *Williams* appears to extend that approach, taking “further steps in limiting the remedial goals punitive damages could serve” with its narrow focus on punishment for the particular facts of the given case.²¹⁴ But were there other factors—factors unique to the tobacco-related context of the case—that caused the Court to move its punitive damages jurisprudence in this particular direction?

There are several reasons why the convoluted result of *Williams* may have been attributable to the fact that the case involved a smoking-related claim. First, the issue of assumption of risk, which has “hovered like a storm cloud over every smoker’s claim against the tobacco companies,”²¹⁵ seems to have played a particularly significant role. Keith Hylton more specifically refers to the issue in *Williams* as one of “heterogeneity.”²¹⁶ In short, the majority seemed particularly concerned that punishing Philip Morris for harm caused to other, non-plaintiff smokers would be unfair to Philip Morris because those other cases may have been significantly different (heterogeneous) from this one. Smoking-related cases raise these heterogeneity issues in abundance, but assumption of risk seems to have been of particular concern to the Court. Would the other, nonparty smokers have chosen to smoke anyway with full knowledge of the dangers? Should they be assigned some portion of the fault for continuing to smoke after the dangers of smoking were known? Justice Breyer highlighted this concern in his decision, writing:

²¹³ *Williams*, 549 U.S. at 360 (Stevens, J., dissenting).

²¹⁴ Allen, *supra* note 205, at 365; see Rustad, *supra* note 212, at 803-04 (“The Court’s latest decision in *Philip Morris USA v. Williams* was the last rites, if not the obituary, for the crimtort paradigm. The Court’s punitive damages cases, taken as a whole, are a step backward into the jurisprudence of the eighteenth and early nineteenth centuries.” (citations omitted)).

²¹⁵ Robert L. Rabin, Review Essay, *Some Thoughts on Smoking Regulation*, 43 STAN. L. REV. 475, 493 (1991).

²¹⁶ Hylton, *supra* note 205, at 19.

[A] defendant threatened with punishment for injuring a nonparty victim has no opportunity to defend against the charge, by showing, for example in a case such as this, that the other victim was not entitled to damages because he or she knew that smoking was dangerous or did not rely upon the defendant's statements to the contrary.²¹⁷

Yet, at least in terms of public health cases, tobacco-related cases are particularly unusual in the degree to which they raise the issue of assumption of risk. In many (though not all) public health cases, it would be absurd to argue that the plaintiff had voluntarily chosen to encounter the risk. For example, imagine a lawsuit involving a company that had secretly polluted the local water supply, causing hundreds of people to become sick. In such a case, there could be no argument that anyone had *chosen* to risk illness (unlike the argument that many people *choose* to smoke, knowing the risks). In such a case, “[c]omplete deterrence of the offender’s conduct is the socially appropriate goal . . . [and] there is no reason *on deterrence grounds* to limit aggregation [i.e., basing punitive damages in part on harm caused to non-parties] because of the problem of claim heterogeneity.”²¹⁸ Thus, the fact that *Williams* was a smoking-related case may have led the Supreme Court to extend Due Process limitations on punitive damages, even though the concern raised by Philip Morris is inapplicable to a wide variety of other contexts.²¹⁹

Secondly, the problem identified by Philip Morris in its appeal—that it was being unfairly punished for acts directed to non-parties in the litigation—is a much more acute issue in tobacco cases than in other types of litigation. If juries actually tried to punish Philip Morris for similar harms suffered by non-parties, the results would be astronomical awards—perhaps along the lines of the \$145 billion punitive damages verdict in *Engle*. If Philip Morris’s conduct is generically described as defrauding smokers by lying about the harmfulness of cigarettes, there are literally millions of Oregonians who would have claims similar to Williams’s. The unparalleled scope of

²¹⁷ *Williams*, 549 U.S. at 353-54.

²¹⁸ Hylton, *supra* note 205, at 20.

²¹⁹ As Hylton writes, the argument about heterogeneity would have been “preposterous on its face” if made by the defendant in *State Farm. Id.* at 21. State Farm could not have argued that “there were some victims of bad faith conduct in the insurance market that did not mind being victimized in this way at all.” *Id.* Yet the rule in *Williams* will operate to shield defendants like State Farm from higher punitive damages in the future.

