

CONNECTICUT LAW REVIEW

VOLUME 41

DECEMBER 2008

NUMBER 2

Article

The Synergy of Toxic Tort Law and Public Health: Lessons From a Century of Cigarettes

JEAN MACCHIAROLI EGGEN

Toxic torts is a relatively new area of the law, but its seeds were sown a century ago with developments in modern culture. The design, manufacture, and marketing of the cigarette constituted one such development, one with far-reaching legal consequences which continue to challenge the legal system today. This Article is built around Allan M. Brandt's 2007 public health history of cigarettes, The Cigarette Century. It uses Brandt's book as a stepping stone to a broader discussion of current critical issues in toxic tort law. The Article begins with a review of the book, then moves into a discussion of the ways in which the watershed events in law and science that surrounded the cigarette in the twentieth century have shaped the major legal issues in toxic tort law today. In conducting this analysis, I focus on the three major areas of toxic tort law: scientific causation, preemption, and mass toxic tort litigation. I demonstrate that the public health history of cigarettes offers many lessons for judges, attorneys, and legal scholars in addressing the most troubling issues that arise in toxic tort litigation.

ARTICLE CONTENTS

I. INTRODUCTION	563
II. <i>THE CIGARETTE CENTURY</i> : SCIENCE AND POPULAR CULTURE IN THE SERVICE OF A PRODUCT	566
A. SOCIAL FACTORS.....	567
B. THE RISE OF THE “NEW EPIDEMIOLOGY”	570
C. THE ROUGH ROAD TO REGULATION.....	575
D. THE ERA OF TOBACCO LITIGATION.....	580
E. GLOBALIZATION	584
III. PERSPECTIVES ON CHRONIC ILLNESS AND TOXIC TORTS	586
A. SCIENTIFIC INVESTIGATION AND CHRONIC ILLNESS AT MID-CENTURY.....	586
B. THE SCIENCE OF TOXIC TORT LITIGATION IN HISTORICAL CONTEXT	589
IV. PREEMPTION AND THE INTERACTION OF PUBLIC AND PRIVATE LAW.....	594
V. MASS TORT LITIGATION AND PUBLIC HEALTH GOALS	600
VI. CONCLUSION.....	607



The Synergy of Toxic Tort Law and Public Health: Lessons From a Century of Cigarettes

JEAN MACCHIAROLI EGGEN*

"A lawyer without history . . . is a mechanic."
-Sir Walter Scott, 1815

I. INTRODUCTION

The study and practice of law are becoming increasingly interdisciplinary. Toxic tort law embodies this trend with its merger of law and science. Toxic tort litigation typically requires attorneys and judges to display a sophisticated understanding of science, rendering legal doctrine only part of a complicated picture that focuses on the interplay of federal and state regulations with the common law. Indeed, toxic tort law represents the quintessential merger of public regulation and private law.¹ Rarely does a tort action involving toxic exposures begin and end with the common law. Rather, most toxic litigation typically invokes an array of regulatory measures based upon scientific studies that have emerged over time with varying degrees of reliability. The result has been that both toxic tort law and the regulation of toxic substances have evolved in unpredictable and synergistic ways.²

Nowhere is the tension between public and private law more evident than in the area of consumer products, due to the availability, desirability, and potential hazard of many products to the consuming

* Professor of Law, Widener University School of Law; member, Widener Health Law Institute. The author wishes to thank Laura Ray and John Culhane for their helpful suggestions on an earlier draft of this article, and Janet Lindenmuth for technical support.

¹ See Jean Macchiaroli Eggen, *Toxic Torts at Ground Zero*, 39 ARIZ. ST. L.J. 383, 385 (2007) ("Toxic torts, in contrast to traditional torts, consistently present mixed issues of private and public law."); Allan Kanner, *Toxic Tort Litigation in a Regulatory World*, 41 WASHBURN L.J. 535, 536 (2002) (discussing "the importance of a continuing role for toxic tort litigation in a world increasingly dominated by the public law").

² One classic example of this synergy relates to the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), 42 U.S.C. §§ 9601–9675 (2000), known as the "Superfund" statute, enacted by Congress in 1980. Congress considered, but expressly declined to include, provisions for compensation of persons who claimed injuries from releases of hazardous substances into the environment. Instead, such claimants were left to seek whatever remedies may be available under the common law. *Id.* § 9659(h) (2000). CERCLA contains a citizens' suit provision, *id.* § 9659, which provides only for injunctive relief and civil penalties. See *id.* § 9659(c) (2000) ("The district court shall have jurisdiction . . . to order such action as may be necessary to correct the violation, and to impose any civil penalty provided for the violation.").

public. In *The Cigarette Century*,³ Allan M. Brandt, the Amalie Moses Kass Professor of the History of Medicine at Harvard Medical School and professor in the Department of the History of Science at Harvard University,⁴ has written a comprehensive public health history of the paradigmatic American consumer product of the twentieth century. While other histories of tobacco⁵ and the tobacco industry⁶ have been published over the years, *The Cigarette Century*, a massive and well-documented 600-page tome, is unique in its intense focus on the broad public health impact and legal implications of the cigarette, a relatively late entry into the tobacco industry's arsenal of products, and in its author's status as a scholar of the history of public health. Brandt has analyzed a century of cigarette production, marketing, and litigation in the United States and, more recently, globally, and has concluded that the tobacco industry has perpetrated the "crime of the century" on the public.⁷

Although *The Cigarette Century* focuses exclusively on the tobacco industry, its value extends far beyond the legal and public health implications of a single product. Indeed, perhaps its greatest value is in illuminating the public health issues, and related legal issues, presented by toxic substances generally. The history of the cigarette embodies the developing tensions between the regulatory and judicial regimes, and the legal struggles sparked by the cigarette have served as a prototype for ongoing legal battles in other areas of toxic tort law.

Traditionally, tort law and public regulation have served separate purposes. Tort law is a remedial regime that exists to compensate persons who have suffered legally cognizable injuries.⁸ While compensation is its most frequently articulated goal, the tort system serves a complex collection of other policy goals. Chief among these goals is deterrence of future harmful conduct through restraints, financial or otherwise, imposed upon liable defendants by the judicial system. In contrast, regulation of potentially toxic substances principally has sought to prevent injuries from occurring in the first instance. Statutes such as the Toxic Substances Control Act,⁹ the Food, Drug and Cosmetic Act,¹⁰ and the Occupational

³ See generally ALLAN M. BRANDT, *THE CIGARETTE CENTURY: THE RISE, FALL, AND DEADLY PERSISTENCE OF THE PRODUCT THAT DEFINED AMERICA* (2007).

⁴ *The Cigarette Century: About the Author*, <http://www.cigarettecentury.com/author.html> (last visited Sept. 12, 2008).

⁵ See, e.g., IAIN GATELY, *TOBACCO: A CULTURAL HISTORY OF HOW AN EXOTIC PLANT SEDUCED CIVILIZATION* (2001); see also *SMOKE: A GLOBAL HISTORY OF SMOKING* (Sander L. Gilman & Zhou Xun eds., 2004) (examining the cultural history of smoking worldwide).

⁶ See generally RICHARD KLUGER, *ASHES TO ASHES: AMERICA'S HUNDRED-YEAR CIGARETTE WAR, THE PUBLIC HEALTH, AND THE UNABASHED TRIUMPH OF PHILIP MORRIS* (1996).

⁷ BRANDT, *supra* note 3, at 493.

⁸ Kanner, *supra* note 1, at 542.

⁹ Toxic Substances Control Act (TSCA), 15 U.S.C. §§ 2601–2692 (2000). TSCA includes a statement that "adequate authority should exist to regulate chemical substances and mixtures which

Safety and Health Act¹¹ exemplify federal regulatory efforts to prevent health or environmental hazards from causing harm. The regulatory approach is founded upon the aspirational notion of democratic decisions achieved through a governmental process that makes use of agency expertise of unimpeachable neutrality.¹² Yet, substantial tension exists between the role of the government and the role of the courts in matters related to toxic exposures. *The Cigarette Century* documents that tension in the context of the battle between the public health community and the tobacco industry.¹³ Cigarettes in many ways serve as a microcosm of the world of toxic torts, and Brandt has meticulously examined that microcosm.

This Article considers the legal lessons that the cigarette offers toxic tort litigation generally. Part II presents a general review of *The Cigarette Century* as a whole. Following Part II, the remainder of this Article focuses on the sections of the book most germane to toxic tort litigation today and the lessons that can be gleaned from examining one toxic tort in historical detail. Part III discusses Brandt's observations on the revolution in epidemiological science and public health policy in the middle of the twentieth century as they relate to our understanding of toxic tort law. This Article demonstrates that the legacy of that pivotal period in public health research continues to impact, for better or worse, current toxic tort litigation. Part IV examines another watershed event in cigarette history—labeling regulation and the United States Supreme Court's decision in *Cipollone v. Liggett Group Inc.*¹⁴ *Cipollone* has become a mainstay of the Supreme Court's product preemption jurisprudence, and this Article shows how that decision impacts toxic tort cases today. Part V addresses mass litigation and the role played by tobacco litigation and the 1998 Master Settlement Agreement in shaping current judicial views toward aggregative litigation. This Article concludes that understanding the ways in which the

present an unreasonable risk of injury to health or the environment, and to take action with respect to chemical substances and mixtures which are imminent hazards" *Id.* § 2601(b)(2).

¹⁰ Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301–399 (2000). One example of the many safety concerns addressed by the Act is the misbranding of food, drugs, and medical devices. *See id.* § 331(b) (prohibiting "[t]he adulteration or misbranding of any food, drug, device, or cosmetic in interstate commerce").

¹¹ Occupational Safety and Health Act, 29 U.S.C. §§ 651–678 (2000). Among the purposes and goals of the Act was "encouraging employers and employees in their efforts to reduce the number of occupational safety and health hazards at their places of employment, and to stimulate employers and employees to institute new and to perfect existing programs for providing safe and healthful working conditions . . ." *Id.* § 651(b)(1).

¹² *See* Kanner, *supra* note 1, at 543 (noting that the "[the agency's] job in the environmental area is to eliminate conflicts or strike balance, where possible, between economic growth and the environment"). Kanner argues that the tort system strikes a better balance in this area. *See id.* at 545 (contrasting the tort system to political and bureaucratic alternatives that are often influenced by narrow interest groups).

¹³ *See, e.g.,* BRANDT, *supra* note 3, at 211.

¹⁴ *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992).

events surrounding a century of cigarettes have shaped current toxic tort law is crucial to shaping the future.

II. *THE CIGARETTE CENTURY: SCIENCE AND POPULAR CULTURE IN THE SERVICE OF A PRODUCT*

Early in *The Cigarette Century*, Brandt reports that “[m]ore than one in five American adults still smoke regularly, and today tobacco still kills more than 435,000 U.S. citizens each year (more than HIV, alcohol, illicit drugs, suicide, and homicide *combined*).”¹⁵ The majority of the book is an effort to analyze and understand the contingencies that gave rise to those shameful statistics and that made tobacco one of the most significant consumer products of the twentieth century.¹⁶ Brandt summarizes his public-health approach to the subject as one that seeks “to layer temporally those forces that serve to explain the changing dynamics of tobacco use and the development of a massive pandemic in the twentieth century.”¹⁷ Brandt achieves this goal admirably, considering that the subject he tackles is as sprawling as the corporate tentacles of the tobacco industry he chronicles.

In contrast, Richard Kluger, in his excellent and comprehensive history of the tobacco industry published in 1996, *Ashes to Ashes*, was concerned more with the business and corporate history of tobacco.¹⁸ Kluger’s view of the business is focused and microscopic, and his book is an encyclopedic survey of the industry. *Ashes to Ashes* was published, however, prior to many of the important events that have occurred in the past decade. *The Cigarette Century* has the advantage of including those events. But more significantly, Brandt, as both an insider in the public health community and a historian, has added a new and valuable dimension to the ignominious story of the tobacco industry. His approach to the book as a whole combines fascinating historical observations of the watershed moments of public health history triggered by tobacco events with a strong measure of public health advocacy. Brandt’s *The Cigarette Century* is a prism through which attorneys, judges, and legal scholars can look and learn so as to shape the future of toxic tort law. It is therefore instructive to

¹⁵ BRANDT, *supra* note 3, at 13.

¹⁶ The cigarette is the most significant consumer product in toxic tort law. While I would argue that asbestos is the single most significant product in toxic tort law generally, the claimants in the vast majority of asbestos cases have been persons who were exposed in the workplace. In contrast, tobacco products are consumer products in the sense that the products were mass marketed to the general public. The result was that anyone could be exposed, either those actually consuming the product, or those persons in the proximity of the consumers.

¹⁷ BRANDT, *supra* note 3, at 13.

¹⁸ KLUGER, *supra* note 6, at xix. In the Foreword, Kluger states: “The question, then, is whether cigarette merchants are businessmen basically like any other, selling a product judged to be highly hazardous long after its usefulness to millions was well established . . . or are they moral lepers preying on the ignorant, the miserable, the emotionally vulnerable, and the genetically susceptible?” *Id.*

begin with a general review of the book and its contents before embarking upon a discussion of its special relevance to the law of toxic torts.

A. *Social Factors*

Brandt sets up his discussion of the public health history of cigarettes by placing the events in their social context. He intertwines his narrative of the social context and symbology of cigarettes in the twentieth century with the broadening quest of the public health community to uncover and comprehend the threat cigarettes pose. Thus, Brandt begins by identifying the social factors that gave rise to the public health crisis of smoking. The first of these factors was the establishment, and subsequent dissolution, of the American Tobacco Company,¹⁹ known as the “Tobacco Trust.”²⁰ Brandt observes that following the United States Supreme Court’s 1911 decision holding that the Tobacco Trust violated the federal Sherman Antitrust Act and ordering the dissolution of the American Tobacco Company,²¹ the industry merely circled its wagons and established a unified and secretive monolithic front.²² This move enabled the industry to promote and market its product for a century with virtually no governmental intrusion.

The second social factor was the transformation within American society from moral opposition to smoking to unprecedented enthusiastic acceptance of a product with known hazards.²³ When American society began to shed the Victorian attitudes that were embodied in the temperance movement, youth and women became avid consumers of cigarettes.²⁴ For America’s youth, the cigarette represented adulthood and rebellion; for women, freedom from the strictures of a society that had prevented them

¹⁹ At its inception, the American Tobacco Company accounted for ninety percent of all sales of cigarettes in the United States. BRANDT, *supra* note 3, at 34.

²⁰ The Tobacco Trust operated as a monopoly, restricting competition, consolidating the industry, and developing a marketing network. *Id.* at 34–37.

²¹ *United States v. Am. Tobacco Co.*, 221 U.S. 106, 181–82, 187–88 (1911).

²² Brandt notes that in the immediate aftermath of this ruling, the industry continued to operate in essentially the same fashion. BRANDT, *supra* note 3, at 41–42 (“Dissolving the monopoly merely put an oligopoly in its place.”).

²³ This transformation occurred as a result of several agents acting in concert. In the early years of the twentieth century, American society was in the clutches of a temperance movement that equated tobacco with alcohol. *Id.* at 45–46. As a result, antismoking organizations pressed for protections for minors, restrictions on smoking in public places, and bans on women smoking. One publication reported an alleged study that demonstrated an association between juvenile smoking and juvenile delinquency. *Id.* at 47 (quoting HENRY FORD, *THE CASE AGAINST THE LITTLE WHITE SLAVER: VOLUME I, II, III & IV* 29 (1916)). An early movement proclaiming the rights of nonsmokers sought restrictions on smoking in restaurants and other public places. *Id.* at 49. In 1908, an ordinance was passed that prohibited women from smoking in public. *Id.* at 57. Brandt states: “Cigarette smoking among young women was often viewed by critics as the first step down a slippery path of moral decline that led to drinking, petting, and ‘other’ sexual behavior.” *Id.* at 58.

