

Paternalism, Self-Governance, and Public Health: The Case of E-Cigarettes

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This article develops a normative framework for assessing public health laws, using the regulation of e-cigarettes as a case study. Although e-cigarettes are likely far less dangerous to individual users than traditional cigarettes, it remains uncertain whether their proliferation will lead to a reduction of smoking-related disease and deaths or to increased morbidity and mortality. This scientific uncertainty, presents regulators with difficult challenges in determining whether and how to regulate e-cigarettes. This article presents a normative framework for analyzing such questions by offering three justifications for public health laws: impaired agency, harm to others, and self-governance. Each justification responds to the common charge that public health laws are impermissibly paternalistic. The self-governance rationale, which is the most robust, and most reflective of public health's own population perspective, has been the least theorized. This article develops that theory, examining the basis for the justification as well as its limitations. The article then applies its normative framework to the regulation of e-cigarettes, focusing on the FDA's so-called deeming regulations, which at the time the article was written were pending but have since been promulgated in a sub-

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stantially similar form. The article supports the FDA's ultimate decision to ban the sales of e-cigarettes to minors and to require the disclosure of warning labels based upon the impaired agency rationale. However, the scientific uncertainty renders the harm rationale inadequate. As a result, the regulations' pre-market review requirement must rely on the self-governance rationale for its normative justification. Given the lack of clear legislative guidance and political engagement, the article concludes that the pre-market review provisions are normatively problematic: if public health advocates want to claim the mantle of self-governance, they must take it seriously.

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INTRODUCTION

After decades of dramatic declines in the rate of cigarette smoking,¹ we face a crossroad in the battle against tobacco-related disease. The increasing popularity of e-cigarettes offers either a novel tool for further reductions in cigarette use or a dangerous lure that may lead a new generation to smoke. The uncertainty as to which role e-cigarettes will play presents public health regulators with a difficult dilemma: whether and how to apply the panoply of tobacco control laws that has been used to reduce cigarette smoking to e-cigarettes. This dilemma implicates not only legal and scientific questions, but also normative ones concerning the government's role in protecting public health, especially in the face of scientific uncertainty. This article tackles these issues and, in so doing, presents a framework for analyzing the justifiability of public health laws.

E-cigarettes are the most popular form of electronic nicotine delivery systems ("ENDS").² They deliver nicotine through the inhalation of a heated vapor rather than combustion. Supporters argue that they offer a safer alternative to smoking and the opportunity for a new regulatory strategy, one based on harm reduction.³ Critics, in

¹ *Trends in Current Cigarette Smoking Among High School Students and Adults, United States, 1965–2011*, CTRS. FOR DISEASE CONTROL & PREVENTION (Nov. 21, 2014), http://www.cdc.gov/tobacco/data_statistics/tables/trends/cig_smoking/ [hereinafter *Trends in Current Cigarette Smoking*]. In 2013, only 17.8% were current smokers. *Current Cigarette Smoking Among U.S. Adults Aged 18 Years and Older*, CTRS. FOR DISEASE CONTROL & PREVENTION (Sept. 1, 2015), http://www.cdc.gov/tobacco/campaign/tips/resources/data/cigarette-smoking-in-united-states.html#all_adults. Rates of smoking among high school students have declined from a high of 36.4% in 1997, to only 9.2% in 2014. *Compare Trends in Current Cigarette Smoking, supra*, with René A. Arrazola et al., *Tobacco Use Among Middle and High School Students – United States, 2011–2014*, 64 MORBIDITY & MORTALITY WKLY. REP. 381, 382 (Apr. 17, 2015), <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6414a3.htm> [hereinafter *Tobacco Use*].

² See *infra* text accompanying notes 201–206.

³ The possibility of using a harm-reduction approach to smoking has long been discussed by health experts. See Jack E. Henningfield, *The Tobacco Endgame: It's All About Behavior*, 68 PREVENTIVE MED. 11, 13 (2014); E. G. Martin

contrast, point to potential health risks. They also worry that e-cigarettes will renormalize smoking and reverse declines in smoking rates.⁴ Critics thus fear that rather than serving to reduce harm, e-cigarettes will prove to be a gateway drug that introduces people to nicotine and revives the social norms of the Mad Men era.⁵

For regulators, the difficulty of the question of how to respond to e-cigarettes is heightened by uncertainty about their long-term health effects. Critically, the evidence whether e-cigarettes will increase or decrease rates of cigarette smoking remains unsettled.⁶ In effect, we don't yet know whether the proliferation of e-cigarettes will lead to more or less smoking, or more or less disease. Nor do we know whether regulations curtailing access to e-cigarettes will safeguard or harm public health.

The uncertain science raises difficult challenges for regulators. Should they follow the precautionary principle and regulate e-cigarettes as if they were harmful until and unless they are proved safe?⁷ Or should regulators wait to see what the science reveals? If they act too soon, they risk delaying the development of a new approach to reducing tobacco-related harm and sparking a backlash against public health laws that are viewed as inappropriately paternalistic. Yet if regulators fail to act quickly, they may face a large entrenched

et al., *Tobacco Harm Reduction: What do the Experts Think?*, 13 TOBACCO CONTROL 123, 124 (2004); Kathleen Stratton et al., *Clearing the Smoke: The Science Base for Tobacco Harm Reduction—Executive Summary*, 10 TOBACCO CONTROL 189, 189–90 (2001); David Sweanor et al., *Tobacco Harm Reduction: How Rational Public Policy Could Transform a Pandemic*, 18 INT'L J. DRUG POL'Y 70, 70 (2007).

⁴ See, e.g., David A. Kessler & Matthew L. Myers, Op-Ed., *It's Time to Regulate E-Cigarettes*, N.Y. TIMES (Apr. 23, 2015), http://www.nytimes.com/2015/04/23/opinion/its-time-to-regulate-e-cigarettes.html?_r=0. One study found that even older smokers believe that advertising for e-cigarettes may renormalize smoking; see Janine K. Cataldo et al., *E-cigarette Marketing and Older Smokers: Road to Renormalization*, 39 AM. J. HEALTH BEHAV. 361, 368 (2015).

⁵ AMC's *Mad Men* is a series about an advertising agency, set in the 1960s.

⁶ For a review of the evidence, see discussion *infra* Section III.B.

⁷ The precautionary principle, long recognized in environmental law, calls for regulations to protect the health or environment from new risks in the absence of scientific certainty. See Daniela Saitta, Giancarlo Antonio Ferro & Riccardo Polosa, *Achieving Appropriate Regulations for Electronic Cigarettes*, 5 THERAPEUTIC ADVANCES CHRONIC DISEASE 50, 52 (2014).

market for a highly addictive product. By the time the science is in, it may well be too late to prevent harm.

In the midst of these uncertainties, states and localities have pondered whether to apply their existing tobacco control regulations, such as laws banning indoor smoking, to e-cigarettes.⁸ Likewise, the Food and Drug Administration (“FDA”) has been forced to consider whether it should subject e-cigarettes to the regulatory regime established by the Family Smoking Prevention and Tobacco Control Act (“TCA”).⁹ In April 2014, the FDA issued a Notice of Proposed Rulemaking (“NPRM”) proposing to do just that.¹⁰ Over 80,000 comments were submitted in response to the NPRM.¹¹ As of April 2016, it remains unclear what the FDA will do, or whether Congress will intervene, as the House Appropriations Committee proposed doing in 2015.¹²

This paper seeks to guide these regulatory decisions by offering a framework for determining the normative justifiability of public health regulations. The framework engages with and responds to

⁸ Regulators in other nations have been quicker to act than those in the U.S. See Henningfield, *supra* note 3, at 14.

⁹ Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, 123 Stat. 1776 (2009).

¹⁰ Deeming Tobacco Products to be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Regulations on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products, 79 Fed. Reg. 23142 (proposed Apr. 25, 2014) (to be codified at 21 CFR pts. 1100, 1140, 1143).

While this paper was in press, the FDA published the regulations deeming tobacco products to be subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act: Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products, 81 Fed. Reg. 28973 (May 10, 2016) (to be codified in 21 CFR pts. 1100, 1140, 1143). The final version of the regulations are in most respects substantially similar to those in the NPRM, however, there are some differences of note. See, e.g., *infra* note 322.

¹¹ *Deeming Tobacco Products to be Subject to the Food, Drug, and Cosmetic Act as Amended by the Family Smoking Prevention and Tobacco Control Act; Regulations on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products*, REGULATIONS.GOV, <http://www.regulations.gov/#!docketDetail;D=FDA-2014-N-0189> (last visited Mar. 9, 2015).

¹² H.R. REP. NO. 114-205, at 74–75 (2015). For a discussion, see *infra* text accompanying notes 324–328.

what I call the “paternalism critique.”¹³ Part of a broader anti-regulatory backlash currently ascendant in the United States, the critique condemns public health laws relating to noncommunicable diseases (NCDs) as illegitimate infringements on individual autonomy.¹⁴ This critique has made its way into judicial decisions reviewing tobacco control regulations. For example, in striking down on First Amendment grounds FDA regulations requiring graphic warning labels on cigarettes, the Court of Appeals for the District of Columbia questioned whether “the government can assert a substantial interest in discouraging consumers from purchasing a lawful product, even one that has been conclusively linked to adverse health consequences.”¹⁵ Underlying the court’s comment, and the broader critique of public health interventions, is the common supposition that public health laws aimed at NCDs are the paternalistic¹⁶ overreachings of the “nanny state.”¹⁷

In response, public health legal theorists have offered several notable normative justifications for laws addressing NCDs. Three broad categories of justifications are especially prominent in the literature. One expounds upon the well-established claim that paternalistic laws are justified when an individual’s agency is impaired

¹³ See discussion *infra* Part I.

¹⁴ See *id.*; Wendy E. Parmet & Peter D. Jacobson, *The Courts and Public Health: Caught in a Pincer Movement*, 104 AM. J. PUB. HEALTH 392, 395 (2014). This critique is not new. Public health has been on the defensive since the Reagan era. See Scott Burris, *The Invisibility of Public Health: Population-Level Measures in a Politics of Market Individualism*, 87 AM. J. PUB. HEALTH 1607, 1607 (1997).

¹⁵ *R.J. Reynolds Tobacco Co. v. FDA*, 696 F.3d 1205, 1218 n.13 (D.C. Cir. 2012), *overruled in part by Am. Meat Inst. v. USDA*, 760 F.3d 18, 22–23 (D.C. Cir. 2014).

¹⁶ The claim that laws aimed at NCDs are paternalistic is widespread. See, e.g., David Adam Friedman, *Public Health Regulation and the Limits of Paternalism*, 46 CONN. L. REV. 1687, 1690–91 (2014); Yofi Tirosh, *Three Comments on Paternalism in Public Health*, 46 CONN. L. REV. 1795, 1797 (2014). However, upon closer analysis, many public health laws that are regarded as paternalistic may be found not to be so. See Wendy E. Parmet, *Beyond Paternalism: Rethinking the Limits of Public Health Law*, 46 CONN. L. REV. 1771, 1783 (2014). For a further discussion of the paternalism critique and responses to it, see *infra* Part I—Section III.C.

¹⁷ Lindsay F. Wiley, Wendy E. Parmet & Peter D. Jacobson, *Adventures in Nannydom: Reclaiming Collective Action for the Public’s Health*, 43 J.L. MED. & ETHICS 73, 73 (2015).

either because of youth, mental impairment, or informational or cognitive deficiencies.¹⁸ Laws that try to protect minors from tobacco use easily satisfy these criteria, but so do, some argue, regulations requiring the disclosure of product information or, more controversially, regulations that seek to “nudge” people to the choices they would make if they were fully rational actors.¹⁹

A second justification relies on a capacious interpretation of the harm principle that exposes the not-always-obvious externalities of public health threats. Utilizing public health’s population perspective,²⁰ which emphasizes the role that population-level social and environmental factors play in determining health risks, this response points to the myriad social factors, including law, that affect rates of NCDs.²¹ From this perspective, NCDs are quite similar to communicable diseases in that they too are caused by factors outside of the individual’s control and therefore warrant state intervention.²²

A third set of responses is predicated on the insight that public health laws advance liberty by helping to secure health.²³ Moreover, public health laws can be viewed as manifestations of a population’s positive liberty of self-governance.²⁴ In other words, public health

¹⁸ See *infra* Section II.A.

¹⁹ Cass R. Sunstein, *The Storrs Lectures: Behavioral Economics and Paternalism*, 122 YALE L.J. 1826, 1854–55, 1887–88 (2013).

²⁰ See WENDY E. PARMET, POPULATIONS, PUBLIC HEALTH AND THE LAW, ch. 1 (2009); see also Micah L. Berman, *Defining the Field of Public Health Law*, 15 DEPAUL J. HEALTH CARE L. 45, 47–48, 79–87 (2013).

²¹ See, e.g., Lawrence O. Gostin, *Bloomberg’s Health Legacy: Urban Innovator or Meddling Nanny?* 43 HASTINGS CTR. REP. 19, 19 (2013); Zita Lazzarini & David Gregorio, *Personal Health in the Public Domain: Reconciling Individual Rights with Collective Responsibilities*, 46 CONN. L. REV. 1839, 1845–46 (2014).

²² For further discussion, see *infra* Section II.B.

²³ For this reason, Sridhar Venkatapuram argues that health is a meta-capability. See SRIDHAR VENKATAPURAM, HEALTH JUSTICE: AN ARGUMENT FROM THE CAPABILITIES APPROACH 20 (2011); see also Peter D. Jacobson, *Changing the Culture of Health: One Public Health Misstep at a Time*, 51 SOC. 221, 222 (2014).

²⁴ Lindsay F. Wiley, Micah L. Berman & Doug Blanke, *Who’s Your Nanny? Choice, Paternalism and Public Health in the Age of Personal Responsibility*, 41 J.L. MED. & ETHICS 88, 90–91 (2013).

laws are the legal tools that populations utilize to “assure the conditions for people to be healthy.”²⁵ Seen from this light, public health laws can enhance liberty as much as restrain it.

What do these justifications suggest about the regulation of e-cigarettes? This paper engages this question, concluding that certain regulations, such as those prohibiting e-cigarette sales to minors or requiring disclosure of ingredients, easily surmount any paternalism critique, while the case for restrictions on adult access to e-cigarettes has not yet been made. More broadly, the approach offered here uses the case of e-cigarettes to examine both the anti-paternalism critique of public health law and the justifications proffered by public health legal theorists. In so doing, the article assesses the strength and viability of the three justifications in an especially difficult case, one in which the science is not yet settled and the public health community is fractured, and offers a framework steeped within public health laws’ own population perspective for analyzing the legitimacy of public health laws.