Philip Morris's fraud (and that of the other tobacco companies) created the possibility for massive punitive damages verdicts that would run counter to the Supreme Court's ongoing efforts to rein in such awards as well as its previously-expressed concern (or deference to Congress's concern) for the tobacco industry's important role in the national economy.²²⁰ It seems that the plaintiff's attorneys were put in a bind—in order to argue that it was appropriate to exceed a single-digit ratio between punitive and compensatory damages in this case, they had to emphasize the fact that Philip Morris had “engaged in one of the longest running, most profitable, and deadliest frauds in the annals of American commerce.”²²¹ By emphasizing the scope of the fraud, however, they may have inadvertently highlighted the potential for nearly limitless punitive damages awards in the future.

The Supreme Court's attempt to finesse these two competing concerns—recognizing the reprehensibility of the tobacco industry's conduct while at the same time protecting it from crippling punitive damages awards—may explain the Court's decision to rule on grounds that allowed it to dodge the question of the single-digit ratio. The role of Justice Breyer may have been particularly significant. Justice Breyer has been a reliable vote to constrain the scope of punitive damages. He was in the majority in *State Farm, Gore, Cooper Industries*,²²² and other cases supporting Due Process limits on punitive damages. At the same time, he has consistently been in the dissent on cases that sought to limit regulation of the tobacco industry, including *Brown & Williamson* and *Lorillard Tobacco Co. v. Reilly*. (Breyer was not on the Court when it decided *Cipollone*.) In particular, Justice Breyer's dissent in *Brown & Williamson* went out of its way to highlight in detail the tobacco industry's history of deception regarding the addictiveness of nicotine.²²³ It seems that Justice Breyer was reluctant to write a decision that would minimize the severity of the tobacco industry's conduct, and yet he also had serious overarching concerns about the role of unconstrained punitive damages. The result was a decision in *Williams* that not only avoided addressing how Philip Morris's conduct fit into *State*

²²⁰ *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 138-39 (2000).

²²¹ Brief for Respondent at 1, *Philip Morris USA v. Williams*, 549 U.S. 346 (2007) (No. 05-1256).

²²² *Cooper Indus., Inc. v. Leatherman Tool Group, Inc.*, 532 U.S. 424, 425 (2001).

²²³ 529 U.S. at 172-74 (Breyer, J., dissenting).

Farm's suggested guideposts for punitive damages, but it also (unlike previous punitive damages decisions) studiously avoided any detailed discussion of the facts of the case.²²⁴ The decision reads more like a theoretical discussion that even avoids applying its holding to the facts of the case. Nowhere in the decision does Justice Breyer specifically say whether the jury instruction proposed by Philip Morris (which had been rejected) should have been accepted or what a proper jury instruction might look like.²²⁵ Instead, it merely provided the vague directive that states must "provide *some* form of protection" to ensure that punitive damages would not be used to punish for harm to non-parties.²²⁶

2. Public Health Impact

With regard to punitive damages, the impact of tobacco-related cases, and *Williams* in particular, is a bit harder to predict. As long as the tobacco-related cases remain at the forefront of the justices' minds, it is likely that at least some (and, for now, a majority) of the justices will decline to impose a hard-and-fast single-digit ratio limit on punitive damages. At the same time, a majority of the justices continue to have intellectual problems with punitive damages awards that they view as unpredictable, unconstrained, and unconstitutionally unfair. For this reason, there may be more decisions like *Williams* that attempt to split the difference but instead end up causing more confusion.

Is this result better or worse than a hard-and-fast rule limiting punitive damages? In part, that will depend on how lower courts choose to apply *Williams*. It is certainly possible, however, that *Williams* provides the more problematic rule from a public health perspective. Indeed, attorneys for corporate defendants are optimistic that *Williams* may not only reduce punitive damages awards, but it may eliminate them

²²⁴ The entire discussion of the facts of the case is limited to three brief sentences. *Williams*, 549 U.S. at 349-50; see Heather R. Klaasen, *Punishment Defanged: How the United States Supreme Court has Undermined the Legitimacy and Effectiveness of Punitive Damages* [Philip Morris USA v. Williams, 127 S. Ct. 1057 (2007)], 47 WASHBURN L.J. 551, 569 (2008) ("Even though the Court's decisions in *Browning-Ferris*, *Haslip*, *TXO*, *Cooper Industries*, *Gore*, and *Campbell* included extensive factual analysis, the Court ignored the substantive facts of *Philip Morris*.").

²²⁵ See 549 U.S. at 364 (Ginsburg, J., dissenting) ("The Court ventures no opinion on the propriety of the charge proposed by Philip Morris, though Philip Morris preserved no other objection to the trial proceedings.").