²⁴ *Id.* at 57.

from experiencing full equality.²⁵ Its appeal was that it represented “virtually all things to all people.”²⁶

The third social factor Brandt examines was the industry’s development of a sophisticated marketing and public relations machine. The industry did not hesitate to take full advantage of the shifting cultural landscape to build its product into the preeminent leisure consumer product.²⁷ It did so, according to Brandt, through a campaign of advertising and promotion designed to lead the consuming public to believe that it had chosen to smoke without undue commercial influence. Brandt’s position is that the tobacco industry manipulated public attitudes and knowledge in such a way as to deprive the consuming public of important facts regarding the health hazards of its products and to associate cigarette smoking with desirable cultural images, such as modernity, acceptance, and attractiveness.²⁸

The conjunction of these three social factors allowed the industry to embrace and promote the concept of free choice, or “consent,” to manipulate the consuming public; this concept would have important implications for both regulation and tort litigation. The public was lured into believing that it had voluntarily chosen to smoke and had not been induced by advertising or, as later scientific studies demonstrated, become addicted. This “engineering of consent”²⁹ was to remain a key component of the industry’s strategy for the promotion of cigarettes through most of the twentieth century.

The notion that smoking was a choice freely made by consumers went a long way toward explaining regulators’ hands-off approach to tobacco

²⁵ Brandt observes that the antismoking movement early in the twentieth century “paradoxically made [the cigarette] a powerful symbol of modernity and burnished its appeal.” *Id.* at 67.

²⁶ *Id.* at 100.

²⁷ “The triumph of the cigarette did not occur by serendipity. Even as smoking seemed to fit with a modern consumer age, the very development of consumption was carefully and artfully constructed by powerful corporations with extensive resources.” *Id.* at 67.

²⁸ The industry’s aggressive advertising campaigns took full advantage of the emerging field of psychology in shaping public opinion. *See id.* at 77–78 (“The public must be given ideas as to what it *should* like The old sales bywords ‘know your customer’s needs’ have been remolded to ‘know what your customer should need and then educate him on those needs.’”). One pervasive advertising technique was to encourage consumers, particularly women, to smoke instead of snacking, so as to maintain a “slender figure.” *Id.* at 72 (citing ROBERT SOBEL, *THEY SATISFY: THE CIGARETTE IN AMERICAN LIFE* 101 (1978)). Brandt describes a 1928 ad for American Tobacco’s Lucky Strike brand—part of a broader ad campaign in the same vein—that showed the famed aviator Amelia Earhart and included the statement, “‘For a Slender Figure—Reach for a Lucky Instead of a Sweet.’” *Id.* (citing ROBERT SOBEL, *THEY SATISFY: THE CIGARETTE IN AMERICAN LIFE* 101 (1978)). Not only did the ad invoke the fashionable figure of the day, but it also made use of a celebrity testimonial to promote the product.

²⁹ The source of this phrase was Edward Bernays, Sigmund Freud’s nephew, who came to the United States and emerged as one of the first public relations experts. *Id.* at 80–81. Bernays took a position with American Tobacco in the late 1920s and launched the campaign that he called “engineering of consent.” *Id.* at 81, 87–88.

products.³⁰ American public opinion has remained equally hands-off, endorsing the right of adults to choose whether or not to smoke.³¹ Moreover, the tobacco industry came to rely upon assumption of the risk as a standard defense—and a largely successful one—in personal injury lawsuits brought by smokers.³² Philip Morris USA has incorporated a version of assumption of the risk into its public position on smoking and health, currently set forth on its web site, which encourages smokers to make their own choices:

There is no safe cigarette. Philip Morris USA agrees with the overwhelming medical and scientific consensus that cigarette smoking causes lung cancer, heart disease, emphysema and other serious diseases in smokers. Smokers are far more likely to develop serious diseases than non-smokers.

These have been, and continue to be, the messages of the U.S. Surgeon General and public health authorities worldwide. Smokers and potential smokers should rely on these messages when deciding whether or not to smoke.³³

The issues of consent and assumption of the risk reflect the complex responses of the public to perceived risks, responses related to numerous factors, not merely mathematical risks.³⁴

Brandt's discussion of the social factors related to smoking during the twentieth century supports his position that the tobacco industry operated out of self-interest and disregard for the health of the entire population, both consumers of cigarettes and nonsmokers exposed to their smoke. Few would dispute this assessment in a long-term sense, although other commentators have examined the industry through a more neutral lens.³⁵

³⁰ See *infra* Part II.C.

³¹ Robert A. Kagan & William P. Nelson, *The Politics of Tobacco Regulation in the United States*, in REGULATING TOBACCO 11, 35 (Robert L. Rabin & Stephen D. Sugarman eds., 2001) ("There is no sign that most Americans wish to prohibit the manufacture and sale of tobacco products, except for sales to juveniles . . .").

³² See, e.g., Glenn Collins, *Cigarette Makers Win Verdict in Suit by a Smoker's Family*, N.Y. TIMES, Aug. 24, 1996, at A8, available at LEXIS, News Library, NYT File (explaining that an Indiana jury placed blame for injuries on the plaintiff because he made a choice to smoke with full knowledge of the hazards); Milo Geyelin, *RJR's Tobacco Unit Wins a Big Victory: Jury Clears It of Blame in Smoker's Death—Wall Street Had Scrutinized Florida Trial as Signal On Future Litigation*, WALL ST. J., May 6, 1997, at A3, available at LEXIS, News Library, WSJNL File (describing a Florida jury's placing of blame for injuries on the plaintiff, who had begun smoking at age 15).

³³ Philip Morris USA, http://www.philipmorrisusa.com/en/cms/Products/Cigarettes/Health_Issues/Cigarette_Smoking_and_Disease/default.aspx (last visited Oct. 22, 2008).

³⁴ See John Slade, *Marketing Policies*, in REGULATING TOBACCO 72, 74–75 (Robert L. Rabin & Stephen D. Sugarman eds., 2001) (discussing studies on the public's perception of risk).

³⁵ For example, in *Ashes to Ashes*, Kluger focused to a large extent on the entrepreneurial nature of the early tobacco executives and their efforts in developing a large multinational industry. See KLUGER, *supra* note 6 (describing those individuals responsible for the development of the tobacco

Still, Brandt's public-health oriented approach is well-served by his argument that these social factors created a perfect storm for the tensions among science, governmental regulators, and the judicial system.

B. *The Rise of the "New Epidemiology"*

The major focus and most important aspect of *The Cigarette Century* is Brandt's examination of the historical development of public health measures to identify and evaluate health risks—such as those posed by smoking and by environmental tobacco smoke (ETS)—that arose slowly over time. Brandt repeatedly demonstrates the ways in which smoking-related illness is significantly different from the infectious and communicable illnesses that preoccupied the public health community throughout most of the twentieth century.³⁶ Those latter illnesses, such as influenza, were borne by biological organisms and typically characterized by acute symptoms arising soon after exposure.³⁷ In contrast, smoking-related illness and other illnesses resulting from toxic exposures typically manifest in symptoms only after a latency period of months, years, or even decades from the time of initial exposure, and often well after exposure has ceased.³⁸

In the mid-twentieth century, as detailed by Brandt, researchers turned their attention to the causes of chronic illness in the population.³⁹ A 1938 study derived from family data suggested a statistical relationship between smoking and a reduction in life span, with greater reduction occurring in persons who smoked more.⁴⁰ But ascertaining whether a causal connection existed between smoking and certain illnesses was a much more difficult endeavor. Thus, the public health community sought a new investigatory strategy that culminated in what Brandt refers to as the "new epidemiology."⁴¹ In the strongest section of *The Cigarette Century*, Brandt explains the shift in epidemiological inquiry away from acute organism-

industry); cf. Kagan & Nelson, *supra* note 31, at 15 ("Many of the distinctive features of American tobacco policy not only appear to be roughly in line with American public opinion . . . but also in tune with enduring characteristics of American political culture.").

³⁶ See, e.g., BRANDT, *supra* note 3, at 122 ("[I]t took a dramatic epidemiologic transition—the decline of infectious disease as a dominant cause of mortality—to make the harms of cigarette smoking fully explicit.").

³⁷ In the 1940s, "[a]ccording to many investigators, proving causation now required the identification of a 'specific' mechanism under laboratory conditions" to reveal the disease-causing organisms. *Id.* at 119.

³⁸ For example, latency periods for manifestation of asbestos-related illness typically run anywhere from ten to thirty years. *Borel v. Fibreboard Paper Prods. Corp.*, 493 F.2d 1076, 1084–85 (5th Cir. 1973) (discussing the findings reported in Selikoff, Churg, & Hammond, *The Occurrence of Asbestosis Among Industrial Insulation Workers*, 132 ANNALS N.Y. ACAD. SCI. 139, 146–47 (1965)).

³⁹ Brandt observes that "[t]he shift in patterns of disease and the increase in life expectancies made new risks possible—and ultimately *visible*." BRANDT, *supra* note 3, at 122.

⁴⁰ *Id.* at 126–27 (citing Raymond Pearl, *Tobacco Smoking and Longevity*, 87 SCI. 216 (1938)).

⁴¹ *Id.* at 123.

induced illness to chronic illnesses with potentially multiple causes. Thus, Brandt states:

Identifying the health risks of a particular behavior like smoking fit [the old] model poorly. The length of time before the disease developed was protracted . . . [and] the large number of intervening variables confounded the emerging notion of specific causality. Everyone “exposed” did not get the disease, and most did not⁴²

This new epidemiology took advantage of statistical comparisons between people who had cancer and a control group of those who did not, attempting to determine what factors may have been responsible for the development of cancer.⁴³ The new studies attempted to account for the latency period and the possibility of intervening and confounding variables. The results of the studies provided concrete evidence of the relationship between smoking cigarettes and various illnesses. Still, such data did not provide the level of causal proof in individual cases that the law generally requires.⁴⁴

Brandt documents the tobacco industry’s strong reaction to the studies, which included a public relations strategy for creating scientific controversy.⁴⁵ This was no small feat: By 1950 the news media published an increasing stream of articles reporting studies that showed a relationship between smoking and lung cancer. Working collectively, in 1953 the cigarette manufacturers began to put into place their public relations plan, which operated on several fronts. The key approach was to bring into their fold scientists skeptical of the studies showing a cigarette-cancer connection and using them to focus public attention on what the industry characterized as “controversy.”⁴⁶ This approach blossomed into the establishment of official-sounding “bureaus” and “committees,” all of

⁴² *Id.* at 120.

⁴³ *Id.* at 123.

⁴⁴ For a discussion of the relationship between the new epidemiology and current toxic tort litigation, see *infra*, Part III. See also Jean Macchiaroli Eggen, *Toxic Reproductive and Genetic Hazards in the Workplace: Challenging the Myths of the Tort and Workers’ Compensation Systems*, 60 *FORDHAM L. REV.* 843, 888–89 (1992) (discussing the same issues in the context of reproductive and genetic injuries). Brandt notes that correlations between smoking and various negative outcomes that were observed in the clinical setting in the early part of the twentieth century eventually were validated through other, more acceptable studies. Of the early clinical observations, he states:

These clinical observations of the impact of smoking are, in retrospect, quite impressive. Almost all the risks that would later come to be attributed to smoking had been well documented by clinicians in the first decades of the century. Even the risks of passive exposure to cigarette smoke had been well articulated.

BRANDT, *supra* note 3, at 128 (footnote omitted).

⁴⁵ BRANDT, *supra* note 3, at 160.

⁴⁶ *Id.* at 167.

which were nothing more than industry mouthpieces.⁴⁷ The industry also launched an aggressive new advertising strategy focused on the alleged benefits of filter cigarettes.⁴⁸

Brandt's discussion of the creation of the Tobacco Industry Research Committee (TIRC) provides the reader with insight into the science strategy of the industry at mid-century. He shows that the industry's professed interest in demonstrating scientific controversy was less about science than about obfuscation of scientific data,⁴⁹ and that the industry's purpose in establishing the TIRC was to support the industry's existing position of scientific controversy. While the TIRC purported to conduct independent—and presumably neutral—scientific research,⁵⁰ Brandt

⁴⁷ For example, in 1953, R.J. Reynolds created the "Bureau of Scientific Information" to challenge the scientific studies showing a connection between smoking and cancer. *Id.* The industry collectively established the Tobacco Industry Research Committee (TIRC) and publicly announced that the TIRC would conduct research into the health effects of smoking, presumably to give the public reason to believe that the industry was committed to providing a safe product. *See id.* at 170–71 (providing a background of the establishment of the TIRC).

⁴⁸ The cigarette manufacturers retreated from their earlier advertising campaigns touting the quasi-health benefits of their particular brands, some of which had made use of physicians. During the 1930s, the manufacturers had made varied claims about the positive aspects of cigarettes. *See* KLUGER, *supra* note 6, at 77 (describing American Tobacco's promotion of Lucky Strikes as appetite suppressants: "Reach for a Lucky instead of a sweet"); *id.* at 86 (describing R.J. Reynolds's promotion of Camels using the image of a pilot to suggest cigarettes' tranquilizing effect: "It Takes Steady Nerves to Fly the Mail at Night. . . . That's why I smoke Camels. And I smoke plenty! Camels never ruffle or jangle my nerves, and I like their mild, rich flavor."); *id.* at 87 (discussing R.J. Reynolds's promotion of Camels' stimulating or energizing effect: "You Get a Lift With a Camel," "A Harmless Restoration of the Flow of Natural Body Energy"); *id.* at 88 (describing R.J. Reynolds's promotion of Camels as a means of improving digestion: "For Digestion's sake, smoke Camels!"); *id.* at 117 (referring to American Tobacco's promotion of Pall Malls as a method of reducing throat scratch: "gentles the smoke"); *see also* BRANDT, *supra* note 3, at 93 (mentioning that Lorillard also promoted Old Golds as gentle on one's throat: "Not a Cough in a Carload"). But in the 1950s, in apparent reaction to the health studies, the industry took a different tack by touting the health protections of filters, such as Lorillard's "Micronite" filter used in the Kent brand. *See* KLUGER, *supra* note 6, at 151 (describing how Lorillard promoted Kents as "The Greatest Health Protection in Cigarette History"); *id.* at 155 (noting Liggett & Myers's use of the actor Fredric March to promote its filter-tip L&M brand, saying "L&M Filters Are Just What the Doctor Ordered!"). Brandt states that this host of health claims demonstrated that the industry sought to make its product something "that could be virtually all things to all people." BRANDT, *supra* note 3, at 100. It turned out that the Kent Micronite filter contained a form of asbestos, so whether or not the filter reduced the amount of nicotine and tar that reached the smoker, it created a different health hazard. *See* *Quickel v. Lorillard, Inc.*, No. 95-5255, 1999 U.S. Dist. LEXIS 23453, at *4–*6, *24–*26 (D.N.J. Mar. 31, 1999) (holding admissible expert evidence of causation in a case claiming that asbestos in Micronite filter cigarettes caused decedent's mesothelioma death).

⁴⁹ BRANDT, *supra* note 3, at 173. Among other facts, the first executive director of the TIRC had no scientific background, and the first full-time chair of the organization was a long-time veteran of Brown & Williamson Tobacco Company. *Id.*

⁵⁰ A press release naming Timothy V. Hartnett, the former president of Brown & Williamson, as the first chair stated that the purpose of the TIRC was "to sponsor research into all phases of tobacco use and health." Press Release, Tobacco Industry Research Committee (July 1, 1954), available at <http://tobaccodocuments.org/ctr/11310600-0601.html>. Hartnett himself stated: "The tobacco industry is determined to find the answers to the public's questions about smoking and health. The appointment of a full-time chairman completes an organization dedicated to carrying on comprehensive and objective scientific and statistical research to establish the facts and report them to the public." *Id.* Furthermore, the press release outlined the following as the position of the TIRC:

presents ample support for his assertions that the TIRC was created to support and promote the industry's position that smoking cigarettes was no more harmful than any other aspect of life. Already predisposed to rejecting the increasing scientific knowledge of the connection between smoking and cancer,⁵¹ the TIRC and the industry adhered to this position for decades in the face of mounting evidence of causation.⁵²

Indeed, Brandt asserts that the TIRC did not really study the effects of smoking and health in the 1950s at all.⁵³ Rather, the TIRC's strategy was to learn of ongoing studies elsewhere and develop a plan for public rebuttal the instant that results were released—and sometimes even before they were released.⁵⁴ The TIRC was not just focused on using the media; it used the medical profession as well. Beginning in 1958, the TIRC disseminated a periodical entitled “Tobacco and Health” free of charge to the medical and dental professions, with the theme that insufficient scientific evidence existed to demonstrate a connection between smoking and lung cancer.⁵⁵

Another pivotal public health development detailed by Brandt is the

It is an obligation of the Tobacco Industry Research Committee at this time to remind the public of these essential points:

1. There is no conclusive scientific proof of a link between smoking and cancer.
2. Medical research points to many possible causes of cancer. Statistics indicating a relationship between smoking and disease could apply with equal force to many other aspects of modern life.