I begin in Part I by reviewing the anti-paternalism critique of public health laws.²⁶ Although the critique is often applied to laws that, upon closer inspection, are not paternalistic, it serves as a powerful rhetorical device that helps to delegitimize public health laws. It warrants a response.

Part II offers three distinct responses.²⁷ These responses justify public health laws relating to NCDs when 1) individual decision-making is impaired due to immaturity, incapacity, lack of information, or cognitive deficiencies; 2) the activities regulated can harm third parties; or 3) the regulation is a manifestation of a population’s self-governance relating to its collective health. Taken together, these justifications provide a powerful rejoinder to the paternalism critique and a framework for assessing the legitimacy of specific public health regulations. The framework offers broader support for public health regulations than many of public health critics

²⁵ COMM. FOR THE STUDY OF THE FUTURE OF PUB. HEALTH, INST. OF MED., THE FUTURE OF PUBLIC HEALTH 19 (NAT’L ACAD. PRESS 1988). For a defense of paternalism, *see generally* SARAH CONLY, AGAINST AUTONOMY: JUSTIFYING COERCIVE PATERNALISM (2013) (“The answer I embrace is that we need external guidance—constraints on our actions through regulation, law, and institutional design.”).

²⁶ *See infra* Part I.

²⁷ *See infra* Part II.

would endorse, but also imposes more restraints on public health laws than many public health advocates would like.

In Part III, I turn to the case of e-cigarettes. I begin by discussing the development of the e-cigarette market and then review what is and is not known about e-cigarettes' health effects.²⁸ Part III concludes by laying out the legal context in which current regulatory decisions are made and the questions pending before the FDA under the TCA.²⁹

In Part IV, I apply the framework to several specific proposed e-cigarette regulations.³⁰ The analysis concludes that the impaired agency rationale strongly supports laws regulating minors' access to e-cigarettes, as well as laws requiring warning labels and ingredient listings. However, given the scientific uncertainty, only self-governance can justify regulations seeking to limit adults' access and use of e-cigarettes. But if such laws must rest on self-governance, self-governance must occur. This has already happened in the hundreds of cities and several states in which democratically elected bodies have chosen to regulate e-cigarette use. The proposed FDA regulations, however, are more problematic because there has not yet been a fulsome national dialog about e-cigarettes.³¹ In the absence of such signs of self-governance or congressional action, and in the midst of scientific uncertainty about the population health effects, the proposed regulations stand on a weak normative foundation.

I: THE PATERNALISM CRITIQUE

The questions surrounding the regulation of e-cigarettes have arisen amid broader debates about the legitimacy of public health laws aimed at NCDs.³² Briefly, during the nineteenth century, public

²⁸ See *infra* Sections III.A–B.

²⁹ See *infra* Sections III.C–D.

³⁰ See *infra* Part IV.

³¹ See *infra* text accompanying notes 375–385.

³² For reasons explained *infra*, the assumption that laws aimed at NCDs are paternalistic is problematic. See *infra* text accompanying notes 59–65. Public health laws have also been subject to a wide range of other critiques, including their impact on marginal populations. See Lindsay F. Wiley, *Health Law as Social Justice*, 24 CORNELL J. L. & PUB. POL'Y 47, 74–75 (2014) (arguing that the use of law to change behaviors often has a “disproportionate impact on socially disadvantaged groups”); Yofi Tirosh, *supra* note 16, at 1801–05.

health focused largely on communicable diseases such as smallpox, tuberculosis, and cholera.³³ In response to these threats, health officials wielded various legal tools, including such coercive measures as isolation, quarantine,³⁴ and mandatory vaccination,³⁵ as well as less coercive measures, such as supplying clean water and establishing food safety standards.³⁶ By the mid-twentieth century, however, chronic diseases, including cancer and coronary artery disease, had replaced infectious diseases as the most significant cause of mortality in developed nations.³⁷ These diseases (and even infectious diseases such as HIV) were widely attributed to individual behavioral choices,³⁸ leading many public health advocates to support laws that seek to alter the individual behaviors associated with chronic disease.³⁹

In this context a heated debate arose regarding the scope and legitimacy of public health laws aimed at NCDs.⁴⁰ In a series of articles, Richard Epstein sought to distinguish what he termed “the old public health” of the nineteenth century, in which, he claimed, public health laws were confined to the control of communicable diseases and public nuisances from contemporary efforts to address

³³ Wendy E. Parmet, *From Slaughter-House to Lochner: The Rise and Fall of the Constitutionalization of Public Health*, 40 AM. J. LEGAL HIST. 476, 489 (1996). Many laws directed at communicable diseases in the nineteenth century sought to alter the environment. *Id.* at 497–98. Conversely, laws often focused on individuals as if they were contagious even when they were not. *See Jew Ho v. Williamson*, 103 F. 10, 25–27 (N.D. Cal. 1900).

³⁴ Wendy E. Parmet, *AIDS and Quarantine: The Revival of an Archaic Doctrine*, 14 HOFSTRA L. REV. 53, 58 (1985).

³⁵ *Jacobson v. Massachusetts*, 197 U.S. 11 (1905).

³⁶ *See* Parmet, *supra* note 33, at 489.

³⁷ Abdel R. Omran, *The Epidemiologic Transition: A Theory of the Epidemiology of Population Change*, 83 MILBANK Q. 731, 736–41 (2005).

³⁸ J. Michael McGinnis & William H. Foege, *Actual Causes of Death in the United States*, 270 J. AM. MED. ASS’N 2207, 2207 (1993).

³⁹ As discussed further below, these health problems may also be understood through a broader, ecological lens that focuses more on social and environmental factors, than individual decisions. *See infra* text accompanying notes 116–23.

⁴⁰ An early focus of the debate was motorcycle helmet laws. *See* Ronald Bayer, *The Continuing Tensions Between Individual Rights and Public Health: Talking Point on Public Health Versus Civil Liberties*, 8 EMBO REP. 1099, 1101–02 (2007) (explaining that “the failure to make a strong case for paternalistic restrictions with regard to motorcycle helmets” ultimately led to an increase in cyclist fatalities).

NCDs.⁴¹ The more traditional understanding, Epstein argued, is superior to the “capacious view” that utilizes law to affect the health of “ordinary individuals.”⁴² To Epstein, “[t]he correct theory of public health tracks the economic conception of public goods, namely those nonexcludable goods that cannot be given to one unless they are also given to another.”⁴³

In a related vein, Mark Hall insisted on the importance of differentiating between “public health *analysis* and public health *authority*, or, if you will, between public health *diagnosis* and public health *treatment*.”⁴⁴ For Hall, precisely because public health powers are so robust, public health laws must be cabined to cases in which there are significant collective action problems, meaning that individuals acting in their own self-interest, even if fully informed and rational, will not effectively address the problem because they do not internalize some of the major costs or benefits of action or non-action, or for other reasons a centralized response is much more *cost-effective*.⁴⁵

Similarly, Mark Rothstein argued that *public health* itself, not just *public health laws*, should be construed narrowly: “[B]ecause public health has been the justification for some overreaching or

⁴¹ Richard A. Epstein, *In Defense of the Old Public Health: The Legal Framework for the Regulation of Public Health*, 69 BROOK. L. REV. 1421, 1427 (2004). Scholars have questioned Epstein’s characterization of the old public health. See, e.g., William J. Novak, *Private Wealth and Public Health: A Critique of Richard Epstein’s Defense of the “Old” Public Health*, 46 PERSPS. BIOL. & MED. S176 (2003) (arguing that Epstein’s reading of the “earlier constitutional history of the police power” is flawed).

⁴² Epstein, *supra* note 41, at 1425.

⁴³ *Id.* at 1425–26; see also Jonny Anomaly, *Public Health and Public Goods*, 4 PUB. HEALTH ETHICS 251, 252–55 (2011). Angus Dawson and Marcel Verweij do not agree that public health is limited to public goods, but concede that public health interventions are most justified “where action contributes to the creation or maintenance of a public good.” Angus Dawson & Marcel Verweij, *Introduction: Ethics, Prevention, and Public Health*, in ETHICS, PREVENTION, AND PUBLIC HEALTH 5 (Angus Dawson & Marcel Verweij eds., 2007).

⁴⁴ Mark A. Hall, *The Scope and Limits of Public Health Law*, 46 PERSP. BIOL. & MED. S199, S202 (2003) (emphasis in original) (“The central point of this essay is that public health law is much more limited than public health science.”); see also Mark A. Rothstein, *Rethinking the Meaning of Public Health*, 30 J.L. MED. & ETHICS 144, 147 (2002) (arguing for a narrower definition of public health).

⁴⁵ Hall, *supra* note 44, at S204 (emphasis in original).

even reprehensible prior government activities, ranging from eugenics to unethical research on human subjects, a narrow definition of public health will help steer public health officials away from activities that are inappropriate for the government.”⁴⁶

Although many public health laws in the twentieth century targeted NCDs, both the scholarly and popular critique of public health laws in this century have largely focused on laws addressing obesity and, to a lesser extent, smoking. To critics, the obesity epidemic is largely the result of individual choices, such as whether to exercise or to eat fast food.⁴⁷ At least when made by competent adults, critics contend, those individual choices should be respected.⁴⁸ Laws seeking to prohibit or even alter individual choices do not address public harms, rather they are paternalistic attempts by the state to interfere in an individual’s choice for the individual’s own good.⁴⁹

This critique of public health laws, which I shall call “the paternalism critique,” is widespread in both popular discourse⁵⁰ and the scholarly literature.⁵¹ For example, Peter Schwartz has lamented:

A precondition of freedom is the recognition of the individual’s capacity to make decisions for himself. If man were viewed as congenitally incapable of making rational choices, there would be no basis for the very concept of rights. Yet that is increasingly how our government views us. It is adopting the role

⁴⁶ Rothstein, *supra* note 44, at 147.

⁴⁷ Richard A. Epstein, *What (Not) to do About Obesity: A Moderate Aristotelian Answer*, 93 GEO. L.J. 1361, 1363 (2005).

⁴⁸ *Id.*

⁴⁹ Richard Epstein contends that “[t]he correct theory of public health tracks the economic conception of public goods, namely those nonexcludable goods that cannot be given to one unless they are also given to another.” Epstein, *supra* note 41, at 1425–26.

⁵⁰ Karen Harned, *The Michael Bloomberg Nanny State in New York: A Cautionary Tale*, FORBES (May 10, 2013, 8:00 AM), <http://www.forbes.com/sites/realspin/2013/05/10/the-michael-bloomberg-nanny-state-in-new-york-a-cautionary-tale/>.

⁵¹ Friedman, *supra* note 16, at 1693.

of a paternalistic nanny, zealously protecting the citizen against his own actions. In the process, our freedom is disappearing.⁵²

Similarly, Jacob Sullum castigated the Centers for Disease Control and Prevention (“CDC”) for failing to appreciate the distinction between smoking and tuberculosis (“TB”): “That distinction matters to people who reject paternalism as a justification for government action. We believe the use of force can be justified to protect the public from TB carriers but not to protect smokers from their own choices.”⁵³

The critique has even made its way, albeit subtly, into judicial decisions. For example, in overturning New York City’s ban on the sale of large portions of sugary soda, the New York Court of Appeals opined that the regulation’s impact on individual autonomy was a factor to be considered in determining whether the regulation constituted policymaking that should be left to the legislature.⁵⁴

In lambasting public health laws as paternalistic, both courts and critics have generally assumed, often with little or no explanation, that paternalism is inherently bad,⁵⁵ or, in the least, that “[t]he burden of proof is on the shoulders of whoever advocates legal coercion.”⁵⁶ By conjuring the image of the nanny who tells the child

⁵² Peter Schwartz, *The Threat of the Paternalistic State*, CAPITALISM MAG. (Aug. 6, 2002), <http://capitalismmagazine.com/2002/08/the-threat-of-the-paternalistic-state/>.

⁵³ Jacob Sullum, *Ebola, Smoking, and Mission Creep at the CDC: Controlling Contagious Diseases is Just One of Many Items on the Agency’s To-Do List*, REASON, Jan. 2015, at 12.

⁵⁴ *N.Y. Statewide Coal. of Hispanic Chambers of Commerce v. N.Y.C. Dep’t of Health & Mental Hygiene*, 16 N.E.3d 538, 547–48 (N.Y. 2014). Notably, the court did not conclude that the state could not regulate in such a manner, only that the Board of Health could not.

⁵⁵ The classic critique of paternalism is from John Stuart Mill, who distinguished between self- and other- regarding behaviors, and argued that the government was, with important exceptions, justified in limiting only the latter. See JOHN STUART MILL, *On Liberty*, in JOHN STUART MILL: A SELECTION OF HIS WORKS 1, 97 (John M. Robson ed., Macmillan Publ’g Co. 1985) (1966). For a lengthy defense of paternalism, see CONLY, *supra* note 25, at 23–25.

⁵⁶ Thaddeus Mason Pope, *Counting the Dragon’s Teeth and Claws: The Definition of Hard Paternalism*, 20 GA. ST. U. L. REV. 659, 664 (2004) (quoting Joel Feinberg).

what to do,⁵⁷ the paternalism critique acts as a trope. Laws labeled as paternalistic are seen as presumptuous and disrespectful.⁵⁸ Often little more needs to be said. As Jeremy A. Blumenthal explained, “‘paternalism’ itself is often a term of opprobrium, used to disparage or reject policies without necessarily addressing their merits or demerits.”⁵⁹

Critics of public health frequently apply the label to public health laws without considering whether the laws in question are actually paternalistic. Under common definitions, laws are paternalistic only if they restrict the autonomy of an individual for that individual’s own good.⁶⁰ Thaddeus Mason Pope states that “[p]aternalism is the restriction of a subject’s self-regarding conduct primarily for the good of that same subject.”⁶¹ So understood, many laws derided as paternalistic may not be. For example, a regulation requiring e-cigarette manufacturers to disclose their ingredients to the FDA does not limit the autonomy of those who inhale; it simply

⁵⁷ Former New York City Mayor Michael Bloomberg was frequently chided as “Nanny Bloomberg” for his attempts to use municipal powers to improve public health. See Friedman, *supra* note 16, at 1689; Gostin, *supra* note 21, at 19.

⁵⁸ See Christian Coons & Michael Weber, *Introduction: Paternalism – Issues and Trends*, in PATERNALISM: THEORY AND PRACTICE 1, 12 (Christian Coons & Michael Weber eds., 2013) (“Paternalism objectionably treats its targets like children.”).