²²⁶ *Id.* at 357 (majority opinion).

altogether. As one attorney who represents both Ford and Wal-Mart put it, the ruling that punitive damages cannot be used to punish defendants for harm to non-parties “gives defendants not only the ability to challenge punitive[] [damages] as excessive but an avenue to eliminate or prevent such a verdict in the first place.”²²⁷ Early applications of *Williams* support this prediction. In *Moody v. Ford Motor Co.*, for example, a U.S. District Court granted Ford’s motion for a new trial in a case involving a Ford Explorer that rolled over on the highway.²²⁸ The driver died of asphyxia when the roof of the Explorer collapsed and prevented him from breathing. In granting the motion for a new trial, the judge suggested that after *Williams*, Oklahoma’s punitive damages statute might be facially unconstitutional. The statute in question provided that punitive damages could be awarded only if the plaintiff has established that the defendant “has been guilty of reckless disregard for the rights of others.”²²⁹ Judge Eagan wrote:

The reckless disregard standard under Oklahoma law [Okla. Stat. tit. 23, § 9.1] is based on harm to others, not just harm to the plaintiff. . . . Under *Philip Morris*, Ford has a due process right to ensure that the jury uses punitive damages to punish it for harm suffered by plaintiff only, not all third parties that may have been injured in a rollover accident. The Court would consider a limiting instruction based on *Philip Morris*, but there is a strong possibility that this would be contrary to the legislative intent and may void any award of punitive damages under section 9.1.²³⁰

²²⁷ Margaret Cronin Fisk, *Punitive Damages Shrink as Court Reins in Lawyers*, KAN. CITY DAILY REC., Jan. 21, 2008 (quoting Ted Boutrous of Gibson, Dunn & Crutcher).

²²⁸ 506 F. Supp. 2d 823, 849, 851 (N.D. Okla. 2007).

²²⁹ OKLA. STAT. ANN. tit. 23, § 9.1 (West 2008).

²³⁰ *Moody*, 506 F. Supp. 2d at 849 n.14. Indeed cases in several states suggest that the *only* legitimate function of punitive damages is a public purpose, focused on the impact that the misconduct has had on the public generally. *See, e.g.*, *Fabiano v. Philip Morris, Inc.*, 862 N.Y.S.2d 487, 490 (App. Div. 2008) (“A claim for punitive damages may, of course, be rooted in personal injury, but for such a claim to succeed the injury must be shown to be emblematic of much more than individually sustained wrong. It must be shown to reflect pervasive and grave misconduct affecting the public generally, to, in a sense, merge with a serious public grievance, and thus merit punitive, indeed quasi-criminal sanction.” (citations omitted)) (reversing award of punitive damages in smoking-related cases because public purpose of punishing tobacco industry misconduct had already been served by the payment provision of the Master Settlement Agreement); *Moskovitz v. Mt. Sinai Med. Ctr.*, 635 N.E.2d 331, 343 (Ohio 1994) (“The purpose of punitive damages is not to compensate a plaintiff, but to punish and deter certain conduct.”). *Williams* provides an argument for eliminating all punitive damages awards in these states.

Even without completely barring awards of punitive damages, the *Williams* rule may prove to be more problematic than a hard-and-fast ratio limiting punitive damages. A ratio limit may be problematic in certain cases, particularly cases where compensatory damages are low or the misconduct was exceedingly profitable or hard to detect.²³¹ The *Williams* holding, however, more directly weakens the ability of punitive damages to act as an effective deterrent in *all* mass tort cases,²³² thereby both jeopardizing public health and undercutting a major argument that litigation has an appropriate role to play in the public health context. Michael Rustad explains:

The Court's "other bad acts" rule of evidence will have the most impact in mass product liability cases where a single defect or failure to warn will result in a portfolio of claims. If this rule had been applicable in the Ford Pinto cases, evidence of other fatalities associated with crash-induced fuel leakage would have been admissible for the purposes of determining reprehensibility, but would not have been admissible to set the punitive damages award. . . . [C]orporate wrongdoers will be tempted to perform a socially harmful cost-benefit analysis deciding that it is profitable to risk the consuming public, especially where the risk of detection is low.²³³

Thus, in mass tort cases, if juries are not allowed to consider the impact on non-parties when fashioning punitive damages awards, the defendants will almost by definition be under-deterred (because not nearly all of those harmed by the conduct will bring their own lawsuits).²³⁴ Adding to this problem is the