. . .
5. The millions of people who derive pleasure and satisfaction from smoking can be reassured that every scientific means will be used to get all the facts as soon as possible.

Id.

⁵¹ See BRANDT, *supra* note 3, at 175–83 for a discussion of the appointment of Clarence Cook Little, a geneticist and eugenicist who elevated laboratory research over other scientific investigation, as the first scientific director of the TIRC. Little was a self-proclaimed skeptic about causal relationships between exposures and illnesses and had focused his own research on heredity and cancer. *Id.* at 175–76, 179.

⁵² This mounting evidence included an extensive study in 1957 of autopsies of deceased smokers. *Id.* at 187 (citing, among other sources, Oscar Auerbach et al., *Changes in the Bronchial Epithelium in Relation to Smoking and Cancer of the Lung: A Report of Progress*, 256 N. ENG. J. MED. 104 (1957)). The research program put into place by TIRC scientific director Clarence Cook Little was one, in Brandt's view, that not only was anti-epidemiology, but was designed to prevent resolution of the precise questions the TIRC allegedly was established to answer. “Little and his . . . colleagues constructed a basic science research program into aspects of carcinogenesis that had little or no potential to resolve the question that the TIRC had promised the American public would be at the center of attention: do cigarettes cause disease?” *Id.* at 182. Ironically, the TIRC at the same time criticized the studies that did show a causal connection as lacking the experimental scientific rigor that the TIRC itself did not embrace. In fact, the research that the industry did conduct seemed to confirm the very studies that the industry was attempting to refute. *Id.* at 199 (referencing industry studies of carcinogenic constituents of tobacco smoke); KLUGER, *supra* note 6, at 362–63 (discussing industry-funded animal studies showing precancerous lesions, which resulted in the researcher being dropped from the program).

⁵³ See BRANDT, *supra* note 3, at 186–87 (discussing TIRC's strategy of avoiding conducting empirical studies).

⁵⁴ *Id.* at 195.

⁵⁵ *Id.* at 196–97.

emergence of scientific evidence demonstrating the relationship of environmental tobacco smoke (ETS) to disease in nonsmokers. Several factors were significant in bringing public attention to ETS. One was the role of grassroots public health advocacy groups in raising media awareness of ETS in the 1970s and 1980s.⁵⁶ Although researchers had difficulty measuring exposure to ETS, many of the studies conducted on nonsmoking spouses of smokers found elevated rates of lung cancer and cardiovascular disease in these subjects.⁵⁷ The grassroots organizations also focused their efforts on urging smoking bans in the states.⁵⁸ The industry's response to the ETS studies mirrored its earlier response to studies on smoking—attacks on the scientific studies⁵⁹ and diversions to other environmental pollutants as possible causes of illness.⁶⁰

In Brandt's assessment, by the 1980s, epidemiology had become an accepted and important tool in the public health arsenal to determine the causal connection between cigarette smoke and disease. He observes:

First, it was no longer possible, as it had been in the 1950s, to denigrate epidemiology and statistics. These elements of medical science had grown to be trusted influences on both public opinion and policy making. Second, the industry's own loss of credibility . . . made the media and the public unwilling to accept industry attacks as scientifically legitimate. . . . Finally, American society had become far more health-conscious since the 1960s—and more risk averse.⁶¹

For example, when smoking on aircrafts became a regulatory battleground in the ETS movement, the industry was on the losing end, culminating in the prohibition of smoking on all domestic flights in 1990.⁶²

As a historian, one of Brandt's major purposes in writing *The Cigarette Century* was to conduct an "examination of those particular social processes by which a culture constitutes and assesses the risks of life—and death."⁶³ His ultimate goal is clear—to avert a potential global health catastrophe in smoking-related illness by illuminating the forces that have allowed the cigarette to remain a powerful consumer product despite its health hazards. This is a most ambitious goal, and his narrative sometimes reads more like a piece of advocacy than a social science

⁵⁶ *Id.* at 288.

⁵⁷ *See id.* at 284–85 (detailing the procedures and results of several ETS studies in different countries).

⁵⁸ *Id.* at 289.

⁵⁹ *Id.* at 292.

⁶⁰ *Id.* at 293.

⁶¹ *Id.* at 295.

⁶² *Id.* at 305.

⁶³ *Id.* at 13.

treatise. But the greatest value of *The Cigarette Century* lies in Brandt's examination of the factors and events in the public health community that led to the health crisis he documents. Thus, as a historian of *science*, Brandt is most interested in the role tobacco played in revolutionizing epidemiological study to address a new set of public health problems—those involving exposures to toxic substances and latent illness.⁶⁴ One area that would have completed his medical and epidemiological analysis would have been a discussion of studies on harm reduction in smokers and the respective effectiveness of methods such as nicotine reduction in cigarettes, smoking cessation, and nicotine substitutes. It is likely, however, that that particular chapter in the history of the cigarette has yet to be clearly written in the scientific literature.⁶⁵

C. *The Rough Road to Regulation*

Brandt also examines the role of public health officials in pursuing regulation of the tobacco industry. He tracks this topic from the early 1960s, through the actions of the country's chief public health official, the Surgeon General, and the industry's efforts to thwart regulation. Once again, Brandt presents these events as pivotal in the history of public health in the United States. The first significant development was the committee established by Luther Terry, President Kennedy's Surgeon General, for the purpose of determining the "nature and magnitude of the health effects of smoking"⁶⁶ and, ultimately, providing recommendations for action.⁶⁷ The report that the committee issued found that smoking caused significant illness in the United States.⁶⁸

The release of the Surgeon General's report in January 1964 constituted a watershed event in the move toward health-based tobacco regulation. Brandt emphasizes that the Surgeon General's report was instrumental in ushering in a salutary new stage in the history of public

⁶⁴ See *infra* notes 151–96 and accompanying text for a discussion of the relationship between Brandt's narrative and the subsequent course of toxic tort law.

⁶⁵ For a public policy orientated survey of smoking cessation methods and issues, see Kenneth E. Warner, *Reducing Harm to Smokers: Methods, Their Effectiveness, and the Role of Policy*, in *REGULATING TOBACCO* 111 (Robert L. Rabin & Stephen D. Sugarman eds., 2001).

⁶⁶ BRANDT, *supra* note 3, at 221 (quoting Surgeon General's Advisory Committee on Smoking and Health, *THE NATURE, PURPOSE, AND SUGGESTED FORMULATION OF THE STUDY OF THE HEALTH EFFECTS OF SMOKING, PHASE I* (1962)).

⁶⁷ *Id.*

⁶⁸ Brandt states: "For the seventy million regular smokers in the United States, the report of the committee's findings confirmed their worst fears. It told them that the death rate from lung cancer was 1,000 percent higher among men who smoked cigarettes than among nonsmokers." *Id.* at 224. The report also concluded that smokers were at a significantly higher risk than nonsmokers of non-malignant lung conditions. *Id.*; see also *id.* at 229 ("At the press conference announcing the committee's findings, Terry was asked whether he would now advise a patient to stop smoking. His answer was an unequivocal 'yes.'" (citation omitted)).

health.⁶⁹ But transforming the committee's conclusions into government action proved problematic, largely as a result of the tobacco industry's continued portrayal of the science as controversial.⁷⁰ Brandt details the difficult, tortuous road toward regulating an industry with substantial political support and an unyielding commitment to creating the illusion of scientific controversy. One fact that demonstrates the tenacity of the industry and its product is that the aftermath of the release of the report did not see any significant immediate decline in smoking in the United States.⁷¹ More problematic, perhaps, was the fact that the Office of the Surgeon General did not have the immediate ability to launch the anti-smoking initiatives that the report seemed to mandate.⁷² The report proved pivotal, nevertheless, as the Office of the Surgeon General thenceforth assumed an active role in public health matters.⁷³

Regulation of tobacco products proved elusive from the very start. Although the tobacco industry had come under the scrutiny of the Federal Trade Commission (FTC) as early as the 1930s because of its advertising campaigns promoting the alleged health benefits of smoking,⁷⁴ the industry remained—and continues to this day to remain—virtually unregulated.⁷⁵ It was not until 1965 that Congress mandated a health warning on cigarette packaging. The resulting legislation required the placement of a warning on packages of cigarettes stating, “Caution: Cigarette Smoking May Be Hazardous to Your Health.”⁷⁶ According to Brandt, the tobacco industry's supporters engineered the legislation to protect the manufacturers from tort judgments and to assist them in advancing their primary defense to tort

⁶⁹ In the future, “[r]esolving controversies in science, medicine, and public health . . . would increasingly require the integration of scientific data from a wide range of experiments, studies, and clinical observations.” *Id.* at 238. The new protocol arising from the process developed by the Surgeon General's Advisory Committee in producing its report consisted primarily of (1) eliminating conflicts of interest among the investigators and evaluators; (2) achieving consensus among participants with diverse scientific proclivities; and (3) providing a means to resolve conflicts among the group. *Id.* A key to this process was conducting a comprehensive review of the existing experimental data, epidemiological studies, and clinical observations. *Id.* With regard to the relationship between smoking and adverse health effects, there was a remarkable consistency among the results of the studies employing different scientific methodologies. *Id.* at 228.

⁷⁰ *Id.* at 231.

⁷¹ Although cigarette sales dropped in early 1964, they immediately rebounded, breaking records for sales, cigarette use, and industry profits. *Id.* at 237. Smoking levels remained strong through 1973. *Id.*

⁷² *Id.*

⁷³ *Id.* at 239. “The 1964 report remains a signal contribution not only to the history of the cigarette but to the history of public health.” *Id.*

⁷⁴ *Id.* at 243; see also KLUGER, *supra* note 6, at 189 (describing the 1958 attempt to regulate tar and nicotine in cigarettes under the auspices of the FTC).

⁷⁵ See BRANDT, *supra* note 3, at 273 (noting that cigarettes were expressly excluded from regulation under the Fair Labeling and Packaging Act of 1966, the Controlled Substances Act of 1970, and the Consumer Product Safety Act of 1972).

⁷⁶ Federal Cigarette Labeling and Advertising Act of 1965, Pub. L. No. 89-92, § 4, 79 Stat. 282–83 (1965).

actions—assumption of the risk.⁷⁷ Subsequent legislation in 1969 changed the warning to state that cigarette smoking “[i]s [d]angerous.”⁷⁸ In 1984, the labels were modified again to the multiple, rotating warnings currently in use.⁷⁹ By any standard, this so-called regulation was minimal at best.

The major test of the tobacco industry’s strategy on regulation occurred in 1992. In *Cipollone v. Liggett Group, Inc.*, the United States Supreme Court ruled on whether the plaintiff’s product liability claims were preempted by the 1965 and 1969 labeling acts.⁸⁰ In a plurality opinion, the Court held that the failure-to-warn claims were expressly preempted,⁸¹ but that claims for misrepresentation, express warranty, and negligent research and testing would be allowed to go forward.⁸² The decision thwarted the industry’s strategy to use regulation as a shield for all tort actions. Instead, *Cipollone* allowed the courts—and common-law tort actions in particular—to serve as a vehicle for redress for people claiming to be harmed by the health risks of smoking. Brandt states: “The industry had long feared the emergence of such aggressively contested litigation In the courts, antitobacco advocates certainly had not found a level playing field; nonetheless they had found a field.”⁸³ The other side of this transition to tort law was the tobacco industry’s insistence that the judicial system was wrongly allowed to legislate in an area where Congress had declined to do so.⁸⁴ The industry’s position was one aspect of a growing tort reform movement committed to limiting or eliminating tort litigation.⁸⁵

Brandt argues that *Cipollone* signaled a “critical transition” in the war against the tobacco industry.⁸⁶ Previously, the industry had adamantly denied—at least publicly—the health risks of smoking, acceding only that there might be a controversy over the relationship between smoking and disease. The industry’s new position was an admission that smoking was a “risk factor” in the development of lung cancer, but that no proof existed

⁷⁷ BRANDT, *supra* note 3, at 254, 257.

⁷⁸ Public Health Cigarette Smoking Act of 1969, Pub. L. No. 91-222, § 4, 84 Stat. 87–88 (1970).

⁷⁹ Comprehensive Smoking Education Act, Pub. L. No. 98-474, §§ 4(a)(1)–(b)(1), 98 Stat. 2200–02 (1984).

⁸⁰ *Cipollone v. Liggett Group*, 505 U.S. 504, 508 (1992) (plurality opinion). For a discussion of the impact of the *Cipollone* decision on subsequent product preemption jurisprudence, see *infra* Part IV.

⁸¹ *Cipollone*, 505 U.S. at 524. For a discussion of express preemption in this context, see Jean Macchiaroli Eggen, *Sense or Sensibility?: Toxic Product Liability Under State Law After Cipollone and Medtronic*, 2 WIDENER L. SYMP. J. 1, 4–11 (1996).

⁸² *Cipollone*, 505 U.S. at 524–29.

⁸³ BRANDT, *supra* note 3, at 353.

⁸⁴ *Id.*

⁸⁵ See, e.g., Product Liability Reform Act of 1997, S. 648, 105th Cong., tit. III, § 2(a)(4) (1997) (referring to the tort system in “Findings” as resulting in “excessive, unpredictable, and often arbitrary damage awards and unfair allocation of liability”).

⁸⁶ Brandt expansively calls it “a critical transition in both the legal and social history of the cigarette in American life.” BRANDT, *supra* note 3, at 352.

that smoking actually caused lung cancer.⁸⁷

This shift in the industry's position opened the door for another federal effort at regulation, this time by the Food and Drug Administration (FDA).⁸⁸ Brandt chronicles the efforts of the FDA to regulate tobacco products, culminating in the United States Supreme Court's 2000 decision, *FDA v. Brown & Williamson Tobacco Corp.*, which struck down provisions regulating cigarettes as nicotine delivery devices.⁸⁹ Brandt identifies several circumstances that created a climate conducive to FDA regulatory efforts. First, he notes that the industry's long-standing strategy of creating controversy, criticizing statistical science, and denying the harms of cigarettes was no longer persuasive. Both the media and the FDA focused on the tobacco industry's own research—mostly on so-called “safer cigarettes”—which confirmed the addictive qualities of nicotine.⁹⁰ When the top executives of the major tobacco companies appeared before a Congressional committee, their denials of the addictive nature of nicotine rang hollow to a public that had been educated by the media about the results of the scientific studies.⁹¹

Second, Brandt credits the release of thousands of previously confidential tobacco industry documents with significantly changing the regulatory climate.⁹² When certain industry documents came into the possession of Stanton Glantz at the University of California at San Francisco, he made them public, revealing the cognitive dissonance between the industry's position over the years and its internal knowledge

⁸⁷ *Id.* at 341.

⁸⁸ For a detailed insider's description of the FDA's efforts, see DAVID KESSLER, A QUESTION OF INTENT: A GREAT AMERICAN BATTLE WITH A DEADLY INDUSTRY (2001) (describing in minute detail his participation in the FDA's efforts to regulate the tobacco industry during the 1990s). See also BRANDT, *supra* note 3, at 579 (referring to former FDA Commissioner Kessler as his major source on the FDA's efforts to regulate the tobacco industry).

⁸⁹ *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120 (2000). The trigger for FDA regulation of cigarettes is whether the product was “intended to affect the structure or any function of the body” 21 U.S.C. § 321(g)(1)(C) (2000). The difficulty with cigarettes was that they are combination products, both a device and a drug (nicotine), which are regulated separately in the FDCA. The FDA viewed the cigarette as a drug delivery device for nicotine. *Brown & Williamson*, 529 U.S. at 127. In the mid-1990s, the FDA Commissioner, David Kessler, became concerned over the evidence that nicotine levels in cigarettes were rising after an earlier period of decline. See KESSLER, *supra* note 88, at 161–64 (discussing the investigation into the manipulation of nicotine levels in cigarettes and providing a very personal and detailed account of his efforts to regulate cigarettes).

⁹⁰ BRANDT, *supra* note 3, at 365.

⁹¹ *Id.* at 366–67.