⁵⁹ Jeremy A. Blumenthal, *A Psychological Defense of Paternalism*, in PATERNALISM: THEORY AND PRACTICE, 197, 197 (Christian Coons & Michael Weber eds., 2013). Despite such use of the term, Blumenthal notes that there is significant public support for many paternalistic laws. See *id.* at 213.

⁶⁰ See, e.g., Gerald Dworkin, *Paternalism*, 56 THE MONIST 64, 65 (1972) (defining paternalism as “the interference with a person’s liberty of action justified by reasons referring exclusively to the welfare, good, happiness, needs, interests or values of the person being coerced”).

⁶¹ Pope, *supra* note 56, at 660. More recently Thaddeus Mason Pope has aptly noted, “contemporary legal and philosophical literature on paternalism employs a different vocabulary than the literature of the preceding three decades.” Thaddeus Mason Pope, *Limiting Liberty to Prevent Obesity: Justifiability of Strong Hard Paternalism in Public Health Regulation*, 46 CONN. L. REV. 1859, 1869 (2014).

burdens manufacturers.⁶² Because these laws regulate other-regarding behavior, they would not be viewed as paternalistic under traditional definitions.⁶³

Other definitions of paternalism, however, are broader and may encompass actions taken for a subject's own good even if they do not necessarily limit that individual's own autonomy. Seana Shiffrin proposes that paternalism exists whenever X acts in a way that limits Y's sphere of agency for Y's good.⁶⁴ Under this approach, a law may be paternalistic even if it does not regulate the actions of the individual whom the law seeks to benefit. Such a definition, however, risks labeling almost all laws paternalistic. For example, a law that prevents X from poisoning Y could be viewed as limiting Y's agency—the option to drink the poison—for Y's own good.⁶⁵

Regardless of whether a particular public health law is paternalistic,⁶⁶ or even if it restricts the liberty of those it wishes to help, the

⁶² Wendy Mariner makes a similar point, arguing that what she calls the “economic definition of paternalism ignores the target of regulation and instead views government regulation from the perspective of the individual, rather than the entity being regulated.” Wendy Mariner, *Paternalism, Public Health, and Behavioral Economics: A Problematic Combination*, 46 CONN. L. REV. 1817, 1823 (2014).

⁶³ Jamie Kelly notes that “[b]ecause both utilitarianism and paternalism share a focus on individual welfare, it can be difficult to distinguish utilitarian and paternalistic positions in political theory.” Jamie Kelly, *Libertarian Paternalism, Utilitarianism, and Justice*, in PATERNALISM: THEORY AND PRACTICE 216, 228 (Christian Coons & Michael Weber eds., 2013). Nevertheless, if the goal of regulating the tobacco company or soda seller is to improve overall health, rather than the good of the individual consumer, the measures should not be considered paternalistic even if we accept that laws can be paternalistic without limiting liberty.

⁶⁴ See, e.g., Seana Valentine Shiffrin, *Paternalism, Unconscionability Doctrine, and Accommodation*, 29 PHIL. & PUB. AFF. 205, 218–19 (2000) (arguing that paternalism exists when X acts in a way that limits Y's sphere of agency for the good of Y). Likewise, Thaddeus Mason Pope suggests that such laws can be thought of as forms of indirect paternalism, arguing that paternalism refers not to a class of actions, but to a class of reasons. See Pope, *supra* note 56, at 687, 694. For a discussion as to why laws that do not limit a subject's liberty should not be viewed as paternalistic, see Gerald Dworkin, *Defining Paternalism*, in PATERNALISM: THEORY AND PRACTICE 25, 31–38 (Christian Coons & Michael Weber eds., 2013).

⁶⁵ For a further discussion, see Parment, *supra* note 16, at 1778.

⁶⁶ Another problem with labeling a law as paternalistic or not is that the determination depends on the reasons for the law. As Douglas Husak notes, “[b]ut

very act of labeling a law paternalistic delegitimizes it.⁶⁷ The label also obscures the fact that not all restrictions on autonomy are equivalent. Without question, many public health laws, such as quarantines or vaccine mandates, impose significant restrictions on well-established liberties.⁶⁸ Such laws may be justifiable, but they warrant careful consideration regardless of whether the behavior they restrain is other-regarding or self-regarding.⁶⁹ Conversely, other public health laws impose relatively trivial restraints on liberty. These laws may be less problematic regardless of whether they aim to protect the individual restrained or someone that individual would harm.⁷⁰ As Peter Jacobson explains, “[n]ot every potential limitation on individual choice rises to the level of an intrusion that compromises individual freedom. For example, banning trans-fats may indeed limit individual choice in using an unhealthy substance, though the intrusion seems more inconvenient than a serious deprivation of liberty.”⁷¹

The paternalism critique, however, points away from a consideration of the nature and extent of the liberty limited, and to the question whether the government is acting like the nanny, insisting on how people should act for their own good. Thus minor inconveniences—having to buy large portions of soda in two servings instead

(especially in a democracy) an attempt to identify the rationale for a *law* is notoriously problematic” Douglas Husak, *Penal Paternalism*, in *PATERNALISM: THEORY AND PRACTICE* 39, 41 (Christian Coons & Michael Weber eds., 2013) (emphasis in original).

⁶⁷ Christian Coons and Michael Weber note, “Normative debates about paternalism—or at least ‘hard’ paternalism—don’t usually concern *whether* it is problematic but rather *how* problematic it is.” Coons & Weber, *supra* note 58, at 2 (emphasis in original); *see also* Mariner *supra* note 62, at 1824.

⁶⁸ Wendy E. Parmet, *Quarantine Redux: Bioterrorism, AIDS and the Curtailment of Individual Liberty in the Name of Public Health*, 13 *HEALTH MATRIX* 85, 95 (2003).

⁶⁹ When the liberty restrained rises to the level of a fundamental right, such laws may trigger strict scrutiny, or at least due process protections, even if they target other-regarding behavior. *See, e.g.*, *R.J. Reynolds Tobacco Co. v. FDA*, 696 F.3d 1205, 1222 (D.C. Cir. 2012) (striking down an FDA regulation requiring graphic warning labels on cigarettes as violating First Amendment protections for commercial speech), *overruled in part by* *Am. Meat Inst. v. USDA*, 760 F.3d 18, 22–23 (D.C. Cir. 2014).

⁷⁰ Jacobson, *supra* note 23, at 222–23.

⁷¹ *Id.*

of one—are treated as normatively equivalent to significant restrictions of fundamental rights. As a result, the paternalism trope reflects and reinforces a libertarian perspective that takes atomistic individuals living in a state of total liberty as its starting point. From that perspective, *any* public health regulation, whether or not it satisfies a technical definition of paternalism, and no matter how onerous, demands justification.⁷² Part II presents the justifications scholars have offered in response.⁷³

II. JUSTIFICATIONS FOR PUBLIC HEALTH LAW

In recent years, scholars have developed a rich and wide-ranging literature in response to the paternalism critique.⁷⁴ This literature suggests three broad justifications that, taken together, provide a framework for ascertaining the normative foundations for public health laws. Briefly, if any one of the three justifications applies to a particular public health law, the paternalism critique has been answered with respect to that law. This does not mean the law is wise, efficacious, or lawful. Other criteria remain relevant to those determinations. The framework simply determines whether the paternalism critique is applicable, and hence whether the infringement of liberty is *prima facie* legitimate or illegitimate according to the paternalism critique.

A. *Impaired Agency*

The defenses of public health laws that highlight informational deficiencies and the impairment of individual decision-making have probably been the most influential. Put most simply, the paternalism critique asserts that *competent adults* should be able to make their own decisions on matters affecting their own health. Paternalism,

⁷² See *id.* at 221 (discussing the libertarian premises behind the paternalism critique).

⁷³ The discussion focuses on the justifications that are preeminent in the public health law literature, not in ethics and academic philosophy, in which there is a rich literature on the justifications, or lack thereof, for paternalism. See GERALD DWORKIN, *THE THEORY AND PRACTICE OF AUTONOMY* 121–129 (1988); JOEL FEINBERG, *THE MORAL LIMITS OF THE CRIMINAL LAW: VOLUME 2: OFFENSE TO OTHERS* 23–24 (1988); Joel Feinberg, *Autonomy, Sovereignty, and Privacy: Moral Ideals in the Constitution?* 58 *NOTRE DAME L. REV.* 445, 490–91 (1983).

⁷⁴ The discussion below is by no means comprehensive.

however, is generally deemed appropriate for children, or others who are not legally competent. John Stuart Mill, for example, qualified his condemnation of state interference of self-regarding behavior with the caveat: “We are not speaking of children, or of young persons below the age which the law may fix as that of manhood or womanhood.”⁷⁵ Such views have won the day; it is now widely accepted that states may use their *parens patriae* power to protect minors, whose agency is assumed to be immature.⁷⁶ Indeed, to the extent that state laws seeking to protect children’s health are condemned, it is usually because they infringe upon the rights of the parent, rather than those of the child.⁷⁷ Accordingly, many public health laws explicitly related to minors, such as prohibitions on selling them cigarettes or alcohol, arouse little controversy, perhaps because such laws are viewed as abetting the preferences of most parents.⁷⁸ Moreover, many public health laws that may have a broader impact, such as limits on cigarette advertising, are often defended successfully as necessary for the health of children.⁷⁹

Adults can also suffer from impaired agency. Mill wrote that “insane persons are everywhere regarded as proper objects of the

⁷⁵ MILL, *supra* note 55, at 14. Mill added an additional troubling exception: “[W]e may leave out of consideration those backward states of society in which the race itself may be considered as in its nonage.” *Id.*

⁷⁶ See Michael S. Merry, *Paternalism, Obesity, and Tolerable Levels of Risk*, 20 DEMOCRACY & EDUC., no. 1, 2012, at 2.

⁷⁷ See Kristin Voigt, *Childhood Obesity and Restrictions of Parental Liberty: A Response to “Paternalism, Obesity, and Tolerable Levels of Risk,”* 20 DEMOCRACY & EDUC., no. 1, 2012, at 1–2.

⁷⁸ This suggests that we are more willing to accept infringements on our liberty when we believe they support our ability to realize our choices. See *infra* text accompanying note 147. With respect to public health laws aimed at minors, vaccination laws are probably the most contested. Amanda F. Dempsey et al., *Alternative Vaccination Schedule Preferences Among Parents of Young Children*, 128 PEDIATRICS 848, 849, 852–54 (2011). The objections, however, are usually not grounded in the paternalism critique. See *id.* Rather, many opponents believe that vaccinations are dangerous. *Id.* (more than 1 out of 10 parents use an alternative vaccination schedule in part due to concerns about vaccine safety); Gary L. Freed et al., *Parental Vaccine Safety Concerns in 2009*, 125 PEDIATRICS 654, 657 (2010).

⁷⁹ This was one justification offered by the FDA in its defense of the graphic warning regulations struck down in *R.J. Reynolds Tobacco Co. v. FDA*, 696 F.3d 1205, 1209 (D.C. Cir. 2012), *overruled in part by Am. Meat Inst. v. USDA*, 760 F.3d 18, 22–23 (D.C. Cir. 2014).

care of the state,”⁸⁰ a view that has faced powerful challenges by advocates for individuals with mental disabilities.⁸¹ More relevant here, addiction can impair an individual’s ability to act in accordance with her preferences, a point used repeatedly to defend the regulation of addictive substances, including cigarettes.⁸²

The impaired agency rationale, however, can be extended beyond the relatively limited cases of immaturity, mental impairment, or addiction. For example, the decision-making of otherwise competent adults may be impaired if they lack sufficient information about or understanding of the health risk at issue, either due to informational asymmetries or lack of expertise. To rectify these deficiencies, governments often mandate the disclosure of health-related information, such as the risks of a medical procedure⁸³ or the calories in a food product. Such laws, which are seldom controversial, can be viewed as exercises of so-called “soft paternalism,” which seek to enhance “autonomy by ensuring that the subject’s choices reflect her true preferences.”⁸⁴

⁸⁰ JOHN STUART MILL, *PRINCIPLES OF POLITICAL ECONOMY WITH SOME OF THE THEIR APPLICATIONS TO SOCIAL PHILOSOPHY* 614 (1948).

⁸¹ Indeed, the disability rights movement has contested what it claims as inappropriate and discriminatory paternalism against people with disabilities. *See, e.g.*, JACQUELINE VAUGHN SWITZER, *DISABLED RIGHTS: AMERICAN DISABILITY POLICY AND THE FIGHT FOR EQUALITY* 153 (2003); Sarah D. Watson, *A Study in Legislative Strategy: The Passage of the ADA*, in *IMPLEMENTING THE AMERICANS WITH DISABILITIES ACT: RIGHTS AND RESPONSIBILITIES OF ALL AMERICANS* 27 (Lawrence O. Gostin & Henry A. Beyer eds., 1993).

⁸² *See* Friedman *supra* note 16, at 1703. Congressional testimony by tobacco executives denying the addictiveness of nicotine, and evidence that tobacco companies manipulated nicotine contents to enhance addiction, have been credited with turning public opinion in favor of increased tobacco regulation. *See* ALLAN M. BRANDT, *THE CIGARETTE CENTURY: THE RISE, FALL, AND DEADLY PERSISTENCE OF THE PRODUCT THAT DEFINED AMERICA* 211 (2007).

⁸³ The argument that disclosure is necessary for the exercise of autonomy has been clearly stated in court decisions affirming the patient’s right to informed consent. *See, e.g.*, *Cruzan v. Dir., Missouri Dep’t Mental Health*, 497 U.S. 261, 269 (1990); *Canterbury v. Spence*, 464 F.2d 772, 780–81 (D.C. Cir. 1972).

⁸⁴ Pope, *supra* note 56, at 671–72. For reasons discussed above, under narrow definitions, such laws are not paternalistic. *See* Stephen A. McGuinness, *Time to Cut the Fat: The Case for Government Anti-Obesity Legislation*, 25 *J.L. & HEALTH* 41, 54 (2012). There is reason, however, for skepticism as to the impact of factual, text-based disclosures. *See* Friedman, *supra* note 16, at 1701–03, 1729–34.

Somewhat more controversially, the existence of informational deficits can also justify regulations that “insulate” individuals from making harmful choices they would not otherwise make but for those deficiencies.⁸⁵ As Thaddeus Mason Pope explains, when an individual lacks information about the risks of an activity, “it cannot fairly be said that the individual’s decision was freely or autonomously made because the individual did not fully understand the dangerous consequences of her behavior.”⁸⁶ Therefore, restricting the individual’s liberty does not impinge her autonomy.