²³¹ See *Mathias v. Accor Econ. Lodging, Inc.*, 347 F.3d 672, 677 (7th Cir. 2003) (Posner, J.) ("If a tortfeasor is 'caught' only half the time he commits torts, then when he is caught he should be punished twice as heavily in order to make up for the times he gets away."); see also A. Mitchell Polinsky & Steven Shavell, *Punitive Damages: An Economic Analysis*, 111 HARV. L. REV. 869, 874 (1998) ("When an injurer has a chance of escaping liability, the proper level of *total damages* to impose on him, if he is found liable, is the harm caused multiplied by the reciprocal of the probability of being found liable.").

²³² See Michael L. Rustad, *The Uncert-Worthiness of the Court's Unmaking of Punitive Damages*, 2 CHARLESTON L. REV. 459, 494 (2008).

²³³ *Id.* at 497, 500. In upholding the amount of a punitive damages award in one of the Ford Pinto cases, the California Appeals Court wrote that "[u]nlike malicious conduct directed towards a single specific individual, Ford's tortious conduct endangered the lives of thousands of Pinto purchasers." *Grimshaw v. Ford Motor Co.*, 174 Cal. Rptr. 348, 388 (Ct. App. 1981). After *Williams*, this appears to be an invalid basis for upholding the size of a punitive damages award.

²³⁴ See Hylton, *supra* note 205, at 31 ("[T]he only sturdy reason that can be discerned for the Court's decision [in *Williams*] is the notion that every person not before the court is capable of bringing his own lawsuit and having it decided on the basis of the issues in his case. While this sounds fine in theory, it is far from what happens in real life. The truth is that relatively few people bring lawsuits."); Klaasen,

fact that companies with deep pockets—having learned from the model of the tobacco industry—can deter lawsuits by making any suit against the company an extremely expensive (and therefore risky) endeavor.²³⁵ Without the potential for punitive damages serving as an effective deterrent, there is little doubt that some companies will choose to endanger the public's health in their pursuit of profit.²³⁶

IV. CONCLUSION

The legal developments catalyzed by tobacco decisions—an expansive preemption doctrine, limits on class certification, and constraints on punitive damages—have severely weakened the ability of personal injury litigation to effectively deter corporate misconduct and protect public health. On the regulatory side, legal decisions shielding the tobacco industry from regulation have opened the door to weakening other important public health regulatory regimes.

In many of the cases discussed above, the unusual context of tobacco litigation—a huge volume of cases (and potential cases) at the intersection of intense cultural and political cross-currents—may have shaped the contours of the decisions. These decisions then served to reshape legal paradigms that were subsequently applied across the field of public health law, even when those context-dependent considerations were absent. In this manner, the “exceptionalism” of tobacco litigation has significantly influenced the development of public health law. Each one of these doctrinal strands discussed above was clearly driven by other broader forces as well. Cause and effect is virtually impossible to establish, given the general movement of the courts towards more conservative positions over the time

supra note 224, at 576-77 (“In fashioning an appropriate measure of deterrence, the jury must be allowed to consider how many other persons the defendant's conduct endangered so that the jury's interest in deterrence has an objective goal: the cost of the misconduct should be greater than or equal to the benefit.”).

²³⁵ Sara Guardino and Richard Daynard have argued that a defendant's “secondary reprehensibility” in obstructing litigation should also be taken into account when calculating punitive damages. Guardino & Daynard, *supra* note 27, at 36-38.

²³⁶ See *Ciraolo v. City of New York*, 216 F.3d 236, 243 (2d Cir. 2000) (Calabresi, J., concurring) (“When the perceived benefits of an activity accrue to the actor, but some significant part of the costs is borne by others, the cost-benefit analysis will necessarily be distorted. In such a case, the actor will have an incentive to undertake activities whose social costs exceed their social benefits. In other words, the actor will not be adequately deterred from undesirable activities. And society will suffer.”).

period examined. Nonetheless, the discussion above suggests that the centrality of tobacco litigation has itself been a significant factor influencing doctrinal development.

The remaining question is the normative issue of how the courts should have addressed tobacco cases—and how they should do so in the future. Here, there are at least three options. First, one could conclude that the cases discussed above were simply wrongly decided and constituted unwarranted departures from past precedent. In *Brown & Williamson*, for example, a strong argument could be made that *Chevron* deference called for a more deferential approach that would have sustained the FDA's actions. This viewpoint would suggest that there is no cause to treat tobacco differently from other products; judges should ignore the uniqueness of the cultural/social/political context and focus solely on the application of precedent.