⁹² Initially, whistleblowers who were former employees of the tobacco industry came forward with testimony and documentary evidence detailing the industry's decades-long knowledge of the hazards of cigarettes. *Id.* at 369–70 (discussing Merrell Williams, a former paralegal for Brown & Williamson's law firm, who stole and released more than 4000 pages of documents); *id.* at 375–84 (discussing Jeffrey Wigand, a former research scientist for Brown & Williamson, who provided the media with information regarding manipulation of nicotine levels in cigarettes). See generally MICHAEL OREY, ASSUMING THE RISK: THE MAVERICKS, THE LAWYERS, AND THE WHISTLE-BLOWERS WHO BEAT BIG TOBACCO (1999) (using interviews and trial records to tell the story of the exposure of tobacco industry practices).

and practices.⁹³ Indeed, the availability of the industry documents dramatically changed the entire debate over the hazards of both smoking and ETS, reaching into courtrooms around the country as well as the halls of Congress.

In seeking to regulate tobacco products, the FDA took the position that it had the discretion to determine whether to regulate cigarettes as either medical devices or drugs, based on the theory that they were nicotine delivery devices.⁹⁴ The resulting device rules were child-centered, involving sales and advertising.⁹⁵ The industry challenged the proposed rules, arguing that the FDA had no jurisdiction to promulgate them. Ultimately, the United States Supreme Court agreed with the industry,⁹⁶ holding that Congress had never intended to grant authority to the FDA to regulate tobacco products.⁹⁷

Brandt's discussion of regulation ends pessimistically, but he may have given up on this possibility too soon. In 2008, the prospect of FDA regulation of cigarettes looms much larger, this time with the support of Philip Morris USA which originally came out in favor of FDA regulation in 2003,⁹⁸ presumably with a renewed eye toward preemption of common-law tort actions. In July 2008, the House of Representatives, by an overwhelming majority, passed a bill that would regulate, though not

⁹³ BRANDT, *supra* note 3, at 371–72. See generally STANTON A. GLANTZ ET AL., THE CIGARETTE PAPERS 30–32 (1996) (describing tobacco industry documents and including edited versions of some of the documents). A vast collection of tobacco industry documents is stored in the Legacy Tobacco Documents Library at the University of California at San Francisco. Legacy Tobacco Documents Library, <http://legacy.library.ucsf.edu> (last visited Sept. 12, 2008).

⁹⁴ *Brown & Williamson*, 529 U.S. at 129; see FDCA, 21 U.S.C. § 360j(e) (2000) (“The Secretary may by regulation require that a device be restricted to sale, distribution, or use . . . upon such other conditions as [the FDA] may prescribe in such regulation, if, because of its potentiality for harmful effect . . . [the FDA] determines that there cannot otherwise be reasonable assurance of its safety and effectiveness.”).

⁹⁵ *Brown & Williamson*, 529 U.S. at 126.

⁹⁶ *Id.* at 133. The FDA had documented in detail the health risks associated with cigarettes. The Court said that if the regulations for devices were intended to apply to tobacco products, the documented hazards would have required the FDA to ban cigarettes from the market. *Id.* at 135, 137. Congress had effectively prohibited this when it enacted a provision that stated: “The marketing of tobacco constitutes one of the greatest basic industries of the United States with ramifying activities which directly affect interstate and foreign commerce at every point, and stable conditions therein are necessary to the general welfare.” 7 U.S.C. § 1311(a) (2000). Thus, an absolute ban would “plainly contradict congressional policy.” *Brown & Williamson*, 529 U.S. at 139. The Court held that the FDA’s attempt to circumvent this problem was an improper application of the regulations. *Id.* at 140.

⁹⁷ *Brown & Williamson*, 529 U.S. at 126. The Court examined the 1938 FDCA and found nothing in the act or in the legislative history to suggest that Congress granted the FDA authority over tobacco. Moreover, the FDA had repeatedly stated over the years that it did not have such authority, and this worked against its argument before the Court. *Id.* at 144–46. At least in partial reliance on this position, Congress has declined to enact any legislation to specifically grant jurisdiction to the FDA. *Id.* at 145–46. When Congress did enact tobacco-specific legislation—in particular, the cigarette labeling acts—it also declined to grant authority to regulate to the FDA, keeping that authority for itself. *Id.* at 149.

⁹⁸ *Philip Morris CEO Tells House Panel FDA Should Get Power to Regulate Tobacco*, TOXICS L. REP., June 6, 2003, at 590.

eliminate, nicotine in cigarettes and ban flavored (but not menthol) cigarettes.⁹⁹ The legislation was developed in part through an agreement with Philip Morris.¹⁰⁰ Other cigarette manufacturers are less enthusiastic than Philip Morris about the prospect of regulation. For example, a representative of R.J. Reynolds Tobacco Company expressed concern about his company having a “competitive disadvantage” in an era of standardized cigarette ingredients.¹⁰¹ The prospect of FDA regulation has raised a question in some public health circles as to whether regulation of cigarettes would create the erroneous and oddly counterintuitive impression that smoking is safe.¹⁰² At the present time, however, Brandt’s concluding point¹⁰³ on regulation continues to be true: More than forty years after the first Surgeon General’s report on smoking, no comprehensive regulation of cigarettes is in place.

D. *The Era of Tobacco Litigation*

The disclosure of the industry documents paved the way for the 1998 Master Settlement Agreement (MSA) between the tobacco industry and the states.¹⁰⁴ Brandt examines the relationship between the failed FDA regulations and the efforts of the states to address the health aspects of smoking using innovative litigation. In 1994, the state of Mississippi filed the first such suit against the tobacco industry, claiming that the state’s taxpayers had suffered losses associated with public expenditures, such as through the Medicaid program, for smoking-related illness.¹⁰⁵ Moreover, the suit included a public nuisance claim seeking forward-looking injunctive relief to abate the nuisance perpetrated by the industry,

⁹⁹ Stephanie Saul, *House Votes to Regulate Tobacco as a Drug*, N.Y. TIMES, July 31, 2008, at C2 (correction appended).

¹⁰⁰ *Id.* (stating that the bill was partly the result of negotiations with Philip Morris, but that not all tobacco companies supported it).

¹⁰¹ See Gardiner Harris, *Path to Tobacco Bill Includes Compromise and Criticism*, N.Y. TIMES, July 17, 2007, at A14, available at LEXIS, News Library, NYT File (quoting R.J. Reynolds representative as stating that the proposed regulation would make it too difficult to “communicate product differences” to smokers, and reporting that cigarette makers object to the competitive advantage regulation would give to Philip Morris, in its dominant position in the market); Gregory Lopes, *Senate Bill to Let FDA Regulate Tobacco; Agency Could Limit Ads, Curb Tar and Nicotine*, WASH. TIMES, July 17, 2007, at C8, available at LEXIS, News Library, WTIMES File (quoting a representative of R.J. Reynolds as stating that “[t]he advertising restrictions in the bill are anti-competitive”).

¹⁰² See Harris, *supra* note 101 (reporting testimony by FDA Commissioner Andrew von Eschenbach that the FDA should not be put in a position to decide whether cigarettes are safe).

¹⁰³ See BRANDT, *supra* note 3, at 396–97 (quoting Republican Congressman J.C. Watts as stating that “[t]he FDA seems to be interested in doing everything except what they are responsible for”).

¹⁰⁴ See *infra* notes 118–26 and accompanying text.

¹⁰⁵ BRANDT, *supra* note 3, at 414. The federal government filed a major action against the tobacco industry as well, which was part reimbursement suit and part civil RICO action. See *United States v. Philip Morris USA, Inc.*, 449 F. Supp. 2d 1 (D.D.C. 2006) (holding that Philip Morris had intended to defraud American citizens with respect to its statements regarding the health effects of smoking).

particularly toward children.¹⁰⁶ Several other state suits followed.¹⁰⁷

In 1997, the attorneys general of the litigating states—with the exception of Minnesota—began negotiating with the tobacco companies to achieve a “global settlement” that would reach beyond the pending lawsuits.¹⁰⁸ Brandt demonstrates that the industry’s concern for revelations in their now-public internal documents and compromises the industry had already made in some personal injury actions placed the industry in a weak position in the state suits. That the industry would end up coming out ahead as a result of the ultimate settlement of these suits is an example of its tenacity, the continued popularity of its product, and the continuing inability of the public health community and the government to fashion a consistent approach to the public health threat of smoking.

The 1997 negotiations led to the ill-fated first global settlement agreement.¹⁰⁹ That agreement contained provisions that resembled the regulations the FDA was attempting to put into place, such as limitations on advertising and marketing. Primarily, the industry agreed to reimburse the states for their costs for smoking-related illnesses and programs. The agreement contained promises to fund and establish public health programs, as well as to allow the FDA to regulate nicotine if youth smoking did not decline to certain prescribed levels.¹¹⁰ Its most dramatic provisions involved limitations on tort litigation. In exchange for the accessions of the industry, the parties agreed to cap damages in tobacco lawsuits, prohibit class actions, and ban punitive damages for any past conduct of the industry.¹¹¹ The agreement did, however, require Congress to act for it to go into effect.¹¹² Congressional disagreement, coupled with a looming trial deadline in the Mississippi suit,¹¹³ stymied the legislation, and it never materialized.

Brandt demonstrates the split in the public health community that contributed significantly to the failure of the 1997 global settlement legislation. One segment of the public health community resisted negotiation and settlement out of a belief that such an approach would benefit only the industry, not the public.¹¹⁴ In the context of the 1997 agreement, this skepticism manifested itself in a resistance to limiting the remedial role of the tort system for tobacco-related injuries.¹¹⁵ In contrast, other segments of the public health community favored the settlement

¹⁰⁶ BRANDT, *supra* note 3, at 414.

¹⁰⁷ *Id.* at 415.

¹⁰⁸ *Id.* at 420–21.

¹⁰⁹ *Id.* at 422.

¹¹⁰ *Id.*

¹¹¹ *Id.*

¹¹² *Id.*

¹¹³ *Id.* at 423.

¹¹⁴ *Id.* at 424.

¹¹⁵ *Id.* at 425.

because it represented, at long last, some form of tobacco regulation.¹¹⁶ In Congress, modifications of the agreement inevitably occurred, and ultimately the tobacco industry itself opposed the legislation.¹¹⁷

Soon after the announcement of the 1997 global settlement agreement, Mississippi settled its suit against the industry, out of necessity, in the days immediately before it was scheduled to go to trial.¹¹⁸ Subsequently, Florida and Texas settled their suits; Minnesota settled during trial.¹¹⁹ With the failure of the legislation in Congress, the other states that had filed similar actions negotiated the MSA that went into effect in 1998, but which bore little resemblance to the 1997 agreement.¹²⁰ The MSA offered an opportunity for all states to sign onto the agreement, including those that had not commenced reimbursement lawsuits against the industry.¹²¹ The top tobacco companies agreed to pay a sum of \$206 billion over a period of twenty-five years to reimburse the states for their public expenditures.¹²² The companies further agreed to fund anti-smoking initiatives in the states and acquiesced to some restrictions in advertising.¹²³ But, as Brandt points out, the provisions had no real teeth. Moreover, the MSA did not require the monies paid to the states to be used for anti-smoking campaigns—or even public health initiatives—and were treated by the states as “a windfall to governors and legislators with little interest in battling tobacco” for use in unrelated programs.¹²⁴

Brandt is at his best in illuminating the public health community’s controversy over these issues, but is less effective in detailing the subtleties of the legal positions. Others have reported the events leading up to the MSA in detail,¹²⁵ but Brandt’s contribution is his ability to place those

¹¹⁶ *Id.*

¹¹⁷ *Id.* at 427–28.

¹¹⁸ *Id.* at 423.

¹¹⁹ *Id.*

¹²⁰ *Id.* at 432.

¹²¹ Master Settlement Agreement (MSA), available at <http://ag.ca.gov/tobacco/msa.php> (last visited Oct. 10, 2008).

¹²² *Id.*

¹²³ *Id.*

¹²⁴ BRANDT, *supra* note 3, at 432. The CDC recommended that a minimum of twenty percent of each state’s payment be dedicated to an anti-smoking agenda, but Brandt reports that by 2005 only four percent had been used for those efforts. *Id.* at 435. Further, because the settlement was to be paid out over a period of twenty-five years, the states needed the continued health of the tobacco industry. In Brandt’s words, “the deal had made the states dependent on tobacco revenues . . . [and p]artners with the tobacco industry.” *Id.* This situation is exacerbated by the practice of the states selling bond issues backed by future tobacco settlement payments. *Id.*

¹²⁵ See, e.g., MARTHA A. DERTHICK, UP IN SMOKE: FROM LEGISLATION TO LITIGATION IN TOBACCO POLITICS 119–50 (2002) (describing the McCain Bill and congressional inaction leading up to the MSA); MICHAEL PERTSCHUK, SMOKE IN THEIR EYES: LESSONS IN MOVEMENT LEADERSHIP FROM THE TOBACCO WARS (2001) (recounting the tobacco industry’s resistance to all serious efforts to enact regulation in the three decades leading up to the MSA); DAN ZEGART, CIVIL WARRIORS: THE LEGAL SIEGE ON THE TOBACCO INDUSTRY (2000) (describing one lawyer’s tenacious battle against the tobacco industry).

events within the context of the history of public health in this country. He argues that the resulting MSA was expedient for most players. It protected the tobacco industry from the risks of taking the state cases to trial; it gave the states the revenues they sought, and the attorneys large fees and the high profiles they desired. But, he says ruefully, “public health got the short end.”¹²⁶

Brandt’s discussion of personal injury litigation in the post-*Cipollone* era focuses primarily on the use of the class action device in two important mass tort cases, one brought by smokers claiming addiction to cigarettes,¹²⁷ the other by nonsmokers.¹²⁸ Rather than retread the many legal developments that led up to and defined these cases, Brandt wisely chooses to place them in the light of the public health developments they represent. He also uses them to advance the argument that resorting to the courts was necessary to bring about some measure of regulation over the tobacco industry when traditional governmental regulation had failed.

Thus, Brandt views the use of the class action device as a natural reaction to the public-health challenges of individual lawsuits that had generally failed for decades. Brandt identifies three factors in particular: (1) the problems encountered by plaintiffs in proving causation by using statistical risk science, i.e. epidemiology; (2) the perception of the public, fueled by the tobacco industry, that smokers bear responsibility for their own smoking; and (3) the fact that “jurors saw an important inequity in enriching a few individual smokers or their survivors” at the expense of the other injured smokers who opted not to sue.¹²⁹ The class action device had the advantage of showing broad patterns of disease that were relevant to a large class of persons—whether the claimants were smokers or nonsmokers—as well as allowing the plaintiffs to more efficiently use their limited resources to fight the apparently bottomless financial resources of the industry.¹³⁰

Although Brandt does not discuss the class actions in detail, the impression he leaves is optimism for the use of aggregative litigation, such as class actions, to bring about some measure of control, if not regulation, of the tobacco industry. He states: “The courts were . . . a critical venue not only for injured smokers but for anyone hoping to advance public health policies regarding smoking.”¹³¹ This optimism is not necessarily warranted. But in the 1990s there was much more reason to be optimistic,

¹²⁶ BRANDT, *supra* note 3, at 438.

¹²⁷ See *Engle v. Liggett Group, Inc.*, 945 So. 2d 1246 (Fla. 2006) (ruling in a class action suit brought by United States citizens who have suffered from addiction to cigarettes).

¹²⁸ *Broin v. Philip Morris Co., Inc.*, 641 So. 2d 888 (Fla. Dist. Ct. App. 1994) (case settled during trial).

¹²⁹ BRANDT, *supra* note 3, at 404–05.

¹³⁰ *Id.* at 405.

¹³¹ *Id.* at 439.

with the MSA and several high-profile class actions applying pressure to the industry simultaneously. The resulting disappointment of the MSA—that the tobacco industry remains in control, with the states dependent on the agreement’s revenue stream—is one reason for deflation of that optimism. Another reason is a trend in judicial rejection of ambitious class actions that seek to advance a public health regulatory agenda, as discussed below.¹³²

E. Globalization

The last section of *The Cigarette Century* focuses on the globalization of the tobacco industry, what Brandt refers to as “exporting an epidemic.”¹³³ Beginning in 1975, cigarette use in the United States finally began to decline, prompting the industry to focus in earnest on other countries¹³⁴ where regulation was scarce.¹³⁵ Brandt argues that it is just a matter of time before the epidemic of smoking-related illness in the United States manifests itself as a global pandemic. This coming pandemic will disproportionately impact developing nations.¹³⁶

Brandt spends some time detailing the course of cigarette consumption abroad, which mirrors, to a large extent, the social history of the cigarette in the United States. Factors such as introducing the cigarette to women and mining the youth market have contributed to the product’s growth abroad.¹³⁷ He further describes the conflict between non-domestic tobacco companies and state-run cigarette monopolies in some countries. Brandt’s basic argument is that free trade has led to an increase in smoking-related illness worldwide, and that this result has been facilitated by a combination of several factors: the tobacco industry protecting its interests; international organizations (such as the International Monetary Fund and the World Bank) ignoring the impact free trade would have on world health; United States trade policy protecting the tobacco industry; and the inability of procedures pursuant to the General Agreement on Tariffs and Trade (GATT) to sufficiently assess the public health impact of the trade practices that came within its jurisdiction.¹³⁸ The result has been that tobacco products are treated like any other product for trade purposes, a situation that has created tension between economic interests and public

¹³² See *infra* Part IV.