In recent years, supporters of public health laws have also pointed to the existence of cognitive biases and “predictable” irrationalities to demonstrate that decision-making capacity is less rational, and more impaired, than traditional liberal or economic theory presupposes.⁸⁷ Relying on the findings of behavioral psychology and economics, legal scholars have noted that rationality is bounded and that individuals rely on various mental heuristics to process information and make decisions.⁸⁸ These mental shortcuts and biases can lead people to over- or underestimate risk and make decisions

⁸⁵ Informational deficiencies have often been cited as a rationale for administrative action, the theory being that the administrative agency is comprised of experts with the information that individuals lack. Jeremy A. Blumenthal, *Expert Paternalism*, 64 FLA. L. REV. 721, 733–36 (2012). For a discussion of so-called insulating strategies, see David Adam Friedman, *Debiasing Advertising: Balancing Risk, Hope, and Social Welfare*, 19 J.L. & POL’Y 539, 558 (2011).

⁸⁶ Thaddeus Mason Pope, *Balancing Public Health Against Individual Liberty: The Ethics of Smoking Regulations*, 61 U. PITT. L. REV. 419, 430 (2000).

⁸⁷ The term “predictable” is from DAN ARIELY, *PREDICTABLY IRRATIONAL: THE HIDDEN FORCES THAT SHAPE OUR DECISIONS* 232 (2009). The discussion of cognitive biases in the legal and public health literature is vast. See, e.g., RICHARD H. THALER & CASS R. SUNSTEIN, *NUDGE: IMPROVING DECISIONS ABOUT HEALTH, WEALTH, AND HAPPINESS passim* (2008); Christine Jolls & Cass R. Sunstein, *Debiasing through Law*, 35 J. LEGAL STUD. 199 (2006) (discussing the effects of debiasing through law on a range of legal areas). For a critique of the use of behavioral economics in public health law, see Mariner, *supra* note 62, at 1824–26.

⁸⁸ See Cass R. Sunstein, *Probability Neglect: Emotions, Worst Cases, and Law*, 112 YALE L.J. 61, 64 (2002). For a critique of Sunstein’s omission of cultural biases influencing mental heuristics, see Dan M. Kahan et al., *Fear of Democracy: A Cultural Evaluation of Sunstein on Risk*, 119 HARV. L. REV. 1071, 1083 (2006) (book review) (focusing on “an important dynamic to which Sunstein is strikingly inattentive: the impact of cultural worldviews”).

that fail to accord with their own more fully developed preferences.⁸⁹

To compensate for cognitive limitations, legal scholars and policymakers have argued that laws can serve an important “debiasing” function.⁹⁰ For example, laws requiring graphic warning labels about dangerous products are sometimes defended as debiasing measures that utilize the availability heuristic to overcome the optimism bias that leads individuals to underestimate risks.⁹¹ Likewise, Thaler and Sunstein argue that government policies that place healthy eating options at optimal sites in a school cafeteria are “nudges” that can compensate for the impact of framing and enable individuals to select the foods they would want to select if they acted with greater deliberation and rationality.⁹² According to Thaler and Sunstein, such policies constitute a soft form of paternalism, which they coin “libertarian paternalism,” that helps people do what they would choose to do if not for their cognitive impairments.⁹³

Not surprisingly, critics have challenged the behavioral economics/impaired agency justification for public health laws. For example, although David Friedman generally accepts that public health law has a role to play in debiasing, he argues that the most coercive public health laws (which he characterizes as exercises of hard paternalism) are highly unpopular and frequently lacking in political legitimacy.⁹⁴ Other scholars, such as Mario Rizzo and Douglas Glen Whitman, have questioned whether the discovery of cognitive bi-

⁸⁹ Jolls & Sunstein, *supra* note 87, at 204–05.

⁹⁰ *Id.* at 206. For several examples of laws serving a debiasing function see Christine Jolls et al., *A Behavioral Approach to Law and Economics*, 50 STAN. L. REV. 1471, 1504, 1527, 1544 (1998).

⁹¹ Jolls & Sunstein, *supra* note 87, at 212–15.

⁹² THALER & SUNSTEIN, *supra* note 87, at 1–4, 10–11.

⁹³ *Id.* at 4–6. The term “soft paternalism” is used differently by different commentators. Some use the term to refer to laws that respond to impaired agency. See N.Y. Ng & J.P. Ruger, *Ethics and Social Value Judgments in Public Health*, 1 ENCYCLOPEDIA OF HEALTH ECON. 287, 289 (2014). Others use it to denote measures to enhance “autonomy by ensuring that the subject’s choices reflect her true preferences.” Pope, *supra* note 56, at 672. Still others use it to refer to laws that are less coercive and leave individuals with choices. See THALER & SUNSTEIN, *supra* note 87, at 5–6.

⁹⁴ Friedman, *supra* note 16, at 1753.

ases justifies regulations by policymakers who are themselves susceptible to irrationalities.⁹⁵ They also worry that the acceptance of cognitive biases as a justification for regulation creates a slippery slope, opening the door for a wide array of paternalistic interventions.⁹⁶

For present purposes, it is not essential to review all of the critiques offered of the behavioral economics approach. Instead, three points warrant consideration. First, by claiming that laws relating to self-regarding behaviors should respect individual preferences except when agency is impaired, the behavioral economics/impaired agency justification largely accepts the libertarian assumptions implicit in the paternalism critique. Indeed, supporters of the behavioral economics/impaired agency approach frame their project as one aimed at empowering individual choice.⁹⁷ Second, by conceding that public health laws targeting NCDs are paternalistic, advocates of the behavioral economics/impaired agency justification overlook the support for such laws offered by a population perspective.⁹⁸ Still, by explaining how cognitive biases interact with social factors to frame and distort choices, the justification points to the critical role that social and environmental factors play in determining behaviors that affect health. This third point suggests a far broader and more robust justification for public health laws than supporters of behavioral economics generally acknowledge.

⁹⁵ See Mario J. Rizzo & Douglas Glen Whitman, *Little Brother is Watching You: New Paternalism on the Slippery Slopes*, 51 ARIZ. L. REV. 685, 723–35 (2009). But see Blumenthal, *supra* note 85, at 725. Jennifer S. Blumenthal-Barby also questions whether the regulator who tries to “nudge” subjects can in fact know the subjects’ preferences. See J. S. Blumenthal-Barby, *Choice Architecture: A Mechanism for Improving Decisions While Preserving Liberty?*, in PATERNALISM: THEORY AND PRACTICE 178, 179, 183, 196 (Christian Coons & Michael Weber eds., 2013).

⁹⁶ See Jeremy A. Blumenthal, *Emotional Paternalism*, 35 FLA. ST. U. L. REV. 1, 5, 66–69 (2007).

⁹⁷ See Russell Korobkin, *Libertarian Welfarism*, 97 CALIF. L. REV. 1651, 1652 (2009); Cass R. Sunstein & Richard H. Thaler, *Libertarian Paternalism Is Not an Oxymoron*, 70 U. CHI. L. REV. 1159, 1201 (2003) (describing libertarian paternalism as “an approach that preserves freedom of choice”).

⁹⁸ See *infra* text accompanying notes 116–148.

B. *The Harm Principle: A Population Perspective*

No one questions that the state is justified in protecting individuals from harms caused by others.⁹⁹ Laws against homicide or drunk driving are commonly accepted without debate as appropriate limits on an individual's ability to harm another.¹⁰⁰ Likewise, even the most ardent critics of public health law concede that the state has a legitimate interest in seeking to prevent public nuisances, communicable diseases, and other harms that constitute public bads.¹⁰¹ In all such cases, state action is directed not at self-regarding behaviors, but at behaviors thought to have a deleterious impact on others. Such regulations, by definition, are not paternalistic.

The broad acceptance of the harm principle raises a critical question for laws targeting NCDs.¹⁰² Under which circumstances are such laws justified by the harm principle? Are they paternalistic regulations of individuals, or limits on other-regarding actions? Public health advocates and scholars have offered many arguments to support the latter conclusion. Three types of arguments are especially prominent.

The first relies on a straightforward application of the harm principle by demonstrating that the particular actions of individuals or corporations are the proximate cause of NCDs in others.¹⁰³ For example, indoor air regulations have been explained as necessary to protect bystanders from the harms of other individuals' secondhand smoke.¹⁰⁴ So viewed, indoor air regulations seem relatively similar to the communicable disease laws, such as quarantine, that characterized the old public health: Both limit individual liberty to prevent harm to others.

⁹⁹ Even Mill conceded this. *See* Mill, *supra* note 55, at 13. Even if they are not paternalistic, laws may be inappropriate for other reasons. For example, a law imposing the death penalty for speeding is not paternalistic, but it is still of dubious legitimacy, not to mention constitutionality.

¹⁰⁰ Laws protecting individuals from harm from others may still be ineffective or cause more harm than good. They may also violate other deeply held principles, including respect for freedom of speech or religion.

¹⁰¹ *E.g.*, Epstein, *supra* note 41, at 1425–26.

¹⁰² Wiley, Berman & Blanke, *supra* note 24, at 89.

¹⁰³ To be sure, different products pose dramatically different degrees of risk, a point whose significance is discussed *infra* text accompanying notes 182–187.

¹⁰⁴ Pope, *supra* note 86, at 441.

Critics of laws relating to NCDs often portray the so-called old public health through an overly rosy lens. In reality, the good old days weren't always so good. Communicable disease laws often subjected vulnerable individuals to highly coercive and often ineffective legal measures such as isolation or mandatory sterilization, on the frequently erroneous belief that they endangered the health of others.¹⁰⁵ All too often these laws reflected and reified the troubling association between disease and marginalized communities.¹⁰⁶

Justifications for NCD laws that rely on the claim that the actions of individuals endanger others create similar risks. Indeed, many of the laws proposed or enacted for reducing smoking or obesity rates reinforce stigmas and disproportionately disadvantage vulnerable populations.¹⁰⁷ For example, laws that limit the foods that can be purchased with food stamps stigmatize low-income individuals by treating them as less capable than others of making healthy dietary choices. In this way, an overly simplistic reliance on the harm principle may reinforce inequities and disparities,¹⁰⁸ highlighting the critical but often overlooked point that even when a public health law may be justified under the harm principle, other considerations may point to its inappropriateness.¹⁰⁹

A second type of argument based upon the harm principle follows from public health's utilitarian and consequentialist tradition by focusing on the aggregate health and economic costs of NCDs

¹⁰⁵ See Wendy E. Parmet, *Dangerous Perspectives: The Perils of Individualizing Public Health Problems*, 30 J. LEGAL MED. 83, 83–84 (2009).

¹⁰⁶ *Id.* at 104.

¹⁰⁷ *Id.*; See also Ronald Bayer & Jennifer Stuber, *Tobacco Control, Stigma, and Public Health: Rethinking the Relations*, 96 AM. J. PUB. HEALTH 47, 47 (2006); Kirsten Bell et al., *Smoking, Stigma and Tobacco 'Denormalization': Further Reflections on the Use of Stigma as a Public Health Tool. A Commentary on Social Science & Medicine's Stigma, Prejudice, Discrimination and Health Special Issue*, 70 SOC. SCI. & MED. 795, 797 (2010); Janet L. Dolgin & Katherine R. Dieterich, *Weighing Status: Obesity, Class, and Health Reform*, 89 OR. L. REV. 1113, 1139 (2011); Ng & Ruger, *supra* note 93, at 290.

¹⁰⁸ Wiley, *supra* note 32, at 77–79.

¹⁰⁹ Sometimes a frankly paternalistic approach, in which the government admits to wanting to help the objects of a law, may be less stigmatizing and certainly less oppressive than a law that regulates vulnerable individuals as if they represented a threat to others.

and similar health threats.¹¹⁰ For example, motorcycle helmet and seatbelt laws have often been accepted as a means of saving taxpayers from the costs of treating accident victims.¹¹¹ Likewise, public health advocates have pointed to the aggregate health effects (including the prospect of reduced longevity) and high medical costs as justifications for legal interventions aimed at obesity. Lawrence Gostin has argued:

Obesity primarily affects the individual, but it also has high socioeconomic costs. The aggregate consequences of individual choices are countless preventable disabilities and deaths, affecting families and the entire community. Obesity-attributable medical expenditures reached \$75 billion in the United States in 2003, with substantial additional indirect costs in lost productivity The government arguably has a legitimate interest in controlling medical and social costs of individuals' unhealthy behaviors that are borne by society at large.¹¹²

Not surprisingly, public health law critics have not been persuaded by such arguments. First, they challenge the underlying empirical claims, noting that prevention has only rarely been shown to save money. Jonny Anomaly, for example, points out that because smoking and obesity shorten life expectancy, they may actually reduce overall health care costs.¹¹³

¹¹⁰ See generally Lawrence O. Gostin et al., *The Law and the Public's Health: A Study of Infectious Disease Law in the United States*, 99 COLUM. L. REV. 59, 63–64 (1999). A similar justification has been used successfully to defend helmet and seatbelt laws. See Pope, *supra* note 86, at 443–44.

¹¹¹ Gostin, *supra* note 110, at 73, 100, 122.

¹¹² Lawrence O. Gostin, *Law as a Tool to Facilitate Healthier Lifestyles and Prevent Obesity*, 297 JAMA 87, 87 (2007).

¹¹³ Jonny Anomaly, *Is Obesity A Public Health Problem?*, 5 PUB. HEALTH ETHICS 216, 218 (2012). Tobacco companies have made similar arguments in defending tort claims. See, e.g., Matthew R. Herington, *Tobacco Regulation in the United States: New Opportunities and Challenges*, 23 HEALTH LAW. 13, 13 (2010). Critics have also pointed to conflicting studies in the scientific literature regarding the mortality impact of obesity. See *Smokers and the Obese Cheaper to Care For, Study Shows*, N.Y. TIMES, (Feb. 5, 2008), http://www.nytimes.com/2008/02/05/health/05iht-obese.1.9748884.html?_r=0.