Second, one could argue that the tobacco cases were correctly decided, but were justified by their unique context and thus should not be applied and extended in non-tobacco cases. In this view, the Supreme Court may have been correct in denying the FDA regulatory authority over tobacco products, but that decision should have been viewed as a one-time exception to the general rules of administrative deference that was justified by the unique political and cultural history of tobacco regulation. This is essentially an argument for tobacco exceptionalism in the broader sense of the word; a claim that a unique set of rules should apply to tobacco cases.

The third possible position is that tobacco cases are just one example of a type of litigation that does not fit well within the current public health law paradigm. When one industry has (allegedly) caused harm on a scale so massive that litigation of all claims would overwhelm the tort system and destroy the industry in question, the typical rules simply cannot be applied. Many of the legal developments discussed above must be seen as having occurred in the shadow of the “asbestos crisis” which, in the words of the Supreme Court, constituted an “elephantine mass [that] . . . defies customary judicial administration and calls for national legislation.”²³⁷ Since far more people die from tobacco-related disease every year than have died from asbestos exposure in the past forty years, it is no wonder that the courts have looked for ways to

²³⁷ *Ortiz v. Fibreboard Corp.*, 527 U.S. 815, 821 (1999).

keep tobacco cases from overwhelming their dockets.²³⁸ Furthermore, beyond the sheer volume of cases, others have argued that since “tobacco is a product bound up with a series of overlapping and often conflicting philosophical, economic, social, political and religious values,” the resolution of such a complex issue is properly left to the legislative process.²³⁹ Thus, the inability of the courts to coherently address the issue of tobacco may simply reflect the fact that some issues are simply too complex for judicial administration.²⁴⁰

While both the size and the complexity of the issue of tobacco call out for comprehensive legislative action, this conclusion fails to provide any guidance as to how the courts should act in the interim. Congress recently passed the Family Smoking Prevention and Tobacco Control Act. It remains to be seen how effective this new Act will be in reducing tobacco-related death and disease.²⁴¹ But, as is relevant here, the Act does not prohibit future litigation and does not give any new guidance to courts as to how they should address tobacco-related cases. Since simply rejecting jurisdiction over tobacco cases is not a viable option, how should the courts address future tobacco cases?

A full resolution of this difficult question is beyond the scope of this Article, but is a ripe subject for discussion by legal scholars, judges, and public health experts. Indeed, the failure of the courts to address this issue head-on is a major source of the problem discussed in this Article. Instead of adopting a clear policy on tobacco cases—that they either will or will not be treated differently from other public health concerns—the courts have stumbled towards a third path: they purport to apply the law in a facially neutral manner, but the unique exigencies of tobacco litigation inevitably influence the outcomes. As a result, tobacco cases are permitted to exert an

²³⁸ Vinicius C. Antao et al., *Asbestosis Mortality in the United States: Facts and Predictions*, 66 J. OCCUP. & ENVTL. MED. 335 (2009) (finding that there were 25,564 asbestosis deaths in the U.S. from 1968 through 2004).

²³⁹ Turley, *supra* note 23, at 435.

²⁴⁰ Cf. OREY, *supra* note 19, at 367 (“[U]sing individual court cases to resolve such a complex issue—a legal product that causes grievous harm to millions of people’s health when used as intended—makes no sense.”).

²⁴¹ The Congressional Budget Office estimated that the Senate version of the bill (nearly identical to the final Act) would reduce youth smoking by eleven percent over the next decade, and would reduce adult smoking by two percent over the same period. CONG. BUDGET OFFICE, CONGRESSIONAL BUDGET OFFICE COST ESTIMATE, S. 982, FAMILY SMOKING PREVENTION AND TOBACCO CONTROL ACT 6 (2009), available at <http://www.cbo.gov/ftpdocs/102xx/doc10254/s982.pdf>.

outsized and troublesome influence on the rest of public health law.

Until these questions are resolved, tobacco litigation will likely continue to produce anomalous outcomes driven by the unusual pressures of smoking-related cases. Just like the cigarettes themselves, tobacco-related decisions should come with a warning label: CAUTION: MAY BE HAZARDOUS TO PUBLIC HEALTH LAW.