¹³³ BRANDT, *supra* note 3, at 449.

¹³⁴ *Id.* at 450.

¹³⁵ *Id.* at 452 (“[T]he tobacco industry maintains strong corporate ties to national governments that typically have little or no history of product regulation.”).

¹³⁶ *Id.* at 451.

¹³⁷ *Id.* at 457.

¹³⁸ See *id.* at 460–67 (discussing how a number of factors associated with globalization and free trade led to an increase in smoking-related illnesses worldwide).

health interests.¹³⁹

Ultimately, Brandt advocates for the development of an international treaty for tobacco with a strong public health theme. The World Health Organization (WHO) developed a Framework Convention on Tobacco Control (FCTC) which is designed to establish minimum standards for a country's control of tobacco products. The FCTC endorses, among other things, package warnings, disclosure that terminology such as "low tar" is misleading, a ban on advertising, and restrictions on sales to minors.¹⁴⁰ In 2003, the member nations of WHO, including the United States, adopted the FCTC.¹⁴¹ The treaty then went into effect in 2005 and entered a phase of negotiations with binding protocols.¹⁴² While 140 nations had ratified the FCTC at the time Brandt's book was published, the United States had not¹⁴³ and has yet to do so.¹⁴⁴

Brandt's discussion of the globalization of tobacco and the efforts at international tobacco control has three basic themes. The first is that, for political and economic reasons, regulating tobacco on an international basis is just as difficult, and likely more so, than regulating it in American society. The second theme returns to the pervasive public health argument throughout the book. Brandt says that the international public health community must abandon the notion that contagious diseases should be managed before chronic non-contagious diseases, such as smoking-related illness. He argues that because the health benefits of tobacco regulation will not be visible for years into the future, political officials are less interested in focusing on a problem that cannot be measured in immediate benefits.¹⁴⁵ Brandt says that the public health effects of tobacco constitute a global pandemic worthy of action to the same degree as any communicable disease.¹⁴⁶ Third, Brandt argues for an international concept of public health in which all persons have a "right to a life free of preventable and treatable disease."¹⁴⁷ He quotes Gro Harlem Brundtland, the former director-general of WHO: "There is . . . an increasing consensus for ethical norms, standards, and codes of rules common to all regions and cultures of the world."¹⁴⁸

The epilogue to the book is clearly an add-on. It is, in part, a preemptive strike on anyone who would question Brandt's objectivity and

¹³⁹ *Id.* at 465.

¹⁴⁰ *Id.* at 478–79.

¹⁴¹ *Id.* at 482.

¹⁴² *Id.* at 485.

¹⁴³ *Id.* at 486.

¹⁴⁴ For a list of signatories and countries that have ratified the FCTC, see http://www.who.int/fctc/signatories_parties/en/index.html.

¹⁴⁵ *Id.* at 487.

¹⁴⁶ *Id.*

¹⁴⁷ *Id.* at 490.

¹⁴⁸ *Id.* (quoting G.H. Brundtland, 1998).

neutrality in relation to the matters on which he reports. He discusses how he came to agree to serve as an expert witness for the Department of Justice in the federal government's case against the tobacco industry and details his experience—ultimately disappointing—in the judicial system.¹⁴⁹ This concluding section is perhaps unnecessary and somewhat disconcerting; few attorneys would feel that serving as an expert witness in major litigation would create a conflict of interest in writing a historical tale. History is, after all, the product of the historians' perspectives. But Brandt is a professional historian, with different sensibilities from an attorney. While he acknowledges his internal conflict between being a witness and a historian, he reconciles the conflict by stating that sometimes the historian must become an advocate.¹⁵⁰ Indeed, that summarizes his dual role as the author of *The Cigarette Century*.

III. PERSPECTIVES ON CHRONIC ILLNESS AND TOXIC TORTS

A. *Scientific Investigation and Chronic Illness at Mid-Century*

As previously discussed, the unique value of *The Cigarette Century* lies principally in its exposition of the public health history of cigarettes. Brandt ably demonstrates the industry's resiliency in the face of increasing scientific evidence of the health hazards of cigarettes. The uniqueness of Brandt's approach lies in his detailed demonstration of the ways in which the industry was able to take advantage of the developing investigatory technique of epidemiology¹⁵¹ in the context of chronic illnesses—such as lung cancer and emphysema—and use it to negate or question the scientific conclusions that emerged. Even more remarkably, the industry used, apparently quite successfully, this manufactured controversy affirmatively in its advertising campaigns for decades.

To understand the impact the new epidemiology has had on toxic tort

¹⁴⁹ *Id.* at 498–503.

¹⁵⁰ *Id.* at 505.

¹⁵¹ Epidemiology may be defined as “[t]he study of the distribution and determinants of health-related states in human and other animal populations. Epidemiological studies involve surveillance, observation, hypothesis-testing, and experiment.” *STEDMAN'S MEDICAL DICTIONARY* 582 (Marjory Spraycar et al. eds., 26th ed. 1995). The task of epidemiology is to examine the relationship between a disease and a particular factor (such as cigarette smoking) to determine if a causal connection exists. Bert Black & David E. Lilienfeld, *Epidemiologic Proof in Toxic Tort Litigation*, 52 *FORDHAM L. REV.* 732, 750 (1984).

The epidemiologist examines this relationship in the context of populations, comparing the disease experiences of people exposed to the factor with those not so exposed. Although the epidemiologist utilizes statistical methods, the ultimate goal is to draw a biological inference concerning the relationship of the factor to the disease's etiology and/or to its natural history. . . . It is an integrative, eclectic science utilizing concepts and methods from other disciplines, such as statistics, sociology and demography for the study of disease in populations.

Id. at 750–51.

litigation, it is useful to follow Brandt's trail of scientific frustration and discovery. Brandt begins his analysis early in the twentieth century, with the public health community's emerging concern about the possible relationship between smoking and illness.¹⁵² Some of the earliest studies sought to determine the chemical composition of cigarette smoke and concluded that smokers were exposed to a variety of substances that were deemed "poisonous."¹⁵³ But the earliest studies that inquired whether a relationship existed between smoking and illness suffered from the biases of investigators who based the studies on their pre-existing assumption that smoking was a health hazard.¹⁵⁴ The public health community had not yet developed a reliable tool to measure statistically the risk of smoking, in part because of the difficulty in designing studies that took into account the variable nature of individual exposures, circumstances, and health status. Accordingly, "[t]hrough the first half of the twentieth century, it proved impossible to categorically substantiate the claims of the harmfulness of smoking."¹⁵⁵

The studies generated in the 1940s were designed to eliminate the kind of bias that had beset the earlier attempts.¹⁵⁶ These studies consisted of, on the one hand, direct medical studies of smokers—such as measuring blood pressure and heart function—and, on the other hand, animal laboratory studies.¹⁵⁷ The direct medical studies on humans, at best, could only demonstrate that smoking may aggravate certain cardiovascular conditions, but they were unable to establish a causal link to smoking.¹⁵⁸ The studies on rats exposed to nicotine demonstrated a negative impact on growth and development, and on fetal development.¹⁵⁹ At least one study on rabbits demonstrated a connection between exposure to substances in tobacco tars and tumors.¹⁶⁰ While useful, none of these studies was able to provide the

¹⁵² This concern was either magnified or clouded, depending upon the observer's perspective, by moral concerns. See BRANDT, *supra* note 3, at 107–08 ("Moral considerations were practically indistinguishable from concerns about the health effects of cigarette smoking. Did smoking cause degeneracy? Or was it simply that degenerates liked to smoke? . . . It would take nearly half a century to disentangle these moral assumptions from medical research on smoking."). By the 1940s, however, the relationship between public health issues related to smoking had been separated from the association with morality. *Id.* at 116.

¹⁵³ *Id.* at 107 (quoting R. Kissling, *The Chemistry of Tobacco*, SCIENTIFIC AM. SUPP., Nov. 25, 1905, at 24999).

¹⁵⁴ *Id.* at 111.

¹⁵⁵ *Id.* at 116.

¹⁵⁶ *Id.* at 117.

¹⁵⁷ *Id.*

¹⁵⁸ *Id.* (citing Robert Maris, *The Facts About Smoking*, HYGEIA, Oct. 1944, at 740–41; Grace M. Roth et al., *The Effect of Smoking Cigaretts*, 125 J. AM. MED. ASS'N 761 (1944)).

¹⁵⁹ See *id.* at 117–18 (citing Floyd De Eds & Robert H. Wilson, *Nicotine Toxicity, III. Effect of Nicotine-Containing Diets on the Estrus Cycle*, 59 J. PHARMACOLOGY & EXPERIMENTAL THERAPEUTICS 260–63 (1937); J.M. Essenberg et al., *The Effects of Nicotine and Cigarette Smoke on Pregnant Female Albino Rats and Their Offspring*, 25 J. LABORATORY & CLINICAL MED. 708 (1940)).

¹⁶⁰ See *id.* at 118 (citing A. H. Roffo, *Tobacco-Induced Carcinoma in Rabbits*, 7 BULL. INST. EXPERIMENTAL MED. FOR CANCER RES. & TREATMENT 2 (1930); A. H. Roffo & L. B. Smith,

direct causal connection between smoking and disease in humans that the public health community sought.

Although epidemiologists had been employing randomized, double-blind clinical trials to investigate the causes of illness, this type of study was ill-suited to investigate connections between tobacco and disease.¹⁶¹ With regard to the effects of smoking, these traditional studies posed several problems. For one thing, the potential long latency period between exposure and manifestation of illness was a deterrent. Additionally, exposing study subjects to a substance with potentially harmful effects—and no therapeutic value—did not comport with appropriate ethical conduct.¹⁶²

In 1948, researchers Richard Doll and A. Bradford Hill developed the retrospective observational study to avoid the disadvantages of the randomized, double-blind trial.¹⁶³ The retrospective study began with a group of ill subjects (in this case, lung cancer patients) and compared them with healthy subjects. The data collected from both groups were statistically compared to determine the existence and identity of risk factors associated with development of the disease.¹⁶⁴ The results of the study demonstrated a strong correlation between cigarette smoking and lung cancer, as well as a dose-response relationship showing more cases of lung cancer among those who smoked more.¹⁶⁵ The Doll and Hill study, and resulting report, form the cornerstone for Brandt's demonstration of a significant evolution in epidemiology at mid-century. Brandt summarizes the value of their methodology as follows:

Doll and Hill worked to eliminate the possibility of bias in the selection of patients and controls, as well as in reporting and recording their histories; they emphasized the significance of a clear temporal relationship between exposure and the subsequent development of disease; and

Tobacco as a Carcinogenic Agent, 63 DEUTSCHE MED. WOCHENSCHRIFT 1267–71 (1937)).

¹⁶¹ Such studies are best suited to, for example, clinical drug trials, where a therapeutic value of the exposure is anticipated. See Black & Lilienfeld, *supra* note 151, at 755–56.

¹⁶² See BRANDT, *supra* note 3, at 136.

¹⁶³ *Id.*

¹⁶⁴ An important feature in the design of such studies was the neutrality of the researchers. According to Brandt, Doll and Hill appeared to have a sufficiently neutral attitude going into the study, as they entered the study with “considerable skepticism” about a causal connection between smoking and lung cancer. *Id.* at 137.

¹⁶⁵ *Id.* at 138 (citing Raymond Pearl, *Tobacco Smoking and Longevity*, 87 SCI. 216–17 (1938); Richard Doll & Austin Bradford Hill, *Smoking and Carcinoma of the Lung: Preliminary Report*, 224 BRIT. MED. J., Sept. 30, 1950, at 742–43, 747). The study also examined gender distinctions in rates of lung cancer among smokers. The researchers concluded that the fewer cases among women appeared to be due to the fact that smoking among women had become commonplace much later than among men. *Id.* (citing Richard Doll & Austin Bradford Hill, *Smoking and Carcinoma of the Lung: Preliminary Report*, 224 BRIT. MED. J., Sept. 30, 1950, at 742–43, 747). This early study demonstrates the importance of the latency period in identifying the causal connection between a particular exposure and the appearance of disease.

they sought to rule out any other factors that might distinguish controls from patients with disease. This explicit search for, and elimination of, possible “confounders” was a critical step toward their conclusion. Further, they insisted on carefully addressing all possible alternative explanations for their findings.¹⁶⁶

The problem with their approach, however, was that they could not state definitively that cigarette smoking caused a particular subject’s lung cancer. They could only provide a statistical probability, or risk factor, relating to smoking and lung cancer.

Shortly after the publication of their retrospective study,¹⁶⁷ Doll and Hill designed a prospective study that looked at a large group of healthy physicians whose health and smoking habits they followed for several years.¹⁶⁸ The prospective study, in which no participants were ill with lung cancer when the study began, eliminated any bias that might have existed in the earlier study where hospital patients with lung cancer were specifically studied. The results confirmed the conclusions they had reached in the retrospective study.¹⁶⁹ Moreover, the new epidemiological studies were consistent with the earlier clinical studies and animal studies. An impressive body of scientific data was accumulating that tended to show a causal connection between cigarette smoking and lung cancer, as well as cardiovascular disease.¹⁷⁰

B. *The Science of Toxic Tort Litigation in Historical Context*

Brandt’s analysis is consistent with the dilemma of specific causation in the law of toxic torts. The specific causation problem in toxic torts has been addressed by many courts, perhaps most pedagogically by the court in *Allen v. United States*, a case involving injuries from radiation exposure during the United States government’s atomic weapons testing program in the 1950s.¹⁷¹ The plaintiffs suffered from leukemia and other cancers that they claimed had been induced by exposure to environmental radiation from the testing program. Several factors complicated their ability to prove causation, including long latency periods between the time of exposure and the manifestation of their illnesses, the possibility that other intervening causes were responsible for the illnesses, and the fact that the

¹⁶⁶ *Id.* at 140.

¹⁶⁷ Doll and Hill came under attack for possible bias in their study design. *Id.* at 142.

¹⁶⁸ *Id.* at 144.

¹⁶⁹ *Id.* (citing Richard Doll & A. Bradford Hill, *Lung Cancer and Other Causes of Death in Relation to Smoking: A Second Report on the Mortality of British Doctors*, 230 BRIT. MED. J., Nov. 10, 1956, at 1071–81).

¹⁷⁰ *See id.* at 145.

¹⁷¹ *Allen v. United States*, 588 F. Supp. 247 (D. Utah 1984), *rev’d on other grounds*, 816 F.2d 1417 (10th Cir. 1987).

illnesses claimed were “non-specific” because radiation-induced cancers were indistinguishable from cancers resulting from other causes or arising idiopathically.¹⁷²

The *Allen* court succinctly summarized the plaintiffs’ causation dilemma:

In most cases, the factual connection between defendant’s conduct and plaintiff’s injury is not genuinely in dispute. Often, the cause-and-effect relationship is obvious: A’s vehicle strikes B, injuring him; a bottle of A’s product explodes, injuring B; water impounded on A’s property flows onto B’s land, causing immediate damage.

In this case, the factual connection singling out the defendant as the source of the plaintiffs’ injuries and deaths is very much in genuine dispute. Determination of the cause-in-fact, or factual connection, issue is complicated by the nature of the injuries suffered . . . , the nature of the causation mechanism . . . , the extraordinary time factors and other variables¹⁷³

As the court suggested, in traditional torts, cause in fact is often a relatively straightforward analysis, a question of drawing an uninterrupted linear connection between the defendant’s conduct (exploding product, motor vehicle collision) and the plaintiff’s injury. While challenges always exist when multiple actors¹⁷⁴ or pre-existing conditions¹⁷⁵ are involved, generally a single analysis of cause in fact will suffice. In contrast, cases involving latent illness, such as toxic torts, typically necessitate a bifurcation of the cause in fact analysis between determination of general causation—the ability of the substance to cause the kind of illness suffered by the plaintiff—and specific causation—proof that the substance actually caused the occurrence of the illness in the plaintiff.¹⁷⁶

Further complicating this inquiry is the fact that medical science has yet to identify a single mechanism that can definitively be said to cause

¹⁷² *Id.* at 406; see also Black & Lilienfeld, *supra* note 151, at 738 (“Because most toxic tort cases involve diseases with long latency or incubation periods, and because many of these diseases may occur in the absence of any identifiable exposure, causation very often becomes a central and complex issue at trial.”).