A second more conceptual criticism claims that aggregate costs arise from health problems such as obesity only because we have chosen to socialize health care costs. Epstein writes, “[b]ut here it is the social response, not the underlying set of choices, that introduces a public goods dimension into the mix. The problem could be reduced or eliminated by reversing the antecedent decision to socialize the expenses of health care through programs like Medicare and Medicaid.”¹¹⁴

To Epstein, the cost argument is a form of bootstrapping that relies on the socialization of health care costs to justify the public interest in protecting health. Yet while Epstein is correct that obesity would not create the same costs to taxpayers if we did not redistribute health care costs, his argument relies on a world in which no health care costs are socialized and ill health creates no externalities. In reality, health care costs are redistributed to varying degrees in *all* nations because untreated health conditions create significant externalities that extend outside of the cost of health care and could not be avoided even if no health care costs were redistributed. Most obvious in the case of preventable infectious diseases, this also applies to NCDs. Consider a single mother with untreated diabetes who cannot afford treatment. Even if taxpayers failed to pay any of the costs of her health care, the public would end up bearing some costs of her disease by way of her reduced productivity, or the state’s need to care for her children if she died prematurely.¹¹⁵ In short, although health has many attributes of a private good, and the market can be used to influence its distribution, it also has numerous aspects of a public good.¹¹⁶ All externalities cannot be eliminated simply by

¹¹⁴ Epstein, *supra* note 47, at 1369.

¹¹⁵ Some libertarians might respond that the state should not care for her children; but few serious thinkers would argue that we should leave orphaned children to the fate they suffered in Dickens’ novels.

¹¹⁶ The economic definition of a public good is one which is nonexcludable and nonrivalrous. Patricia Illingworth & Wendy E. Parmet, *Solidarity and Health: A Public Goods Justification*, 43 *DIAMETROS* 65, 66 (2015). Health is generally nonrivalrous in that one person’s health does not diminish another’s (to the contrary, it can enhance another’s). *Id.* However, many of the so-called access goods that help support health, especially medical services, are excludable. *Id.* at 67. But with a broader public health perspective, health appears to take on more characteristics of a public good in that its absence has broad externalities; moreover, its existence depends significantly on nonexcludable access goods, such as social determinants. *See id.* at 67–68.

abolishing private or public health insurance. This gives the government an inherent economic stake in preventing NCDs, although the strength of the state's interest may vary depending upon the underlying empirical facts.

The claim that health has more attributes of a public good than libertarians acknowledge underlies the third type of argument that public health advocates use to place laws targeting NCDs under the harm principle. This argument relies on public health's own population perspective, which emphasizes the role that population-level (non-individual) factors play in determining population-level health outcomes.¹¹⁷ From the population perspective, NCDs are less the result of individual preferences and behaviors and more the sequelae of a thick web of social factors, often coined "the social determinants of health."¹¹⁸ Thus, public health researchers and advocates have noted that a wide range of government policies, marketing practices, and social norms have coalesced to create what some have called an obesogenic environment,¹¹⁹ which is uncondusive to physical activity, abundant with fast food, and devoid of health options. This toxic environment exudes the same type of externalities found in the public nuisances targeted by the old public health.¹²⁰

The fact that obesity and other NCDs are determined at a population level by social factors suggests a further point. If health conditions are affected by population-level factors, the health and health-affecting behaviors of individuals can impact the health of

¹¹⁷ See PARMET, *supra* note 20, at 13–22; see also Micah L. Berman, *A Public Health Perspective on Health Care Reform*, 21 HEALTH MATRIX 353, 360 (2011).

¹¹⁸ Adam Benforado et al., *Broken Scales: Obesity and Justice in America*, 53 EMORY L.J. 1645, 1664–84 (2004). The term "social determinants" is often used to refer to the wide range of social factors that influence population health. See, e.g., Michael Marmot et al., *Closing the Gap in a Generation: Health Equality Through Action on the Social Determinants of Health*, 372 LANCET 1661, 1661 (2008).

¹¹⁹ See Boyd Swinburn et al., *Dissecting Obesogenic Environments: The Development and Application of a Framework for Identifying and Prioritizing Environmental Interventions for Obesity*, 29 PREVENTIVE MED. 563, 566–68 (1999).

¹²⁰ See, e.g., Lawrence O. Gostin & Maxwell Gregg Bloche, *The Politics of Public Health: A Response to Epstein*, 46 PERSP. BIOLOGY & MED. S160, S172 (2003); Elizabeth Weeks Leonard, *The Public's Right to Health: When Patient Rights Threaten the Commons*, 86 WASH. U. L. REV. 1335, 1391–92 (2009); Lindsay F. Wiley, *Rethinking the New Public Health*, 69 WASH. & LEE L. REV. 207, 267 (2012).

others. This is most apparent in the case of cigarette smoking. Not only may an individual's decision to smoke create proximal harm to others through secondhand smoke, it may also help normalize smoking, reinforcing an environment that induces others to smoke.¹²¹ Likewise, researchers have found network effects with respect to obesity, suggesting that the diet and exercise decisions of individuals have spillover effects on others within their social network.¹²² This suggests that laws regulating NCDs may be justified by the harm principle because health is largely determined at a population level.

To critics, the recognition that health is determined as much or more by social factors as individual decisions is deeply troubling. As Adam Benforado and colleagues have explained, we are predisposed to believe that we have more individual agency than we have.¹²³ We deeply want to believe we can control our fate, and that our actions are the result of our own reasoned choices rather than the environment we inhabit.¹²⁴ Moreover, as Mark Rothstein has argued, public health's population perspective may justify a remarkably broad range of state interventions.¹²⁵ This is troubling precisely because public health laws may overreach and trump other important values, as they often did in the days of the old public health. Thus, as noted above, Mark Hall seeks to cabin public health *laws* to those relating to communicable diseases even while recognizing that public health science cannot be so limited.¹²⁶ Yet by relying on an overly simplistic distinction between infectious diseases and NCDs to limit public health laws' reach, this approach risks diverting our attention from the potential overreach of infectious disease laws¹²⁷ as well as other normative limits on laws addressing

¹²¹ See Jennifer O'Loughlin et al., *Determinants of First Puff and Daily Cigarette Smoking in Adolescents*, 170 AM. J. EPIDEMIOLOGY 585, 588 (2009).

¹²² See Nicholas A. Christakis & James H. Fowler, *The Spread of Obesity in a Large Social Network over 32 Years*, 357 NEW ENG. J. MED. 370, 370 (2007).

¹²³ Benforado et al., *supra* note 118, at 1661.

¹²⁴ *Id.*

¹²⁵ Rothstein, *supra* note 44, at 148–49.

¹²⁶ Hall, *supra* note 44, at S202.

¹²⁷ In his writings about communicable disease laws Rothstein has articulated important principles for limiting the reach of infectious disease laws. See Mark A. Rothstein, *The Moral Challenge of Ebola*, 105 AM. J. PUB. HEALTH 6, 6–7 (2015);

NCDs.¹²⁸ Thus, this view permits an overly narrow but excessively powerful role for public health law.

Underlying the acceptability of the various arguments and counterarguments waged within the confines of the harm principle are several critical questions: How readily do we see harm to others? And how strong must the harm to others be before we see a law as resting within the harm principle? Do we view the decision to use e-cigarettes as simply fulfilling the endogenous preference of the vaper, or do we see it as a function of a web of social factors? Likewise, do we consider only the proximal harm that comes to bystanders from vaping, or do we look more broadly at the impact of vaping on population health? In other words, what factors do we deem material? What perspective do we hold? The research on social determinants and NCDs suggests that if we care about health, our perspective must indeed be broad.

That recognition, however, does not mean all health threats, infectious or not, merit all plausible legal responses. The magnitude of the harm to be prevented matters. Moreover, if we take a public health perspective seriously, so does the state of the empirical evidence. Without empirical evidence indicating that a particular action harms population health, its regulation cannot be justified on the basis of the harm principle, a point that becomes especially salient in the case of e-cigarettes, the health effects of which remain unclear.

C. *Self-Governance*

In recent years, public health law scholars have articulated a third important justification for laws targeting NCDs: Such laws

see also Mark A. Rothstein, *Ebola, Quarantine, and the Law*, 45 HASTINGS CTR. REP. 5, 5–6 (2015).

¹²⁸ *See infra* text accompanying notes 176–187.

may represent a manifestation of a population's liberty to take collective action to protect its health via self-governance.¹²⁹ This justification, with roots in civic republicanism,¹³⁰ as well as social contract theory,¹³¹ provides a robust defense of many public health laws, but it also implies critical limitations.

The self-governance argument depends upon three claims. The first is that health is a prerequisite to positive liberty,¹³² worthy of special moral importance and legal respect. In effect, health is not simply another good, but one necessary to enable individuals to exercise their other liberties, or attain their personal goals.¹³³ According to Sridhar Venkatapuram, because "a person's health is an assessment of her abilities to be and do some basic things," health is a "metacapability."¹³⁴ Other theorists agree health has a special moral importance because of its critical role in enabling individuals to exercise their agency and fulfill other life choices.¹³⁵

Second, because health is largely a public good, and is at least partially determined at a population level, individuals cannot secure their health on their own. Rather, to varied degrees, health requires collective action. For example, individuals are relatively limited in their ability to protect themselves against many infectious diseases

¹²⁹ E.g., Lazzarini & Gregorio, *supra* note 21, at 1855; Wiley et al., *supra* note 24, at 91.

¹³⁰ Bruce Jennings, *Public Health and Civic Republicanism: Toward an Alternative Framework for Public Health Ethics*, in *ETHICS, PREVENTION AND PUBLIC HEALTH* 30, 31–34 (Angus Dawson & Marcel Verweij eds., 2007).

¹³¹ Wendy E. Parmet, *Health Care and the Constitution: Public Health and the Role of the State in the Framing Era*, 20 *HASTINGS CONST. L.Q.* 267, 316–19 (1993).

¹³² "Positive liberty is the possibility of acting—or the fact of acting—in such a way as to take control of one's life and realize one's fundamental purposes." Ian Carter, *Positive and Negative Liberty*, *THE STANFORD ENCYCLOPEDIA OF PHILOSOPHY* (Edward N. Zalta ed., 2016), <http://plato.stanford.edu/entries/liberty-positive-negative/>.

¹³³ The persuasiveness of this argument depends upon defining health relatively narrowly. If health is defined too broadly it loses its priority among other goods. For a discussion of the possible definitions of health and their relationship to the understanding of health as a metacapability, see VENKATAPURAM, *supra* note 23, at 44–72.

¹³⁴ *Id.* at 20.

¹³⁵ See NORMAN DANIELS, *JUST HEALTH: MEETING HEALTH NEEDS FAIRLY* 17–21 (2008); see also MADISON POWERS & RUTH FADEN, *SOCIAL JUSTICE: THE MORAL FOUNDATIONS OF PUBLIC HEALTH AND HEALTH POLICY* 85 (2006).

prevalent in a community. Nor can individuals protect themselves from the health effects of air pollution, traffic hazards, unwholesome water, or a wide range of social determinants. Less obviously, smokers who want to quit smoking may have much less success if they live in a community in which smoking is ubiquitous. And those who want to lose weight may find it hard to do so if they live in food deserts. In all these cases and many more, individual health can be best, and sometimes only, secured through collective action that alters the environment.

The collective actions that protect health and therefore support positive liberty often require that other liberties be restrained. As the Supreme Court recognized in upholding a Massachusetts law mandating smallpox vaccination, “[r]eal liberty for all could not exist under the operation of a principle which recognizes the right of each individual person to use his own, whether in respect of his person or his property, regardless of the injury that may be done to others.”¹³⁶ The Court thus affirmed that liberty not only exists in the absence of state action; state action may at times be necessary to ensure liberty.¹³⁷

Third, in a democratic polity, public health laws can be the fruit of a population’s exercise of its own political liberty. According to the Institute of Medicine, “[p]ublic health is what we, as a society, do collectively to assure the conditions for people to be healthy.”¹³⁸ Or as Marcel Verweij and Angus Dawson explain, public health consists of the “collective interventions that aim to promote and protect the health of the public.”¹³⁹ In effect, public health laws are a

¹³⁶ *Jacobson v. Massachusetts*, 197 U.S. 11, 26 (1905).

¹³⁷ Bruce Jennings argues that public health interventions “inherently” involve state action. Bruce Jennings, *Relational Liberty Revisited: Membership, Solidarity and a Public Health Ethics of Place*, 8 *PUB. HEALTH ETHICS* 7, 7 (2015). This seems somewhat of an overstatement, as private individuals operating in concert can undertake interventions that promote their health, as is evident by the actions undertaken by AIDS support groups early in the epidemic. See RAYMOND A. SMITH & PATRICIA D. SIPLON, *DRUGS INTO BODIES: GLOBAL AIDS TREATMENT ACTIVISM* 15 (2006).

¹³⁸ COMM. FOR THE STUDY OF THE FUTURE OF PUB. HEALTH, INST. OF MED., *supra* note 25, at 19.

¹³⁹ Marcel Verweij & Angus Dawson, *The Meaning of ‘Public’ in ‘Public Health’*, in *ETHICS, PREVENTION AND PUBLIC HEALTH* 14, 21 (Angus Dawson & Marcel Verweij eds., 2007).

primary mechanism by which individuals, acting within populations, engage their political right to secure their health, which, as noted above, is a prerequisite to the exercise of their other liberties.¹⁴⁰

This engagement of populations around the shared goal of public health can and should be understood as an act of solidarity, enhanced by the recognition of the mutual dependency that arises from populations' shared vulnerability to disease and injury.¹⁴¹ Critically, such solidaristic actions are both exemplars and constituents of self-governance. In effect, recognition of shared vulnerability to health problems, be they infectious diseases, environmental toxins, or NCDs, brings people together to engage their political system. They decide upon the levels of risk they are willing to tolerate, the trade-offs they are willing to make, and the robustness of the evidence they will demand. Exercising their political liberty to make these choices, they seek and enact laws to protect their mutual health, as AIDS activists did in the 1980s and 1990s, and as anti-tobacco groups have done for decades.¹⁴² As Bruce Jennings explains, “[a]n aggregation

¹⁴⁰ The extent to which laws are necessary for fulfilling the liberty of health depends on the degree to which health requires collective action—in other words, the extent to which health is a public good. Illingworth & Parmet, *supra* note 116, at 67–69. As noted above, from a public health perspective, health appears to be a public good. *Id.* at 66. But even if health is not a public good, public health laws have significant public good attributes in that they provide individuals and populations with benefits that would be far more costly if not impossible to attain on their own. This is perhaps most obvious with vaccine laws that help establish so-called herd immunity, allowing individuals who are unable to be vaccinated, or for whom vaccines don't work, to escape the dangers of vaccine-preventable diseases by stopping the spread of infection within a community. Lawrence O. Gostin, *Law, Ethics and Public Health in the Vaccination Debates: Politics of the Measles Outbreak*, 313 JAMA 1099, 1099 (2015). But laws targeting NCDs can also enable individuals to reap health benefits difficult to attain on their own. Illingworth & Parmet, *supra* note 116, at 68. For example, although many individuals can stop smoking without them, such laws may make it far easier for people addicted to nicotine to avoid the temptation of succumbing to their habit. *Id.*

¹⁴¹ See Illingworth & Parmet, *supra* note 116, at 68–69; Jennings, *supra* note 137, at 12–14; Barbara Prainsack & Alena Buyx, *Solidarity in Contemporary Bioethics – Towards a New Approach*, 26 BIOETHICS 343, 347 (2012).

¹⁴² See, e.g., SMITH & SIPLON, *supra* note 137, at 14–34 (discussing the rise of AIDS activism and its impact on U.S. policy); Elizabeth Laposata et al., *When Tobacco Targets Direct Democracy*, 39 J. HEALTH POL. POL'Y. & L. 537–40

of individuals becomes a people, a public, a political community when it is capable of recognizing common purposes and problems in this way”¹⁴³

As the legal embodiment of populations’ political engagement, public health law can be understood as the product of self-governance.¹⁴⁴ Although similar arguments can be made for other types of laws, this understanding of public health laws gains special traction because health is a metacapability and a public good largely determined at a population level. Health is, therefore, different from many other goods subject to the political system precisely because it is a prerequisite to positive liberty, and because it can be secured only by collective action. Indeed, health exposes our mutual vulnerability and demonstrates unequivocally the extent to which the good of individuals is dependent upon the environment in which they live and the laws they authorize to shape that environment.¹⁴⁵ Especially when epidemics threaten, the positive liberty of self-governance is essential to securing the positive liberty of health. For this reason, public health laws can also be understood as part of the founding motivation for the social contract.¹⁴⁶ As John Locke stated, people agree to be governed precisely “for the mutual *Preservation* of their Lives, Liberties and Estates, which [Locke called] by the general Name, *Property*.”¹⁴⁷ Without public health laws, people’s lives and

(2014) (discussing the use of forms of direct democracy by grassroots anti-tobacco groups).

¹⁴³ Jennings, *supra* note 130, at 48.

¹⁴⁴ The concept of self-governance has a long pedigree within civic republicanism, *see, e.g.*, Frank I. Michelman, *The Supreme Court 1985 Term—Foreword: Traces of Self-Government*, 100 HARV. L. REV. 4, 17–19 (1986); James Gray Pope, *Republican Moments: The Role of Direct Popular Power in the American Constitutional Order*, 139 U. PA. L. REV. 287, 296 (1990), and First Amendment theory, *see, e.g.*, ALEXANDER MEIKLEJOHN, *POLITICAL FREEDOM: THE CONSTITUTIONAL POWERS OF THE PEOPLE* 75 (1965) (stating that the First Amendment exists “to give to every voting member of the body politic the fullest possible participation in the understanding of those problems with which the citizens of a self-governing society must deal.”).

¹⁴⁵ This is most obvious in the case of communicable diseases, but individuals are also unable, on their own, to control the social determinants of health. Nor can anyone be wholly self-sufficient when ill. *See supra* text accompanying notes 118–23.

¹⁴⁶ Parmet, *supra* note 131, at 312.

¹⁴⁷ JOHN LOCKE, *TWO TREATISES OF GOVERNMENT* 350 (Peter Laslett ed., 1988) (1689).

liberties are as insecure as they would be if the government failed to protect them from foreign foes.

Once public health laws are viewed in this light, the paternalism critique, which looks only at the restraint of an individual's negative liberty, seems misplaced. Rather than as mere restraints upon liberty, public health laws now appear to be mechanisms by which positive liberty is both exercised and enhanced.¹⁴⁸ Hence the presumption of illegitimacy implied by the paternalism critique threatens to *diminish* liberty, undermine health, and weaken self-governance, leaving "we the people" without important tools for improving *our* health.

This perspective has important doctrinal implications. Most critically it suggests that public health laws should (at least when they are exercises of self-governance) be granted the presumption of constitutionality normally accorded to acts of the political branches,¹⁴⁹ rather than being viewed, as the paternalism critique implies, as presumptively illegitimate. Indeed, once we see public health laws as exercises of self-governance, judicially imposed restraints on paternalism, especially when unmoored from clearly established constitutional rights or statutory limitations, are exposed as countermajoritarian efforts to limit liberty while imposing a libertarian perspective on the body politic. In other words, the paternalistic critique "[re]enact[s] Mr. Herbert Spencer's Social Statics."¹⁵⁰

This is not to say the self-governance rationale justifies all public health laws. To the contrary, the justification proffers its own important limits. Most critically, the recognition of public laws as manifestations of self-governance places upon public health laws all the typical limits imposed upon the state by liberal theory.¹⁵¹ Hence, the

¹⁴⁸ Dawson & Verweij, *supra* note 43, at 2.

¹⁴⁹ See *United States v. Carolene Prods. Co.*, 304 U.S. 144, 152 (1938). This argument is similar to one that First Amendment scholars have recently made regarding the impact of the Supreme Court's absolutist interpretation of the First Amendment on self-governance. See Robert Post & Amanda Shanor, *Adam Smith's First Amendment*, 128 HARV. L. REV. F. 165, 165–67, 172 (2015); see generally Rebecca L. Brown, *The Harm Principle and Free Speech* (U.S.C. GOULD LEGAL STUDIES RESEARCH PAPERS SERIES NO. 15-11 2015), http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2584080.

¹⁵⁰ *Lochner v. New York*, 198 U.S. 45, 75 (1905) (Holmes, J., dissenting).

¹⁵¹ John Coggon argues that the normative foundations for public health essentially conflate with those that underlie liberal political theory. JOHN COGGON,

primary limitations on public health laws are to be found within the confines of the rule of law and the recognition of individual rights. Thus norms of due process and respect for individual rights, such as those protected by the Bill of Rights and Fourteenth Amendment, remain as critical checks on public health powers.¹⁵² Further, the most trenchant critiques of public health laws derive not from their paternalistic nature, but from the failings of our polity to adhere to its democratic principles and facilitate self-governance.¹⁵³ This, however, is not a problem unique to public health laws, or even to the new public health.

The self-governance rationale, however, also contains within it additional caveats that, while applicable to other types of laws, are especially salient to public health laws. The first arises from the diverse and contingent nature of populations. Public health law's population perspective recognizes a multiplicity of ever-shifting populations.¹⁵⁴ In reality there is no one public. There are many publics comprising different populations that face different health risks and bear different burdens from public health laws.

The multiplicity and differential position of varied populations counsel against presuming that any specific public health law can be justified as the expression of any particular population's exercise of self-governance. It also requires us to remember that public health laws are often the restraints on liberty that one population imposes on another, often less powerful, population, as the fear of disease often incites the tendency to scapegoat those already vulnerable.¹⁵⁵

WHAT MAKES HEALTH PUBLIC? A CRITICAL EVALUATION OF MORAL, LEGAL, AND POLITICAL CLAIMS IN PUBLIC HEALTH 205–34 (2012).

¹⁵² See LAWRENCE O. GOSTIN, *PUBLIC HEALTH LAW: POWER, DUTY, RESTRAINT* 113–44 (rev. 2d ed. 2008) (discussing the constitutional limits on public health powers).

¹⁵³ See Lani Guinier, *Beyond Electocracy: Rethinking the Political Representative as Powerful Stranger*, 71 *MOD. L. REV.* 1, 20–22 (2008).

¹⁵⁴ PARMET, *supra* note 20, at 54. The self-governance argument has roots in the communitarian as well as civic republican traditions. *Id.* at 1, 13–14. However, the recognition of the contingent nature of populations suggests a critical distinction from traditional communitarianism. *See id.* at 18. Populations are not necessarily fixed demographic or geographic communities. *See id.*

¹⁵⁵ This was and remains a common characteristic of the old public health laws. *See, e.g., Jew Ho v. Williamson*, 103 F. 10, 26 (N.D. Cal. 1900) (finding unconstitutional a quarantine of the Chinese community in San Francisco). For a longer discussion, *see* Parmet, *supra* note 34, at 64–71.

This underscores that public health laws must adhere to norms of equality, and that the self-governance justification applies only when populations restrain their own liberty, not when they impose the costs of health onto others.¹⁵⁶

Second, the self-governance justification depends upon a degree of political engagement and popular rooting for public health laws that is often lacking. This is not because public health laws are generally unpopular. Even many paternalistic public health laws enjoy more public support than the paternalism critique presupposes.¹⁵⁷ Still, public acceptance of a law does not alone constitute the type of active citizen engagement that underpins the self-governance justification.¹⁵⁸ Perhaps, for that reason, public health scholars have exhorted public health practitioners “to engage with people at the grassroots level.”¹⁵⁹ When public health laws emerge from grassroots activism, there is a far stronger basis for claiming that they are acts of self-governance than when affected populations have not mobilized for the laws.

The importance of grassroots involvement may help explain the leading role localities have played in developing public health law innovations.¹⁶⁰ As Paul Diller has documented, many of the most notable innovations in laws relating to both tobacco and obesity

¹⁵⁶ Michael Walzer similarly argues that although communities should be able to self-govern, they should not be able to impose laws on those not accorded membership within their community. MICHAEL WALZER, *SPHERES OF JUSTICE: A DEFENSE OF PLURALISM AND EQUALITY* 61–63 (1983).

¹⁵⁷ See Parmet, *supra* note 16, at 1787. Many public health laws that initially face strong public resistance become popular over time. *See id.*

¹⁵⁸ Exactly what type of popular engagement constitutes adequate support for a public health law in a complex society is a fundamental question for democratic theory beyond the scope of this paper. For present purposes, I simply claim that to the extent the justification for a public health law rests upon self-governance, the law should plausibly be the product of self-governance.

¹⁵⁹ Jennings, *supra* note 130, at 34; Wiley, Berman & Blanke, *supra* note 24, at 90 (arguing that we need to “think[] about how we can come together as a community to address [public health problems].”).

¹⁶⁰ There are also constitutional reasons for viewing public health law as primarily state and local law. *See* GOSTIN *supra* note 152, at 92 (discussing the police power). Although related to the theory of federalism, this argument does not depend on the fact that the Constitution leaves the police power to the states. Rather, the point is that the self-governance claim is more persuasive in smaller jurisdictions in which citizen groups can have greater influence.

have emerged in cities.¹⁶¹ Diller attributes this in part to the more liberal predilections of urban residents.¹⁶² Regardless, it remains relevant that affected populations are also closer to the lawmaking bodies at the local level,¹⁶³ while industry groups may have less influence there for a variety of reasons.¹⁶⁴ All things being equal, community engagement is more apt to be present and influential at the local level.¹⁶⁵

A similar issue relates to the fact that public health law is largely administrative law.¹⁶⁶ Most public health laws are not enacted by legislatures, but promulgated by administrative bodies at the local, state, and federal levels.¹⁶⁷ If we are to respect the positive liberty of

¹⁶¹ See generally Paul A. Diller, *Why Do Cities Innovate in Public Health? Implications of Scale and Structure*, 91 WASH. U. L. REV. 1219 (2014) (discussing cities' public health regulation); see also Kathleen Hoke Dachtler, *Using Law to Improve Public Health: The Example of Tobacco Regulation*, 17 N.Y. ST. B. ASS'N HEALTH L.J. 32, 32 (2012) ("History and current experience show that fundamental changes in public health regulation in the United States often start at the local level; this is particularly true with respect to tobacco control.").

¹⁶² Diller, *supra* note 161, at 1281. Katherine Pratt also argues that health officials may be more nimble at the local level. Katherine Pratt, *Lessons from the Demise of the Sugary Drink Portion Cap Rule*, 5 WAKE FOREST J.L. & POL'Y 39, 71 (2015).

¹⁶³ There is also reason to believe that state legislatures are more susceptible to "capture" by industries that manufacture products associated with NCDs. See Michael S. Givel & Stanton A. Glantz, *Tobacco Lobby Political Influence on US State Legislatures in the 1990s*, 10 TOBACCO CONTROL 124, 124–25 (2001) ("The [tobacco] industry's public policy objective has been to preserve and expand its customer base, sales, and profits through sophisticated lobbying and political efforts in state legislatures These policy objectives and approaches have led to and are also connected to collective state legislative outputs or governmental actions relating to tobacco control legislation and programmes, including enactment of state laws preempting local clean indoor air and other tobacco control ordinances and keeping state tobacco excise taxes low.").

¹⁶⁴ See Paul Diller, *Local Health Agencies, The Bloomberg Soda Rule, and the Ghost of Woodrow Wilson*, 40 FORDHAM URB. L.J. 1859, 1886 (2013).

¹⁶⁵ Matthew J. Parlow, *Civic Republicanism, Public Choice Theory, and Neighborhood Councils: A New Model for Civic Engagement*, 79 UNIV. COLO. L. REV. 137, 153–57 (2008).

¹⁶⁶ See Edward P. Richards, *Public Health Law as Administrative Law: Example Lessons*, 10 J. HEALTH CARE L. & POL'Y 61 (2007).

¹⁶⁷ For a discussion of local administrative rulemaking and innovation with respect to public health see Diller, *supra* note 164, at 1884–1900.

populations to protect their own health, we need to accept their ability to rely on experts to implement their wishes.¹⁶⁸ As Oren Bar-Gill and Cass Sunstein have argued, administrative agencies can be viewed as the public's agents—as entities that enhance rather than restrain liberty.¹⁶⁹ This is especially the case during epidemics. Indeed, the history of public health demonstrates that boards of health evolved in response to cholera epidemics, in which populations came to recognize the need for powerful expert bodies that could quickly respond to the calamity at hand.¹⁷⁰ But even with respect to NCDs, a population may still need to rely upon an administrative body to achieve its desired degree of health protection. For example, it is difficult to think of how populations could adequately protect themselves against dangerous pharmaceuticals without an entity similar to the FDA. Likewise, a population that worries about obesity may want administrative agencies to use their expertise to implement policies to make the environment less obesogenic. Moreover, epidemics often arise suddenly and require the type of rapid response that only standing administrative agencies can supply. If epidemics could be addressed only when the public mobilized, public health would be sorely compromised.

Still, the self-governance justification for public health laws offers an important caution for such regulations arising from administrative action, especially in the absence of clear legislative guidance. If self-governance is a critical rationale for public health laws (when no other rationale suffices), the actuality of self-governance needs to be taken seriously. This suggests that when neither the impaired agency rationale nor harm principle applies, public health agencies must be careful to respect the choices of the democratically elected branches (which represent the self-governed) as to priorities, the population's willingness to bear risks, and the degree of evidence it

¹⁶⁸ See Blumenthal, *supra* note 85, at 728 (explaining why individuals may prefer to have experts make decisions for them).

¹⁶⁹ Oren Bar-Gill & Cass R. Sunstein, *Regulation as Delegation*, 7 J. LEGAL ANALYSIS 1, 15 (2015).