¹⁷³ *Allen*, 588 F. Supp. at 405.

¹⁷⁴ See, e.g., *Landers v. E. Tex. Salt Water Disposal Co.*, 248 S.W.2d 731, 734 (Tex. 1952) (finding both polluting defendants liable for property damage where each was a substantial factor in damage).

¹⁷⁵ See, e.g., *Dillon v. Twin State Gas & Elec. Co.*, 163 A. 111, 115 (N.H. 1932) (holding defendant liable only for hastening decedent’s death which was certain to occur from other causes).

¹⁷⁶ See *Sterling v. Velsicol Chem. Corp.*, 855 F.2d 1188, 1200 (6th Cir. 1988) (requiring plaintiffs to prove both that the allegedly injurious substances could cause the claimed illnesses and that the substances actually caused the plaintiffs’ specific illnesses).

cancer. As a result, in the words of one expert, “any statement about the role of any agent as a carcinogen is hedged with assumptions and hypotheses. Because scientists do not yet understand the molecular model of carcinogenesis, it is impossible to state that a given carcinogen caused any individual tumor.”¹⁷⁷ Even where a particular substance is known to be carcinogenic, thus establishing general causation, a plaintiff may have difficulty demonstrating that the exposure to the substance actually caused his or her individual cancer.¹⁷⁸ If cause in fact cannot be established, a plaintiff will not be able to sustain his or her case for damages, unless a court is willing to ease the causation requirements.¹⁷⁹

Brandt details this medical dilemma which led to the causation problems that have shaped so much of toxic tort litigation. Brandt admits that a probabilistic conclusion such as that achieved in the Doll and Hill study was a major shift in scientific inquiry, and argues that these new studies were useful for determining the causes of the new kinds of chronic illnesses emerging in the twentieth century. He states: “For those in search

¹⁷⁷ Troyen A. Brennan, *Causal Chains and Statistical Links: The Role of Scientific Uncertainty in Hazardous-Substance Litigation*, 73 CORNELL L. REV. 469, 475 (1988).

¹⁷⁸ See Jean Macchiaroli Eggen, *Toxic Torts, Causation, and Scientific Evidence After Daubert*, 55 U. PITT. L. REV. 889, 899 (1994) (noting that a statistical study alone is not enough to prove that a carcinogenic substance caused a particular individual’s case of cancer). In *Sterling v. Velsicol Chemical Corp.*, the court stated:

It was first established that Velsicol was responsible for the contamination and that the particular contaminants were *capable* of producing injuries of the types allegedly suffered by the plaintiffs. . . . This enabled the court to determine a kind of generic causation—whether the combination of the chemical contaminants and the plaintiffs’ exposure to them had the capacity to cause the harm alleged. This still left the matter of *individual* cause to be determined. . . . [G]eneralized proofs will not suffice to prove individual damages.

Sterling, 855 F.2d at 1200.

¹⁷⁹ In *Allen v. United States*, for example, the court accommodated the plaintiffs by allowing them to state a case, absent traditional proof of cause in fact, based upon the following test:

Where a defendant who negligently creates a radiological hazard which puts an identifiable population group at increased risk, and a member of that group at risk develops a biological condition which is consistent with having been caused by the hazard to which he has been negligently subjected, such consistency having been demonstrated by substantial, appropriate, persuasive and connecting factors, a fact finder may reasonably conclude that the hazard caused the condition absent persuasive proof to the contrary offered by the defendant.

Allen v. United States, 588 F. Supp. 247, 415 (D. Utah 1984). The “connecting factors” included:

(1) [T]he probability that plaintiff was exposed to ionizing radiation due to nuclear fallout from atmospheric testing at the Nevada Test Site at rates in excess of natural background radiation; (2) that plaintiff’s injury is of a type consistent with those known to be caused by exposure to radiation; and (3) that plaintiff resided in geographical proximity to the Nevada Test Site for some time between 1951 and 1962. Other factual connections may include but are not limited to such things as time and extent of exposure to fallout, radiation sensitivity factors such as age or special sensitivities of the afflicted organ or tissue, retroactive internal or external dose estimation by current researchers, a latency period consistent with a radiation etiology, or an observed statistical incidence of the alleged injury greater than the expected incidence in the same population.

Id.

of a 'definitive' demonstrative experiment, notions of probabilistic, quantitative findings were anathema. Many researchers now pointed out, however, that much in medicine and science could not necessarily be confirmed in the laboratory."¹⁸⁰

In toxic tort litigation, the utility of retrospective and prospective studies such as those conducted by Doll and Hill is immeasurable. More than half a century later, however, these studies still carry a legal stigma associated with their inability to provide a conclusive causal connection between exposure and disease. Simply put, epidemiological studies are predictive of the probability that a particular person's illness may have resulted from exposure to the particular toxic substance, but do not establish that the illness *actually* resulted from the exposure.¹⁸¹ In toxic tort litigation, epidemiological studies have become the most important evidence of causation. Thus, in *Brock v. Merrell Dow Pharmaceuticals, Inc.*, a product liability case involving the drug Bendectin, the Fifth Circuit Court of Appeals stated that "[u]ndoubtedly, the most useful and conclusive type of evidence in a case such as this is epidemiological studies."¹⁸² But plaintiffs have encountered difficult admissibility problems when using epidemiological evidence because of its probabilistic nature.¹⁸³

Brandt acknowledges that at the time the new epidemiology was emerging, its greatest critics were some of the researchers' scientific colleagues who clung to traditional investigative methods. Brandt states: "Epidemiological findings like those of Doll and Hill would come under attack from scientists unilaterally committed to experimental laboratory investigation. But the lab offered no way of resolving the question of smoking's harms."¹⁸⁴ Brandt argues that the history of scientific inquiry into biomedical matters has rejected a single, monolithic investigational method of the sort these critics favored.¹⁸⁵ He further contends that the tobacco industry was particularly instrumental in keeping alive the notion of a single-cause modality and in creating a fictional "battle between laboratory and statistical science" to further its own interests in maintaining the idea that smoking was safe.¹⁸⁶

¹⁸⁰ BRANDT, *supra* note 3, at 150.

¹⁸¹ Eggen, *supra* note 178, at 899.

¹⁸² *Brock v. Merrell Dow Pharms., Inc.*, 874 F.2d 307, 311 (5th Cir. 1989), *modified*, 884 F.2d 166 (5th Cir. 1989).

¹⁸³ *Id.*; Eggen, *supra* note 178, at 909–31 (discussing admissibility issues under the Federal Rules of Evidence).

¹⁸⁴ BRANDT, *supra* note 3, at 151.

¹⁸⁵ "[T]here has never been, as some would later claim, a single gold standard of disease causality. That the biomedical paradigm of single cause and single disease was a chimera was well understood by even its most vigorous advocates. And medical knowledge was always provisional and contingent." *Id.* at 152.

¹⁸⁶ *Id.* at 153.

The vestiges of this attitude appear in contemporary toxic tort litigation and continue to present problems for plaintiffs. *General Electric Co. v. Joiner* is a case in point.¹⁸⁷ Best known as the second in the trio of rulings by the United States Supreme Court on the admissibility of scientific evidence under the Federal Rules of Evidence,¹⁸⁸ *Joiner* was a toxic tort suit brought by a worker with lung cancer who claimed workplace exposure to polychlorinated biphenyls (PCBs), but who also had a history of smoking and a family history of lung cancer.¹⁸⁹ The district court held that the epidemiological and animal studies proffered by the plaintiff to prove causation were inadmissible.¹⁹⁰ While the Eleventh Circuit reversed,¹⁹¹ the Supreme Court held that an admissibility decision was reviewable only for abuse of discretion and that ample evidence existed in the record to support the decision of the district court.¹⁹² The Court was particularly concerned that the proffered studies did not prove the specific causation the plaintiff was required to show. The Court stated:

Trained experts commonly extrapolate from existing data. But nothing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert. A court may conclude that there is simply too great an analytical gap between the data and the opinion proffered.¹⁹³

The Court thus rejected the notion that a study, such as an epidemiological study, that may demonstrate some measure of general causation could be made to demonstrate specific causation simply because that was the position of the plaintiff's qualified expert.

The *Joiner* decision raises the legal question connected to the epidemiological revolution detailed by Brandt in *The Cigarette Century*: Can the analytical gap between epidemiological evidence and proof of specific causation ever be narrowed? This is one of the most pervasive problems in all of toxic torts. Indeed, some courts have attempted to apply a statistical standard to the admissibility of epidemiological studies in an

¹⁸⁷ *General Electric Co. v. Joiner*, 522 U.S. 136 (1997).

¹⁸⁸ The best known of the cases is *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 595–96 (1993) (discussing the various factors that should be considered in determining reliability of evidence, and holding that the Federal Rules of Evidence require that scientific evidence must be both scientifically reliable and relevant). See also *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 147 (1999) (holding that the *Daubert* admissibility test applies not just to scientific studies, but to any expert scientific, technical, or other evidence sought to be admitted under Federal Rule of Evidence 702).

¹⁸⁹ *Joiner*, 522 U.S. at 139–40.

¹⁹⁰ *Joiner v. General Electric Co.*, 864 F. Supp. 1310, 1326 (N.D. Ga. 1994), *rev'd*, 78 F.3d 524, 534 (11th Cir. 1996), *rev'd*, 522 U.S. 136, 147 (1997).

¹⁹¹ *Joiner v. General Electric Co.*, 78 F.3d 524, 534 (11th Cir. 1996), *rev'd*, 522 U.S. 136 (1997).

¹⁹² *Joiner*, 522 U.S. at 146–47.

¹⁹³ *Id.* at 146.

effort to impose some sort of objective threshold on the admissibility process. For example, in *Hall v. Baxter Healthcare Corp.*, a silicone gel breast implant case, the federal district court held that only evidence based upon studies on the relationship between implants and various autoimmune diseases that had a statistical relative risk factor greater than 2.0 would be admissible.¹⁹⁴ But such efforts remain problematic, largely because disagreement exists over the significance of statistical relative risk and the arbitrariness of choosing a particular threshold for admissibility.¹⁹⁵

Scientific inquiry is an evolving process, and “arguably there are no certainties in science.”¹⁹⁶ The enterprise of the law, particularly the judicial system, requires resolution and closure at a definite point in time. Thus, science and the law may sometimes appear incompatible. In toxic tort litigation, however, the judicial system must find a point of consensus. Courts would do well to heed the lessons of the public health community in fashioning forward-looking rules to accommodate plaintiffs’ causation difficulties in such cases.

IV. PREEMPTION AND THE INTERACTION OF PUBLIC AND PRIVATE LAW

Brandt’s discussion of the attempts at regulating the tobacco industry resonates throughout other areas of toxic tort law as well. His observations on regulatory efforts in the area of tobacco products illuminate the current legal dilemma in federal preemption as it applies to product liability generally and toxic products in particular. Preemption is a major battlefield in toxic torts, playing out in litigation related to cigarettes,¹⁹⁷ medical devices,¹⁹⁸ prescription drugs,¹⁹⁹ and pesticides.²⁰⁰ The current state, and future shape and scope, of toxic product litigation was, in large part, determined by regulatory events related to tobacco products in the middle of the twentieth century.

As Brandt demonstrates, the enactment of the Federal Cigarette Labeling and Advertising Act of 1965²⁰¹ marked the first time the tobacco

¹⁹⁴ *Hall v. Baxter Healthcare*, 947 F. Supp. 1387, 1403–05 (D. Or. 1996).

¹⁹⁵ For a discussion of risk factors in epidemiological studies, see Black & Lilienfeld, *supra* note 151, at 757–58; Junius C. McElveen & Pamela S. Eddy, *Cancer and Toxic Substances: The Problem of Causation and the Use of Epidemiology*, 33 CLEV. ST. L. REV. 29, 39 (1985); see also Lucinda M. Finley, *Guarding the Gate to the Courthouse: How Trial Judges Are Using Their Evidentiary Screening Role to Remake Tort Causation Rules*, 49 DEPAUL L. REV. 335, 352–60 (1999) (discussing breast implant litigation and arguing that trial courts have conflated the standard of evidentiary admissibility and legal sufficiency of claims).

¹⁹⁶ *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 590 (1993).

¹⁹⁷ See, e.g., *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 530–31 (1992) (plurality opinion).

¹⁹⁸ See, e.g., *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 474, 486–89 (1996).

¹⁹⁹ See, e.g., *Levine v. Wyeth*, 944 A.2d 179, 182 (Vt. 2006), *cert. granted*, 128 S. Ct. 1118 (2008).

²⁰⁰ See, e.g., *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 447–48, 452 (2005).

²⁰¹ Federal Cigarette Labeling and Advertising Act of 1965, Pub. L. No. 89-92, 79 Stat. 282 (codified and amended at 15 U.S.C. §§ 1331–1340 (2000)).

industry took a concerted stand on regulation with tort litigation in mind. While the specter of tort litigation had been a threat to the industry from the earliest emergence of studies connecting smoking and cancer, following the Surgeon General's report in the 1960s tort litigation emerged in the foreground. Brandt discusses the contingent nature of the industry's accession to regulation: The industry was only interested in regulation to the extent that it would operate to preempt state tort actions based upon smoking and health, thereby immunizing the industry from tort liabilities.²⁰² The point Brandt makes, however, is that throughout this period of minimal labeling and advertising regulation in the 1960s and 1970s, the tobacco industry continued to thrive, with cigarette sales flourishing and profits rising.²⁰³ Thus, the appearance of package warnings seemed to have failed to produce the desired governmental purpose.²⁰⁴

The efforts of the tobacco industry to achieve preemption of state common-law tort actions against them based upon smoking and health did not meet with complete success. As Brandt discusses, an important feature of the legal landscape in the 1960s was the appearance of strict product liability, made manifest in Section 402A of 1965's *Restatement (Second) of Torts*, which eschewed negligence in favor of requiring the plaintiff to show that the product was "in a defective condition unreasonably dangerous to the ultimate user or consumer."²⁰⁵ Under the emerging strict product liability regime,²⁰⁶ the tobacco industry worked to establish a position that would best shield it from what it feared would be a flood of tort claims by smokers.

The United States Supreme Court addressed the issue of whether the federal cigarette labeling acts preempted tort claims against the tobacco companies in *Cipollone v. Liggett Group, Inc.*, a product liability action brought on behalf of a deceased smoker.²⁰⁷ The Supreme Court's decision

²⁰² BRANDT, *supra* note 3, at 254.

²⁰³ *See id.* at 256–57.

²⁰⁴ *See id.* at 257.

²⁰⁵ RESTATEMENT (SECOND) OF TORTS § 402A(1) (1965).

²⁰⁶ Product manufacturers logically perceived the requirements of strict liability as releasing plaintiffs from the more difficult showings of duty and breach of duty that negligence claims require. *The Second Restatement of Torts* was also important in making explicit the abrogation of privity of contract in the product liability context, which made it easier for injured persons to sue under strict product liability. *See id.* § 402A(1)(b) (1965) (providing that a seller of a defective product is liable for a plaintiff's physical injury if the seller could expect the product to reach the user).

²⁰⁷ *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 512 (1992) (plurality opinion). Brandt spends substantial time discussing the trial of the *Cipollone* case, which occurred much earlier, following a ruling by the Third Circuit Court of Appeals in *Cipollone v. Liggett Group, Inc.*, 789 F.2d 181, 186–87 (3d Cir. 1986), that effectively preempted many of the plaintiff's claims. *See* BRANDT, *supra* note 3, at 329–35. The jury found that Liggett had breached its duty to warn of the health hazards of its cigarettes prior to the 1966 package warnings, but that Rose Cipollone was eighty percent responsible for her own injuries, which barred any recovery on the negligence claims. *Cipollone*, 893 F.2d at 554. The jury awarded \$400,000 to her husband, however, for his damages on the claim for breach of express warranty, but awarded no damages to Rose Cipollone's estate on the warranty claim. *Id.* at

on the preemption issue reflected the deep ambivalence in legal circles over the treatment of smokers' health claims. On the one hand, the decision did not provide the tobacco industry with the blanket protection it had sought and ensured that the courtroom battles over manufacturer liability for smoking-related illness would continue unabated. On the other hand, it shielded the industry from several major claims. After examining the language of the preemption provisions contained in the 1966 and 1969 cigarette labeling acts, the Court determined that only the 1969 act preempted tort claims, and preempted only those asserting that the company failed to adequately warn of the health hazards of smoking.²⁰⁸ The failure-to-warn claims included negligent failure-to-warn, strict liability, and claims that the company had neutralized the impact of the package warnings through its advertising.²⁰⁹ The Court ruled that the claims not preempted were negligent testing and research, misrepresentation claims not specifically relating to packaging or advertising, and the express warranty claim.²¹⁰

The preemption battle has become heated in toxic tort litigation in the years since the *Cipollone* decision. Indeed, preemption is one of the most important legal issues involving allegedly toxic products currently confronting the bench and bar. *Cipollone* initiated the analytical process for determining the relationship between personal-injury tort claims and health-based federal legislation. The Supreme Court has subsequently employed that analytical process in a variety of toxic product preemption actions involving several statutes.

Thus, in *Bates v. Dow Agrosciences LLC*, the Court held that the express preemption provision in the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)²¹¹ did not preempt most of the product liability claims raised in the case, including claims for defective product design, defective manufacturing, negligent testing, and express warranty.²¹² In *Bates*, Dow brought a declaratory judgment action against farmers who claimed that Dow's pesticide, Strongarm, damaged their crops. Dow

555. Although this was the first plaintiff's verdict in a tort action for smoking-related illness, the victory proved short-lived. The Third Circuit remanded the case for a new trial on the basis of erroneous jury instructions. *Id.* at 569. Still, the *Cipollone* verdict was another watershed event, signaling the willingness of the public—as represented by the jury—to view the actions of the industry negatively.

²⁰⁸ *Cipollone*, 505 U.S. at 524. The distinction between the Court's interpretation of the 1966 act and the 1969 act vis-à-vis preemption related to the change in language in the preemption provision. *Id.* at 520. For a discussion of the Supreme Court's decision and its importance in cigarette litigation generally, see Eggen, *supra* note 81, at 8–18.

²⁰⁹ See *Cipollone*, 505 U.S. at 509, 524, 528.

²¹⁰ *Id.* at 522, 524–27. Back in the district court for yet another trial, the former trial judge was removed, and the plaintiff's attorney withdrew. KLUGER, *supra* note 6, at 676–77. Subsequently, the family decided not to pursue the case further. BRANDT, *supra* note 3, at 352.

²¹¹ 7 U.S.C. § 136v(b) (2000).

²¹² *Bates v. Dow Agrosciences LLC*, 544 U.S. 431 (2005).

sought a determination that the farmers' product liability claims would be preempted by FIFRA.²¹³ In its decision, the Court—in an opinion authored by Justice Stevens, the author of the plurality opinion in *Cipollone*—directly followed its reasoning in *Cipollone* even though *Bates* involved a different federal statute and property damage claims rather than personal injuries.²¹⁴

In 2008, the Court embraced *Cipollone* yet again in an important product preemption decision, *Riegel v. Medtronic, Inc.*²¹⁵ *Riegel* picks up where the Court left off in *Medtronic, Inc. v. Lohr*,²¹⁶ with both cases involving the preemption provision in the Medical Device Amendments (MDA) of the Food, Drug, and Cosmetic Act (FDCA).²¹⁷ In *Lohr*, the Court had relied heavily on *Cipollone* in holding that none of the plaintiffs' personal injury product liability claims was preempted.²¹⁸ But in *Riegel*, the Court seems to have moved even closer to *Cipollone*'s result, in which some claims were deemed to be preempted and others not.²¹⁹ The Court leaned on *Cipollone* in ruling that the term “requirements” in a preemption provision—one stating that no state requirements different from those imposed under the relevant federal statute would be allowed—could encompass common-law claims. The Court stated:

Congress is entitled to know what meaning this Court will assign to terms regularly used in its enactments. 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. And while the common-law remedy is limited to damages, a liability award “can be, indeed is designed to be, a potent method of governing conduct and controlling policy.”²²⁰

Even though *Riegel* involved a different statute, a textually different

²¹³ *Id.* at 434–35. The farmers counterclaimed with claims based upon strict liability, negligence, fraud, breach of warranty, and violation of the Texas Deceptive Practices-Consumer Protection Act. *Id.* at 435–36.

²¹⁴ See Jean Macchiaroli Eggen, *The Normalization of Product Preemption Doctrine*, 57 ALA. L. REV. 725, 747, 750–51 (2006) (“[T]he Court clearly was contemplating *Cipollone* and establishing some consistency between that case and *Bates*.”).

²¹⁵ *Riegel v. Medtronic, Inc.*, 128 S. Ct. 999 (2008).

²¹⁶ *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996).

²¹⁷ 21 U.S.C. § 360k(a) (1999).

²¹⁸ See *Lohr*, 518 U.S. at 494–502 (citing *Cipollone*, the Court held that the MDA did not preempt the Lohrs' claims).

²¹⁹ To a large extent, this movement is attributable to the composition of the Court in 2008.

²²⁰ *Riegel*, 128 S. Ct. at 1008 (quoting *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 521–22 (1992)) (internal citations omitted).

preemption provision, and different underlying purposes and policy goals, the Court held that “there is nothing to contradict this normal meaning” of the term “requirements” as it had been defined in *Cipollone*.²²¹ The Court went on to hold that claims based upon alleged defects in the defendant’s cardiac balloon catheter were expressly preempted by the MDA because the extensive premarket approval process that the device underwent established specific health and safety requirements for the device that potentially contradicted state tort liability.²²²

In *Riegel*, the Supreme Court used *Cipollone* as the legal standard for express preemption, holding that the term “requirements” in a preemption provision will be presumed to encompass liabilities under state common law. This extension of *Cipollone* to other statutes is significant and may have far-reaching implications. So far, however, preemption has not extended to all claims related to smoking and health.

In 2008, the United States Supreme Court granted certiorari in what could prove to be an important test of *Cipollone*’s strength—and of the tobacco industry’s power. In October 2008, the Court heard arguments in *Good v. Altria Group, Inc.*, in which the First Circuit Court of Appeals addressed another aspect of cigarette labeling invoking the preemption provision of the cigarette labeling act.²²³ The plaintiffs claimed that defendant Philip Morris had used unfair and deceptive practices when it sold certain “light” cigarettes or cigarettes advertised as containing “lowered tar and nicotine.”²²⁴ The plaintiffs alleged that Philip Morris was aware that smokers of these cigarettes unconsciously drew in more smoke or covered ventilation holes so as to make up for the reduced amounts of nicotine they otherwise would inhale; thus, the plaintiffs claimed that Philip Morris’s labeling had materially misrepresented the cigarettes as being a safer alternative for smokers.²²⁵ The First Circuit closely followed the *Cipollone* decision in reversing the district court’s dismissal of the claims²²⁶ and held that the cigarette labeling act neither expressly²²⁷ nor impliedly²²⁸ preempted the claims. Furthermore, the court held that the claims were not preempted by the Federal Trade Commission’s action on light cigarette labeling, which was ambiguous at best and had not

²²¹ *Id.*

²²² *Id.* at 1011.

²²³ *Good v. Altria Group, Inc.*, 501 F.3d 29, 30 (1st Cir. 2007), *cert. granted*, 128 S. Ct. 1119 (2008).

²²⁴ *Id.* at 30.

²²⁵ *Id.* at 31.

²²⁶ The district court had characterized the claims as failure-to-warn claims, rather than misrepresentation and/or fraud claims. Accordingly, the district court followed the direct holding of *Cipollone* and ruled that the claims were preempted by the labeling act. *See id.* at 33, 37.

²²⁷ *Id.* at 39.

²²⁸ *Id.* at 49.

amounted to formal rulemaking.²²⁹

Indisputably, *Cipollone* was a watershed event in preemption jurisprudence, but what remains to be seen is the degree to which the case has continued longevity. In *Riegel*, the Court continued to rely upon *Cipollone*'s interpretation of "requirements" in the 1969 cigarette labeling act's express preemption provision to allow for the preemption of state tort actions, and extended the force of *Cipollone* to other statutes with similar language. But *Good* will demonstrate whether the Court will take a more expansive position on preemption and move beyond *Cipollone*, either in interpreting the scope of the cigarette labeling act's preemption provision or in applying implied preemption, or both.²³⁰ If the Court holds for Philip Morris, it will move away from the direct holding in *Cipollone*. Either way, the case has potential for far-reaching implications in other types of product liability actions, involving other federal statutes. Furthermore, the tobacco industry is still lobbying for some measure of regulation, this time by the FDA.²³¹ The regulation would presumably include a clear preemption provision to shield it from liability.

In the wake of *Good*, it is possible that product preemption doctrine will turn yet another corner with the potential result of restricting or eliminating many common product claims. Indeed, the tobacco industry's strategy has proved to be a template for the approach of other industries toward regulation when faced with the prospect of extensive tort liabilities. In another important 2008 development, the United States Supreme Court has granted certiorari in a pharmaceutical case in which the manufacturer of the anti-nausea drug Phenergan has argued that a plaintiff's state-law tort claims are impliedly preempted by the FDCA, an act that does not contain a preemption provision applicable to drugs. In *Levine v. Wyeth*, the Vermont Supreme Court held that implied conflict preemption did not bar the plaintiff's claims.²³² This case moves away from the express

²²⁹ See *id.* at 51–54 (discussing the preference of agencies to formulate policy through case-by-case adjudication rather than rulemaking).

²³⁰ Oral argument in the *Good* case was held on October 6, 2008. For the full transcript of the argument, see http://www.supremecourtus.gov/oral_arguments/argument_transcripts/07-562.pdf. During argument, Justice Ginsberg questioned the attorneys on what the MSA said about deceptive practices of the industry. See *id.* at 18, 36. Presumably, Justice Ginsberg thought the contents of the MSA may have some impact on the preemption question before the court. Ultimately, *Good* will reveal whether the Court will follow *Cipollone* directly or take it in a different direction.

²³¹ See PHILIP MORRIS USA GOV'T. AFF., FDA & TOBACCO: WHERE WE STAND 32 (2008), available at http://www.philipmorrisusa.com/en/cms/Responsibility/Government_Relations/Legislative_Issues/pdfs/fda_and_tobacco.pdf.aspx (discussing the key legislative provisions of the Family Smoking Prevention and Tobacco Control Act).

²³² *Levine v. Wyeth*, 944 A.2d 179, 188–89 (Vt. 2006), cert. granted, 128 S. Ct. 1118 (2008) (oral argument held on Nov. 3, 2008). *Contra Colacicco v. Apotex Inc.*, 521 F.3d 253 (3d Cir. 2008) (holding that preemption bars the plaintiff's action). For arguments against preemption of drug product liability claims, see David A. Kessler & David C. Vladeck, *A Critical Examination of the FDA's Efforts to Preempt Failure-to-Warn Claims*, 96 GEO. L.J. (forthcoming 2008), which discusses these issues in light of the FDA's new policy favoring drug claim preemption. *But see* Richard A. Epstein,

preemption issues addressed in *Cipollone* and takes the product preemption debate to the next level, that of implied preemption, and will possibly expand preemption further. The arguments of the drug manufacturer in *Levine* are the direct descendants of the arguments raised by the tobacco industry in *Cipollone*, and will determine the scope and character of toxic product litigation well into the future.

As 2008 wanes, the outgoing Bush administration has developed a strategy to apply preemption expansively to many product claims. This move is directly connected to the events documented by Brandt generally, and to the administration's dissatisfaction with the *Cipollone* line of cases, which has continued to allow many product liability claims. Reports indicate that administration officials have written approximately fifty rules to bar product liability claims involving a broad array of products.²³³ The current focus on preemption is testimony to the continued vitality of the tort reform movement and to the legacy of the tobacco industry, whose initial—and continuing—efforts have made preemption one of the most significant legal issues of our time.

V. MASS TORT LITIGATION AND PUBLIC HEALTH GOALS

Another aspect of toxic tort law affected by the events detailed in *The Cigarette Century* is mass toxic tort litigation. During the 1990s, the anti-tobacco bar turned its attention to the judicial system with mixed results. Brandt declares, “[B]etween 1994 and 1997, more lawsuits were filed against tobacco firms than in the previous thirty years.”²³⁴ Brandt gives the impression that much of the impetus for resorting to the courts was the frustrating efforts at regulation of tobacco. While this is true to some extent, the situation was legally far more complex.

The increase in tobacco product liability lawsuits was a natural outgrowth of the toxic tort phenomenon that took hold following the 1984 settlement of *In re “Agent Orange” Product Liability Litigation*²³⁵ and the 1986 settlement during trial of *Anderson v. W.R. Grace*,²³⁶ given household recognition by the publication of Jonathan Harr's book, *A Civil Action*.²³⁷ Toxic tort litigation became a recognizable feature of the legal landscape

Why the FDA Must Preempt Tort Litigation: A Critique of Chevron Deference and a Response to Richard Nagareda, 1 J. TORT. L. 1 (2006), available at <http://www.bepress.com/jtl/vol1/iss1/art5/> (arguing in favor of drug claim preemption).

²³³ Alicia Mundy, *Bush Rule Changes Could Block Product-Safety Suits*, WALL ST. J., Oct. 15, 2008, available at http://online.wsj.com/article/SB122403828537735379.html?mod=dist_smartbrief (stating that the rules include “everything from motorcycle brakes to pain medicine”).

²³⁴ BRANDT, *supra* note 3, at 404.

²³⁵ *In re “Agent Orange” Prod. Liab. Litig.*, 597 F. Supp. 740 (E.D.N.Y. 1984) (“Fairness Opinion” approving settlement).

²³⁶ *Anderson v. W.R. Grace & Co.*, 628 F. Supp. 1219 (D. Mass. 1986).

²³⁷ JONATHAN HARR, *A CIVIL ACTION* (1995).

throughout the late 1980s and 1990s. A natural adjunct of this was an increase in smoker suits and nonsmoker ETS suits. Developments in asbestos litigation had driven the legal issues in toxic product liability suits since the 1970s, particularly with respect to the application of the doctrine of strict product liability, and plaintiffs were achieving success.²³⁸ Asbestos mass litigation reached epidemic proportions in the 1990s, with attorneys and courts working to develop means to manage the influx of claims. Accordingly, there was an increased interest in the use of the class action device and other aggregative procedures to resolve mass tort actions,²³⁹ many of which had public health implications.

Tobacco claims seemed uniquely suited to an aggregative device such as the class action. Although the section on litigation in *The Cigarette Century* is relatively small in relation to other sections of the book, it demonstrates that the use of aggregative procedures was instrumental in making litigation a formidable challenge for the otherwise impervious tobacco industry. Brandt is correct in suggesting that the governmental suits for reimbursement of public expenditures for smoking-related illnesses arose primarily from a frustration over the lack of industry regulation which resulted in high health costs for the states.²⁴⁰ He proceeds to demonstrate the way in which these suits were affirmatively used to apply pressure to the industry in an attempt to effect “global” regulation. Although the 1997 global settlement ultimately failed—because it was contingent upon Congress acting to implement its provisions, something Congress declined to do—that agreement highlighted the conflicts within the public health community over the advisability of negotiations with the tobacco industry. As Brandt states:

[T]he proposed Global Settlement Agreement brought to light an intense social and political debate about the role of litigation in the tobacco wars and in the public health generally. Some advocates saw litigation as incremental, inefficient, and inappropriate. . . . Others saw the history of congressional legislation as powerfully shaped, if not corrupted, by industry interests and largesse, and viewed the courts as the critical venue for public health reform.²⁴¹

This debate within the tobacco public health community is a reflection of the larger debate over the role of mass toxic tort litigation, a discussion that

²³⁸ See, e.g., *Borel v. Fibreboard Paper Prods. Corp.*, 493 F.2d 1076 (5th Cir. 1973) (affirming a judgment in favor of the plaintiff for asbestos injury).

²³⁹ See Linda S. Mullenix, *Beyond Consolidation: Postaggregative Procedure in Asbestos Mass Tort Litigation*, 32 WM. & MARY L. REV. 475 (1991) (discussing districtwide and nationwide class actions).

²⁴⁰ BRANDT, *supra* note 3, at 412–13.