¹⁷⁰ For example, the first standing board of health in the United States was appointed during a cholera outbreak. CHARLES E. ROSENBERG, *THE CHOLERA YEARS: THE UNITED STATES IN 1832, 1849, AND 1866*, at 19 (Univ. of Chicago Press 3d ed. 1971). Previously, New York and other jurisdictions appointed boards of health and vested them with broad power during epidemics, only to allow the board to disband once the crisis had passed. *Id.*

demands. No simple imperative to promote health in the absence of clear evidence should prevail unless there is good reason to believe the affected population has chosen it. For this reason, health agencies should be wary about getting too far ahead of the populations they claim to protect by using standing grants of broad authority in novel ways.¹⁷¹ The ready use of emergency powers, which grant public health agencies broad authority to relax otherwise existing legal processes and rights, is especially problematic in the absence of firm evidence of imminent harm to others.¹⁷²

The need for public health agencies to consider the popular foundation for their regulations is perhaps one lesson from the Supreme Court's decision in *FDA v. Brown & Williamson Tobacco Corporation*, in which it rejected the FDA's assertion of jurisdiction over tobacco on the theory that Congress did not intend for the agency to regulate tobacco.¹⁷³ Although the Court's opinion was troubling for its failure to accept the potency of the impaired agency and harm principle rationales, the Court correctly recognized that the FDA's regulations went beyond the scope that the political branches intended when the Food, Drug, and Cosmetic Act was enacted.¹⁷⁴ Likewise, the New York Court of Appeals' decision to invalidate the New York City Board of Health's sugary soda portion rule in *New York Statewide Coalition of Hispanic Chambers of Commerce v. New York City Department of Health and Mental Hygiene* can be understood as an attempt to confine the Board's rulemaking in the absence of clear legislative authority when "the connection of the regulation with the preservation of health and safety is [not] very direct"¹⁷⁵ Although these decisions are problematic for their

¹⁷¹ See Peter D. Jacobson & Wendy E. Parmet, *Defending Public Health Regulations: The Message Is the Medium*, 44 HASTINGS CTR. RPT. 4, 4–5 (2014).

¹⁷² See Rebecca Haffajee et al., *What is a Public Health "Emergency"?*, 371 NEW ENG. J. MED. 986, 986–88 (2014).

¹⁷³ *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 161 (2000). It should, however, be noted that the impaired agency rationale was relatively robust as applied to the regulations at issue in *FDA v. Brown & Williamson Tobacco Corp.*, given that the FDA was focused on regulating the marketing of cigarettes to youth, and that cigarettes are addictive. See *id.* at 127–28.

¹⁷⁴ *Id.* at 143–56.

¹⁷⁵ *N.Y. Statewide Coal. of Hispanic Chambers of Commerce v. N.Y.C. Dep't of Health & Mental Hygiene*, 16 N.E.3d 538, 548 (N.Y. 2014). The court in effect limited the scope of the Board's policymaking in cases in which individual autonomy was at stake and the harm to others was indirect. In applying this approach

failure to adopt a population perspective and recognize the strength of the impaired agency and harm principle justifications, they serve as useful reminders that self-governance provides not only a justification but also a limit on public health law.

D. *Constraints on Public Health Law*

To summarize the argument thus far, the public health law literature offers three broad responses to the paternalism critique. The first two, impaired agency and the harm principle, can be presented either narrowly, using the traditional Millian justifications for constraints on liberty, or more broadly, relying upon the findings of behavioral economics in the case of impaired agency or public health's population perspective in the case of the harm principle. The third rationale, based on a population's positive liberty to self-govern to improve its own health, rests firmly upon public health's population perspective.

Although potentially broad, each of the three justifications implies its own restraints. Most critically, the conditions underlying a justification need to be met for the justification to be persuasive in any particular case. Thus, the persuasiveness of the impaired agency justification requires a reasonably strong basis for believing that the subject's agency is in fact impaired, or that *material* information is lacking (if the law in question purports to overcome informational deficiencies).¹⁷⁶ Likewise, if a public health law's legitimacy rests upon the harm principle, persuasive evidence must exist that the activity regulated creates harm to others. Many public health laws justified under the harm principle, including quarantines and forced

to the Board's portion cap rule, however, the court failed to adopt a population perspective and recognize the ways in which the sale of large soda portions affects population health. See Lindsay F. Wiley, *Sugary Drinks, Happy Meals, Social Norms, and the Law: The Normative Impact of Product Configuration Bans*, 46 CONN. L. REV. 1877, 1883–85 (2014); see also Laura Hoffman, *Cigarettes vs. Soda?: The Argument for Similar Public Health Regulation of Smoking and Obesity*, 46 CONN. L. REV. 1889, 1893–96 (2014).

¹⁷⁶ Cf. *Canterbury v. Spence*, 464 F.2d 772, 780 (D.C. Cir. 1972) (“True consent . . . is the informed exercise of a choice, and that entails an opportunity to evaluate knowledgeably the options available and the risks attendant upon each.”).

sterilizations, have not met that test.¹⁷⁷ In such cases, public health laws cannot withstand scrutiny under any justification that relies on public health's own population perspective. As we shall see, that raises a problem for those arguing for broad regulation of e-cigarettes.

Likewise, the self-governance justification suggests important limitations to its own expansive application. As discussed above, some constraints relate to limits implied broadly by democratic theory and the rule of law. Other limitations pertain to the propensity of populations to impose costs on others to protect their own health, or the lack of popular anchoring for many public health laws, especially those enacted by the federal government or promulgated by administrative agencies pursuant to broad delegations of authority.¹⁷⁸ In addition, as with the other rationales, the science matters. Respect for self-governance counsels that populations should have a wide berth to determine the value they ascribe to population health as compared with other goods. Self-governance also suggests populations should be granted broad deference in determining where to place the burden of scientific uncertainty; in other words, how strong must be the evidence of harm (or mitigation of harm) before legal interventions are taken? In effect, populations themselves should be able to decide whether to adopt a precautionary principle or demand significant evidence before regulating a product or activity. Self-governance does not, however, justify any and all actions undertaken in the name of public health.¹⁷⁹ Empirical evidence still matters. Adoption of the precautionary principle, for example, can-

¹⁷⁷ The precautionary principle adopted as an exercise of self-governance may at times provide a different rationale for such measures. Further, respect for self-governance suggests that populations should be able to determine within a broad range the strength of evidence that is required for determining harm. Nevertheless, as discussed below, the evidence matters. *See infra* text accompanying notes 179–81.

¹⁷⁸ *See supra* text accompanying notes 166–75.

¹⁷⁹ This is another way of saying that if public health is to matter, it must be taken seriously. *See* PARMET, *supra* note 20, at 268–69. This is not to say that courts should apply strict scrutiny in all public health cases. Rather, the point here is simply that if the justification for a law rests on public health, its validity must necessarily depend upon the strength of the public health evidence.

not justify banning the measles, mumps, and rubella (MMR) vaccine, even though many believe it causes autism.¹⁸⁰ The science is too clear: Banning the vaccine would undermine public health. If public health is the goal, public health science matters to the normative justifications for the law.¹⁸¹

The limitations discussed thus far are internal to the framework and responsive to the paternalism critique. When one justification is present, and its limitations are met, a public health law answers the paternalism critique. But other important constraints are external to the framework and unrelated to the paternalism critique. For example, the magnitude of the harm to individuals warrants consideration. In its seminal public health law decision, *Jacobson v. Massachusetts*, the Supreme Court recognized the importance of the relationship between a public health law's impact on individuals and the magnitude of the harm the law sought to prevent.¹⁸² In upholding Massachusetts' mandatory smallpox vaccination law, the Court warned that public health laws "might be exercised in particular circumstances and in reference to particular persons in such an arbitrary, unreasonable manner, or might go so far beyond what was reasonably required for the safety of the public, as to authorize or compel the courts to interfere for the protection of such persons."¹⁸³

The Court's caution has led Lawrence Gostin to argue that public health laws are constitutional only when there is "public health necessity, reasonable means, proportionality, harm avoidance, and fairness."¹⁸⁴ Whether that remains the constitutional standard is debatable,¹⁸⁵ nevertheless, the test serves as a useful reminder that the

¹⁸⁰ See Sally Greenberg, *State of Confusion: One-Third of American Parents Continue to Link Vaccines and Autism*, HUFFPOST HEALTHY LIVING (Apr. 28, 2014, 11:53 AM), http://www.huffingtonpost.com/sally-greenberg/vaccines_b_5169266.html.

¹⁸¹ This is not to say that populations could not choose to ban the vaccine for other reasons, perhaps for religious reasons. But the ban could not be supported by a precautionary principle aimed at protecting public health when the evidence is overwhelming that the ban would harm public health.

¹⁸² *Jacobson v. Massachusetts*, 197 U.S. 11, 27–28 (1905).

¹⁸³ *Id.* at 28.

¹⁸⁴ GOSTIN, *supra* note 152, at 126.

¹⁸⁵ Gostin's approach does not perfectly track contemporary constitutional doctrine. For one thing, despite the growing influence of the paternalism critique, public health laws that do not implicate constitutionally protected interests routinely survive constitutional attack even in the absence of a showing of necessity.

degree of coerciveness and the nature of the harm matter, a principle captured by the Nuffield Council on Bioethics' proposal that public health laws be assessed according to a ladder of intervention.¹⁸⁶ As the council explained,

The least intrusive step is generally 'to do nothing', or at most monitor the situation. The most intrusive is to legislate in such a way as to restrict the liberties of individuals, the population as a whole, or specific industries. In general, the higher the rung on the ladder at which the policy maker intervenes, the stronger the justification has to be.¹⁸⁷

In other words, public health laws that simply provide individuals with information, or pose minor inconveniences, require lesser showings of harm, and less robust evidence, than more highly coercive laws such as quarantines.

In addition, the nature of the individual interest matters. By questioning the legitimacy of any limitation of self-regarding actions, the paternalism critique risks treating all restraints on individual action as the same. A law forbidding someone from traveling in a car without a seatbelt is treated the same as one that violates bodily integrity or denies freedom of speech. But in our constitutional tradition, some liberties are constitutionally protected fundamental rights. Others are not, and with good reason. If self-governance is to have any reign, populations must be able to enact laws to shape their environment and protect their health. To do so, we need to accept some infringements on individual liberty. On the other hand, the Constitution recognizes that certain liberties are of greater value, and can be limited only when there are compelling reasons.

This is certainly not the place to review which rights are fundamental, or which ought to be. For present purposes it is simply important to note that fundamental rights serve as another external

See, e.g., *Gallagher v. City of Clayton*, 699 F.3d 1013, 1019–20 (8th Cir. 2012) (upholding ban on outdoor smoking on public property using rational basis test because there was no fundamental right to smoke outdoors).

¹⁸⁶ NUFFIELD COUNCIL ON BIOETHICS, PUBLIC HEALTH: ETHICAL ISSUES vi (2007), <http://nuffieldbioethics.org/wp-content/uploads/2014/07/Public-health-ethical-issues.pdf>.

¹⁸⁷ *Id.* at xviii.

limit on public health laws, even when they are otherwise justified by the self-governance rationale. Indeed, precisely because constitutional rights are designed to be countermajoritarian, they are especially important in such cases. That the Constitution secures such rights should also serve to remind us that it presumes, in fact secures, a wide degree of latitude for acts of self-governance, an obvious point that the paternalism critique too often neglects.

III: THE RISE OF E-CIGARETTES

A. *The Market*

In large measure, the debates about the appropriateness of regulating cigarettes have been settled. During the past two decades tobacco control laws have proliferated at the federal, state, and local levels.¹⁸⁸ What remains contentious is whether a new approach, one emphasizing harm reduction¹⁸⁹ rather than abstinence, should be adopted.¹⁹⁰

Until recently, the debate over employing harm reduction strategies was largely hypothetical. Although the tobacco industry marketed filtered and “light” cigarettes as if they were safer than more traditional cigarettes, they were not.¹⁹¹ Nicotine gum and nicotine patches do offer less dangerous alternatives, but they are generally recommended for short-term use as individuals try to break the

¹⁸⁸ See *infra* text accompanying notes 266–94.

¹⁸⁹ For a definition of harm reduction, see *What Is Harm Reduction?*, HARM REDUCTION INT’L, <http://www.ihra.net/what-is-harm-reduction> (last visited Nov. 1, 2015) (defining harm reduction as “policies, programmes and practices that aim to reduce the harms associated with the use of psychoactive drugs in people unable or unwilling to stop.”).

¹⁹⁰ See, e.g., Martin et al., *supra* note 3, at 123; Stratton et al., *supra* note 3, at 189, 195.

¹⁹¹ See Lynn T. Kozlowski et al., *Smokers’ Misperceptions of Light and Ultra-light Cigarettes May Keep Them Smoking*, 15 AM. J. PREVENTIVE MED. 9, 9 (1998). This deception has likely added to the suspicions of many tobacco control advocates toward harm reduction.

habit.¹⁹² Moreover, they have only limited efficacy in real-life settings.¹⁹³

Supporters contend that e-cigarettes can alter the landscape dramatically.¹⁹⁴ Available in many shapes and varieties, e-cigarettes utilize a battery-operated heat source to vaporize liquid containing nicotine, water, flavorings, and other additives that users inhale.¹⁹⁵ Some early models had a light-up tip that glowed to resemble the light on a conventional cigarette.¹⁹⁶ More recent models look less like cigarettes and often have larger batteries and e-fluid reservoirs.¹⁹⁷ Some models also have variable voltage or wattage batteries that allow users to adjust the power to the atomizer.¹⁹⁸

¹⁹² Scientists have identified various health risks associated with long-term use of nicotine gum, see Björn Eliasson, Marja-Riitta Taskinen & Ulf Smith, *Long-term Use of Nicotine Gum is Associated with Hyperinsulinemia and Insulin Resistance*, 94 CIRCULATION 878, 878 (1996), and the patch, see Neal L. Benowitz & Steven G. Gourlay, *Cardiovascular Toxicity of Nicotine: Implications for Nicotine Replacement Therapy*, 29 J. AM. C. CARDIOLOGY 1422, 1422 (1997).

¹⁹³ See Ricardo Polosa & Neal L. Benowitz, *Treatment of Nicotine Addiction: Present Therapeutic Options and Pipeline Developments*, 32 TRENDS PHARMACOLOGICAL SCI. 281, 281 (2011).