²⁴¹ *Id.* at 425.

is ongoing and heated.²⁴²

Following Congress's failure to enact the terms of the 1997 global settlement, the states signed onto the newly negotiated MSA with the tobacco industry in 1998. As previously discussed, the provisions of the MSA had neither the scope nor the anticipated teeth that the 1997 agreement envisioned.²⁴³ The MSA contained what Brandt refers to as "a chain of loopholes" that ultimately passed along the costs of the agreement's provisions to consumers and made the states more dependent on tobacco money than they had previously been.²⁴⁴ The money received by the states pursuant to the MSA contained no spending restrictions. Thus, as Brandt documents, by 2005, only about four percent of the monies received by the states had been used for tobacco control.²⁴⁵

The disappointment of the MSA highlighted some fundamental problems with attempting to bring about public health regulation through mass litigation. Other cases raise additional problems. In *Castano v. American Tobacco Company*,²⁴⁶ a nicotine addiction case, the district court had certified a class action pursuant to Rule 23(b)(3) of the Federal Rules of Civil Procedure.²⁴⁷ The Fifth Circuit Court of Appeals decertified the class and held that the action could not be maintained as a class action because the district court had abused its discretion in, among other things, deciding that class questions predominated over individual questions.²⁴⁸ In particular, the Fifth Circuit noted that the district court had not considered the impact a class comprised of persons from all fifty states—representing many different product liability regimes—would have on a trial on the merits.²⁴⁹

While other areas of toxic torts have not gone the route of state reimbursement suits, numerous efforts at bringing about comprehensive "global" resolution of pervasive toxic tort litigation have met with resistance and defeat. For example, in *In re Rhone-Poulenc Rorer Inc.*, the Seventh Circuit Court of Appeals granted a writ of mandamus on the matter of class certification in an action brought on behalf of thousands of hemophiliacs who claimed to have received contaminated blood

²⁴² For a discussion of the policies favoring and disfavoring use of aggregative procedures, with particular discussion of asbestos litigation, see Edward F. Sherman, *Aggregate Disposition of Related Cases: The Policy Issues*, 10 REV. LITIG. 231 (1991).

²⁴³ See *supra* notes 118–24 and accompanying text for discussion of the MSA.

²⁴⁴ BRANDT, *supra* note 3, at 432–33.

²⁴⁵ *Id.* at 435.

²⁴⁶ *Castano v. Am. Tobacco Co.*, 870 F. Supp. 1425 (E.D. La. 1994).

²⁴⁷ See FED. R. CIV. P. 23(b)(3) (requiring that questions of law or fact applicable to the class predominate over those applicable only to individuals, and that the class action device be superior to other procedural devices available to manage the litigation).

²⁴⁸ *Castano v. Am. Tobacco Co.*, 84 F.3d 734 (5th Cir. 1996).

²⁴⁹ See *id.* at 741–43 ("The district court's review of state law variances can hardly be considered extensive; it conducted a cursory review of state law variations and gave short shrift to the defendant's arguments concerning variations.").

products.²⁵⁰ The court determined, among other things, that aggregation of the actions into a class action was prejudicial to the defendant because it had the effect of pressuring the company into settling the suit, even though the company had won twelve of the first thirteen individual lawsuits that had previously gone to trial on the same issue.²⁵¹

Brandt does not discuss the disadvantages of using the class action device for mass toxic torts or the swing of the judicial pendulum away from embracing aggregative procedures. In toxic torts litigation, that trend generally has made relief more difficult to achieve for plaintiffs. The class action device has accumulated more negatives the more frequently it has been used in mass tort actions, and particularly in mass product liability litigation. Many members of the plaintiffs' bar are cautious about seeking class certification or advising their clients to join a class action if they perceive that their clients may not receive a truly equitable share in a class action settlement.²⁵² There is no uniformly fair method for allocating settlement payments in a class action, and even methods that use a special master to determine fair compensation have their limits.²⁵³

Another reason for rejecting the use of class actions in mass product liability litigation has been the fragmentation of questions of law and fact among a large plaintiff class whose exposures and injuries arose at different times and places and under different circumstances. In general, many questions relating to the defendant's conduct, the nature of the product, and general causation can be decided on a class basis. Specific causation and damages, however, are individual questions. As the Sixth Circuit Court of Appeals stated in *Sterling v. Velsicol Chemical Corporation*, "generalized proofs will not suffice to prove individual damages."²⁵⁴ Accordingly, the plaintiffs would have to separately prove their individual damages, using their evidence of specific causation. In certifying the *Agent Orange* class action, Judge Weinstein of the Eastern District of New York held that the determination of whether the herbicide was a defective product and whether the manufacturers had acted

²⁵⁰ *In re Rhone-Poulenc Rorer Inc.*, 51 F.3d 1293 (7th Cir. 1995).

²⁵¹ *Id.* at 1298.

²⁵² Federal Rule of Civil Procedure 23 acknowledges that it may not be in the best interests of all potential class members to join in a class action. In determining whether to certify a 23(b)(3) class action, the rule asks the court to consider "the class members' interest in individually controlling the prosecution or defense of separate actions." FED. R. CIV. P. 23(b)(3)(A).

²⁵³ See Francis E. McGovern, *Resolving Mature Mass Tort Litigation*, 69 B.U. L. REV. 659, 659–88 (1989) (discussing the many factors that must be considered in settling a class action and comparing the respective challenges of different mass tort cases).

²⁵⁴ *Sterling v. Velsicol Chem. Corp.*, 855 F.2d 1188, 1200 (6th Cir. 1988). In *Mertens v. Abbott Labs.*, the court refused to certify a class action because individual proof of the harmful effects of exposure to the drug DES would have to be shown by each class member. *Mertens v. Abbott Labs.*, 99 F.R.D. 38, 43 (D.N.H. 1983); see also *Engle v. Liggett Group, Inc.*, 945 So. 2d 1246, 1268 (Fla. 2006) ("We conclude that continued class action treatment for Phase III of the trial plan is not feasible because individualized issues such as legal causation, comparative fault, and damages predominate.").

negligently were issues capable of class resolution.²⁵⁵ These class issues, in the court's estimation, outweighed the numerous individual issues of exposure and injuries.²⁵⁶ As the Fifth Circuit noted in *Castano*, the individual issues are amplified considerably when the choice-of-law analysis determines that different states' tort laws apply to class members from different states.

In 2008, with these same concerns in mind, the Second Circuit Court of Appeals decertified a "light" cigarette class action alleging that the tobacco industry violated the Racketeer Influenced and Corrupt Organizations Act (RICO)²⁵⁷ by misrepresenting the health benefits of its products. In *McLaughlin v. American Tobacco Company*, the court held that the putative class action "suffers from an insurmountable deficit of collective legal or factual questions."²⁵⁸ Although the plaintiffs argued that the course of conduct alleged to violate RICO was conducted class-wide by the tobacco industry, the court determined that each plaintiff had to provide evidence on the issues of reliance, economic injury, and damages.²⁵⁹

Such decisions raise the critical question: Should the class action device be used at all in mass toxic tort litigation? The 1966 Advisory Committee Notes to Federal Rule of Civil Procedure 23 stated: "A 'mass accident' resulting in injuries to numerous persons is ordinarily not appropriate for a class action because of the likelihood that significant questions, not only of damages, but of liability and defenses to liability, would be present, affecting the individuals in different ways."²⁶⁰ While the Committee was thinking only of single-accident situations, their words apply equally, if not more forcefully, to the kind of mass product liability actions of which the tobacco personal injury litigation is one example. Still, the class action device can be useful in much mass toxic tort litigation because the efficiencies can far outweigh the burdens.

Another anti-class action sentiment expressed by courts has been the notion that class actions place undue pressure on defendants to settle.²⁶¹ The Fifth Circuit emphasized this point in the *Castano* nicotine addiction litigation:

In the context of mass tort class actions, certification

²⁵⁵ *In re "Agent Orange" Prod. Liab. Litig.*, 100 F.R.D. 718, 722–23 (E.D.N.Y. 1983).

²⁵⁶ *Id.* at 722–24.

²⁵⁷ 18 U.S.C. §§ 1961–1968 (2000).

²⁵⁸ *McLaughlin v. Am. Tobacco Co.*, No. 06-4666, 2008 U.S. App. LEXIS 7093, at *1, *3 (2nd Cir. Apr. 3, 2008).

²⁵⁹ *Id.* at *14–*15.

²⁶⁰ FED. R. CIV. P. 23 1966 advisory committee's note.

²⁶¹ See *supra* notes 250–51 and accompanying text for an illustration of this pressure in the context of a class action brought by several thousand hemophiliacs who received contaminated blood products.

dramatically affects the stakes for defendants. Class certification magnifies and strengthens the number of unmeritorious claims. Aggregation of claims also makes it more likely that a defendant will be found liable and results in significantly higher damage awards.

In addition to skewing trial outcomes, class certification creates insurmountable pressure on defendants to settle, whereas individual trials would not. The risk of facing an all-or-nothing verdict presents too high a risk, even when the probability of an adverse judgment is low. These settlements have been referred to as judicial blackmail.²⁶²

The negative effect of this may be outweighed by the fact that per capita awards in class action settlements are typically far less than payments made pursuant to settlement agreements in individual actions.²⁶³

Furthermore, the United States Supreme Court has expressed dissatisfaction with attempts to create the equivalent of a legislative solution to mass torts through the mechanism of the courts. In *Amchem Products, Inc. v. Windsor*, the action was filed as a “settlement class action,” along with a settlement agreement that had been previously negotiated between representatives of the defendant asbestos manufacturers and their insurers and representatives of some of the plaintiff class members.²⁶⁴ The parties sought class certification and approval of the settlement. The proposed settlement included a court-supervised compensation scheme, which would have required class members to apply for monetary awards, and set forth parameters for the awards, including a ban on punitive damages and caps on compensatory damages. In rejecting class certification, the Court observed: “The argument is sensibly made that a nationwide administrative claims processing regime would provide the most secure, fair, and efficient means

²⁶² *Castano v. Am. Tobacco Co.*, 84 F.3d 734, 746 (citations omitted). The other side of this argument is that the imbalance of resources between an individual and a large industry, such as the tobacco industry, is corrected by a class action, which gives the individuals leverage against an industry that would otherwise have a substantial advantage in resources and experience. See JACK B. WEINSTEIN, *INDIVIDUAL JUSTICE IN MASS TORT LITIGATION* 41 (1995).

²⁶³ A useful example is the Agent Orange litigation, in which the settlement approved by the court provided for individual cash payments to class members for death and long-term total disability only, with only class assistance available to others. *In re “Agent Orange” Prod. Liab. Litig.*, 611 F. Supp. 1396, 1410 (E.D.N.Y. 1985). That meant that each eligible class member would receive \$12,000. John C. Coffee, Jr., *The Regulation of Entrepreneurial Litigation: Balancing Fairness and Efficiency in the Large Class Action*, 54 U. CHI. L. REV. 877, 923 n.116 (1987) (generally analyzing the market efficiency rationales of class actions). In contrast, an individual class member with a total disability would not be limited to this small amount of damages in an individual lawsuit. Furthermore, injured persons without total disability, if successful in their individual actions, would have had appropriate money damages available.

²⁶⁴ *Amchem Prods., Inc. v. Windsor*, 521 U.S. 591, 601–02 (1997).

of compensating victims of asbestos exposure. Congress, however, has not adopted such a solution.²⁶⁵

Federal court hostility toward mass tort class actions has made the state courts attractive to some litigants who perceive them as being more receptive to the class action device. Thus, in *In re West Virginia Rezulin Litigation*, the West Virginia Supreme Court of Appeals held that the trial court should have certified a class action for drug product liability claims.²⁶⁶ The class sought an order for medical monitoring, and the court determined that common questions concerning the need for monitoring predominated over individualized issues.²⁶⁷ Although the West Virginia class action rule was identical to the federal rule, the court refused to automatically follow related federal court decisions on mass tort class actions.²⁶⁸

Congress has become involved in the debate over the use of the class action device, enacting the Class Action Fairness Act of 2005 (CAFA).²⁶⁹ CAFA has had the effect of moving certain mass actions involving more than one hundred persons into federal court, where the strictures of the federal rules and *Amchem* would apply. CAFA demonstrates the power of the business lobby,²⁷⁰ including the U.S. Chamber of Commerce,²⁷¹ which pressed Congress to enact the legislation in response to widely publicized reports from the American Tort Reform Foundation arguing that class action abuses abound.²⁷²

The above developments, including the enactment of CAFA, demonstrate the suspicion and even disdain with which the class action device is viewed in some circles. To some degree, this was a result of tobacco litigation; but the broader picture suggests that it was due to a much larger array of mass tort litigation problems, most of which involved alleged toxic substances. Brandt argues in favor of using aggregative litigation to advance societal goals precisely because tobacco regulation was not a political priority. Thus, in his opinion, the courts should be

²⁶⁵ *Id.* at 628–29; *cf.* *Ortiz v. Fibreboard Corp.*, 527 U.S. 815, 864–65 (1999) (holding improper the certification of a Rule 23(b)(1)(B) “limited fund” asbestos class action for many of the same reasons as those stated in *Amchem*).

²⁶⁶ *In re W. Va. Rezulin Litig.*, 585 S.E.2d 52, 58 (W. Va. 2006).

²⁶⁷ *Id.* at 72–73.

²⁶⁸ The court stated that its analysis was intended “to avoid having our legal analysis of our Rules ‘amount to nothing more than Pavlovian responses to federal decisional law.’” *Id.* at 61.

²⁶⁹ Pub. L. 109-2, 119 Stat. 14 (2005) (codified in 28 U.S.C. *passim*).

²⁷⁰ See generally Jean Macchiaroli Eggen, *The Impact of the Class Action Fairness Act on Plaintiffs in Mass-Tort Actions*, 12 ANDREWS CLASS ACTION LITIG. REP., at 16 (Apr. 2005) (discussing impetus for CAFA and provisions impacting plaintiffs in mass tort litigation).

²⁷¹ See Letter from Bruce R. Josten, Executive Vice President, U.S. Chamber of Commerce, Governmental Affairs, to U.S. House of Representatives (Feb. 15, 2005), available at www.uschamber.com/issues/letters/2005/050218classactionletter.html (urging support of the “Class Action Fairness Act”).

²⁷² See AMERICAN TORT REFORM FOUNDATION, *JUDICIAL HELLHOLES 2004*, at 43 (arguing for class action reform).

viewed as a workable alternative to achieve public health goals. Brandt further argues that the judicial system is an important front on which public health initiatives can be addressed: “Tobacco litigation—even when plaintiffs lost—had a major impact on the larger social and political debates about cigarette smoking, the industry, and responsibility for harm.”²⁷³ *The Cigarette Century* demonstrates that the public health achievements in relation to smoking were a combined effort on three fronts—the scientific community, regulatory officials, and the courts. Toxic torts generally have taken a lesson from that play-book.

VI. CONCLUSION

Events in the history of public health related to cigarettes have had far-reaching implications in the law of toxic torts. Although Brandt’s *The Cigarette Century* is specific to the tobacco industry and its related social and legal circumstances, it serves to illuminate the major issues and problems that are unique to toxic torts and that complicate efforts to develop a law of toxic torts. To reflect on the events chronicled in *The Cigarette Century* is to see clearly the source of the legal developments and turmoil characteristic of toxic tort law in the twenty-first century.

Chief among these legal issues are the problems plaintiffs encounter in attempting to demonstrate causation. As Brandt has shown in *The Cigarette Century*, the history of the cigarette in the United States is largely about the protracted process of scientific discovery and investigation related to chronic latent illness. It is equally about the industry’s resistance to the mounting evidence of its products’ hazards and its public relations machine’s successful efforts to create a benign and appealing image for the cigarette. The story of the cigarette in the twentieth century combines public law and private law in a variety of ways, but none more significantly than in legislation regarding the role of cigarette warnings in the development of modern product preemption doctrine. Finally, the efforts of attorneys and state attorneys general to use aggregative litigation to achieve public health goals were an integral part of an overall mass tort initiative that set up the ongoing debate over tort reform and the respective roles of litigation and regulation in the public health arena.

These issues resonate in current toxic tort litigation, and it is advisable for the toxic torts legal community to heed their lessons. Brandt’s *The Cigarette Century* is a prism through which attorneys, judges, and scholars can look and learn to shape the future of toxic tort law.

²⁷³ BRANDT, *supra* note 3, at 439.