¹⁹⁴ See Amy L. Fairchild & Ronald Bayer, *Public Health: Smoke and Fire Over E-Cigarettes*, 347 SCI. 375 (2015) (describing the “pitched battle” between scientists and health experts over e-cigarettes, and arguing that the intensity of the debate stems from the tensions between the precautionary principle and harm reduction). Another product that has been offered as providing the potential for a harm-reduction approach to tobacco is Snus, a tobacco pouch that its manufacturer claims has substantially lower risks than cigarettes or other tobacco products. See Sabrina Tavernise, *Swedish Company Asks F.D.A. to Remove Warnings From Smokeless Tobacco Product*, N.Y. TIMES (Apr. 8, 2015), http://www.nytimes.com/2015/04/09/health/swedish-company-asks-fda-to-remove-warnings-from-smokeless-tobacco-product.html?_r=0.

¹⁹⁵ See AM. INDUS. HYGIENE ASS’N, WHITE PAPER: ELECTRONIC CIGARETTES IN THE INDOOR ENVIRONMENT 4 (2014), https://www.aiha.org/government-affairs/Documents/Electronic%20Cig%20Document_Final.pdf; see also Daniel F. Hardin, *Blowing Electronic Smoke: Electronic Cigarettes, Regulation, and Protecting the Public Health*, 2011 U. ILL. J.L. TECH. & POL’Y 435, 439 (2011).

¹⁹⁶ Lorillard, Inc., Comment Letter on Proposed Rule to Deem Tobacco Products to Be Subject to the Federal Food, Drug, and Cosmetic Act 8 (Apr. 25, 2014), <http://www.regulations.gov/#!documentDetail;D=FDA-2014-N-0189-75711> [hereinafter Lorillard Comment Letter].

¹⁹⁷ *Id.* at 9.

¹⁹⁸ *Id.* at 8.

In contrast to conventional cigarettes, e-cigarettes deliver nicotine without exposing users to the byproducts of tobacco combustion. In addition, because they “replace most of the sensory, behavioural and social components associated with smoking,”¹⁹⁹ e-cigarettes may provide users with a safer way to experience the pleasures of smoking (or simply satisfy the craving for nicotine).²⁰⁰

According to the World Health Organization (“WHO”), “the use of ENDS [electronic nicotine delivery systems] is apparently booming,” with “use at least doubl[ing] among both adults and adolescents from 2008 to 2012.”²⁰¹ As of 2013, 47% of smokers in the U.S. had tried e-cigarettes and 4% were regular users.²⁰²

E-cigarettes are especially popular among teens; between 2011 and 2012 recent use of e-cigarettes among middle and high school students in the U.S. doubled.²⁰³ In 2013 alone, 250,000 young people who had never smoked a cigarette used an e-cigarette.²⁰⁴ By 2014, current use of e-cigarettes had eclipsed use of traditional cigarettes among high school and middle schools students in the United

¹⁹⁹ Saitta et al., *supra* note 7, at 50; *see also* Hardin, *supra* note 195, at 449 (explaining that “electronic cigarettes not only provide nicotine, but also simulate the physical act of smoking, which might provide a psychological ‘placebo’ effect which helps to increase the rate of cigarette abstinence”).

²⁰⁰ *See, e.g.*, Spring Vapor LLC, Comment Letter on Proposed Rule to Deem Tobacco Products to Be Subject to the Federal Food, Drug, and Cosmetic Act 8–9 (Aug. 8, 2014), <http://www.regulations.gov/#!documentDetail;D=FDA-2014-N-0189-82033>; Joe Nocera, *Is Vaping Worse than Smoking?*, N.Y. TIMES (Jan. 27, 2015), http://www.nytimes.com/2015/01/27/opinion/joe-nocera-is-vaping-worse-than-smoking.html?_r=0.

²⁰¹ WHO FRAMEWORK CONVENTION ON TOBACCO CONTROL, ELECTRONIC NICOTINE DELIVERY SYSTEMS 2 (July 21, 2014), http://apps.who.int/gb/fctc/PDF/cop6/FCTC_COP6_10-en.pdf?ua=1.

²⁰² *Id.* at 2–3.

²⁰³ Centers for Disease Control and Prevention, *Notes from the Field: Electronic Cigarette Use Among Middle and High School Students—United States, 2011–2012*, 62 MORBIDITY & MORTALITY WKLY. RPT. 729 (2013), <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6235a6.htm>.

²⁰⁴ Press Release, Centers for Disease Control and Prevention, More Than a Quarter-Million Youth Who had Never Smoked a Cigarette Used E-cigarettes in 2013 (Aug. 25, 2014), <http://www.cdc.gov/media/releases/2014/p0825-e-cigarettes.html> [hereinafter Press Release, Centers for Disease Control and Prevention].

States.²⁰⁵ Importantly, minors who used e-cigarettes were more likely to express the intention to start smoking cigarettes than non-smoking youth who had not used e-cigarettes.²⁰⁶

Many public health experts believe the common practice of adding sweet flavors to the liquid nicotine used in e-cigarettes enhances the products' popularity with young people.²⁰⁷ Researchers have also suggested that the popularity of e-cigarettes is "related to the fact that they can be used in smoke-free areas, to their competitive price, and to the perceived potential for harm reduction compared with traditional cigarettes."²⁰⁸ The wide marketing of e-cigarettes²⁰⁹ has also undoubtedly helped spread their popularity. Nancy Kaufman and Margaret Mahoney explain that the marketing for ENDS "pervades traditional and social media, using many tactics now banned for cigarettes such as free samples, billboard ads, event (e.g., auto racing, music festivals) or cause sponsorship, and television ads in prime time."²¹⁰ Whether the popularity of e-cigarettes will continue to grow is unclear. In 2014, sales of e-cigarettes fell after three years of heavy growth.²¹¹ Yet overall use of e-cigarettes tripled be-

²⁰⁵ Arrazola et al., *supra* note 1, at 384.

²⁰⁶ CENTERS FOR DISEASE CONTROL AND PREVENTION, *supra* note 203; Arrazola et al., *supra* note 1, at 383–84.

²⁰⁷ E.g., Kim Krisberg, *CDC: American Youth Now Use E-cigarettes More than any Other Tobacco Product*, SCI. BLOGS (Apr. 17, 2015), <http://scienceblogs.com/thepumphandle/2015/04/17/cdc-american-youth-now-use-e-cigarettes-more-than-any-other-tobacco-product/>. A study sponsored by a manufacturer, however, disputes this claim. See Lindsay Fox, *New Study: E-Cigarette Flavors Don't Appeal to Youth Non-Smokers*, ECIGARETTE REVIEWED (Jan. 10, 2015), <http://ecigaretterevuewed.com/E-cigarette-flavors-dont-appeal-to-teens>.

²⁰⁸ Saitta, Ferro & Polosa, *supra* note 7, at 51.

²⁰⁹ Jennifer C. Duke et al., *Exposure to Electronic Cigarette Television Advertisements Among Youth and Young Adults*, 134 PEDIATRICS 1, 1 (2014).

²¹⁰ Nancy Kaufman & Margaret Mahoney, *E-Cigarettes: Policy Options and Legal Issues Amidst Uncertainty*, 43 J.L. MED. & ETHICS SUPPLEMENTAL ISSUE 23 (2015).

²¹¹ WHO FRAMEWORK CONVENTION ON TOBACCO CONTROL, *supra* note 201, at 2.

tween 2013 and 2014 among high school and middle school students.²¹² Much of the growth in sales may be occurring via the Internet²¹³ or in vape shops, which specialize in e-cigarettes. According to the Smoke-Free Alternatives Trade Association (“SFATA”), the number of vape-shops more than tripled between 2013 and 2014.²¹⁴

In contrast to the market for cigarettes, which is highly concentrated among brands owned by big tobacco, the e-cigarette market has been relatively fragmented. According to the WHO, in 2014 there were an estimated 466 brands of e-cigarettes world-wide.²¹⁵ This diversity brings both strengths and dangers. Some smaller companies, for example, have attempted to position themselves as innovators for harm reduction.²¹⁶ On the other hand, the large number of small brands, many of which import their products from China, has raised alarms about the lack of standardization of ingredients and the potential for adulteration.²¹⁷

Recently, large tobacco companies have begun investing heavily in ENDS and have gained market share. In 2012, for example, Lorillard, Inc. acquired blu eCigs (“blu”) as a wholly owned subsidiary.²¹⁸ By 2014, blu had over 40% of the retail market in the U.S.²¹⁹ As of August 2014, Altria Group Inc. and Reynolds American Inc.

²¹² Arrazola et al., *supra* note 1, at 383.

²¹³ Alexandra Sifferlin, *It's Really Easy for Teens to buy E-Cigs Online*, TIME MAG. (Mar. 2, 2015), <http://time.com/3725939/teens-buy-ecigarettes-online/>.

²¹⁴ Mike Esterl, *Big Tobacco's E-Cigarette Push Gets a Reality Check*, WALL ST. J., (Aug. 26, 2014, 2:38 PM), <http://www.wsj.com/articles/big-tobaccos-e-cig-push-gets-a-reality-check-1409078319>.

²¹⁵ WHO FRAMEWORK CONVENTION ON TOBACCO CONTROL, *supra* note 201, at 2.

²¹⁶ iVape/JP Ventures LLC, Comment Letter on Proposed Rule to Deem Tobacco Products to Be Subject to the Federal Food, Drug, and Cosmetic Act (Aug. 8, 2014), <http://www.regulations.gov/#!documentDetail;D=FDA-2014-N-0189-81964>; American E-Liquid Manufacturing Standards Association, Comment Letter on Proposed Rule to Deem Tobacco Products to Be Subject to the Federal Food, Drug, and Cosmetic Act (Aug. 8, 2014), <http://www.regulations.gov/#!documentDetail;D=FDA-2014-N-0189-81964>.

²¹⁷ David Barboza, *China's E-Cigarette Boom Lacks Oversight for Safety*, N.Y. TIMES (Dec. 13, 2014), <http://www.nytimes.com/2014/12/14/business/international/chinas-e-cigarette-boom-lacks-oversight-for-safety-.html>.

²¹⁸ Lorillard Comment Letter, *supra* note 196, at 9.

²¹⁹ *Id.*

had captured about 25% of convenience store sales.²²⁰ Ironically, the increasing presence of big tobacco in the market may reduce the dangers of adulteration, as large companies may be better able to control ingredients.²²¹ Large tobacco companies are also at the vanguard of putting warning labels on their products,²²² and they have supported significant regulation by the FDA.²²³ Of course, such regulations may disproportionately affect smaller companies lacking the resources to navigate a complex regulatory process. If so, regulation may benefit the very companies that have the greatest interest in ensuring that e-cigarette use does not threaten the market for traditional cigarettes.

B. *The Health Risks and Benefits of E-Cigarettes*

Reviewing the risks and benefits of e-cigarettes involves a calculus far more complex than a mere assessment of whether vaping a single e-cigarette is more or less dangerous to the user than smoking a single cigarette. Ultimately, a public health analysis must also weigh the impact of vaping on an individual's likelihood of smoking traditional cigarettes. In addition, the analysis must consider whether the spread of vaping within a population is more or less likely to increase rates of smoking and exposure to nicotine within that population. In other words, the critical public health question is how the growth of e-cigarettes affects the overall incidence of morbidity and mortality within populations.

Given the short time e-cigarettes have been on the market, it is not surprising that more research is needed before the public health risks are fully known. Although there are over 1,000 studies published in the literature, the findings are inconsistent.²²⁴ Moreover, many studies suffer from serious methodological flaws or are compromised by conflicts of interest. As the WHO noted in 2014,

²²⁰ Esterl, *supra* note 214.

²²¹ Barboza, *supra* note 217.

²²² Matt Richtel, *Bluntly Dire Warnings from Big Tobacco on Electronic Cigarettes*, N.Y. TIMES (Sept. 28, 2014), <http://www.nytimes.com/2014/09/29/business/dire-warnings-by-big-tobacco-on-e-smoking-.html>.

²²³ Lorillard Comment Letter, *supra*, note 196, at 18.

²²⁴ Charlotta Pisinger & Martin Døssing, *A Systematic Review of Health Effects of Electronic Cigarettes*, 69 PREVENTIVE MED. 248, 248 (2014) (reviewing 76 published studies). The science regarding e-cigarettes is rapidly developing. The discussion here is based on the literature as of October 2015.

“[m]ost ENDS products have not been tested by independent scientists”²²⁵

A few points, however, seem relatively clear.²²⁶ The first is that e-cigarettes are “likely to be much less harmful than tobacco smoking.”²²⁷ As a review of the scientific literature by the American Industrial Hygiene Association explained, “[m]any of the toxic and carcinogenic agents in tobacco cigarette smoke are combustion by-products, including nitrosamines, VOCs, polycyclic aromatic hydrocarbons (“PAHs”), and carbon monoxide. Because e-cigarettes do not have a combustion source, the health risks of vaping are believed to be greatly reduced compared with traditional cigarette smoking.”²²⁸ The lack of combustion also means that e-cigarettes pose a far smaller fire risk than traditional cigarettes.²²⁹

Being safer than cigarettes is not the same as posing no risk. Although nicotine, the primary ingredient of most e-cigarette liquids, is not considered a carcinogen,²³⁰ WHO warns that it “can have adverse effects during pregnancy and may contribute to cardiovascular

²²⁵ WHO FRAMEWORK CONVENTION ON TOBACCO CONTROL, *supra* note 201, at 3.

²²⁶ For a summary of some what is known about e-cigarettes, see Eric N. Lindblom, *Effectively Regulating E-Cigarettes and Their Advertising—and the First Amendment*, 70 FOOD & DRUG L.J. 57, 60–63 (2015).

²²⁷ AM. INDUS. HYGIENE ASS’N, *supra* note 195, at 3; Peter Hajek et al., *Electronic Cigarettes: Review of Use, Content, Safety, Effects on Smokers and Potential for Harm and Benefit*, 109 ADDICTION 1801, 1806 (2014) (“[L]ong-term use of EC [electronic cigarettes], compared to smoking, is likely to be much less, if at all, harmful to users or bystanders.”).

²²⁸ AM. INDUS. HYGIENE ASS’N, *supra* note 195, at 5. *See also* Saitta, Ferra & Polosa, *supra* note 7, at 53.

²²⁹ *See* U.S. FIRE ADMIN., HOME FIRE SAFETY TIPS FOR SMOKERS, http://www.usfa.fema.gov/downloads/fief/up_in_smoke_smokers_brochure.pdf (noting that smoking is the top cause of home fire deaths); U.S. FIRE ADMIN., ELECTRONIC CIGARETTE FIRES AND EXPLOSIONS (Oct. 2014), http://www.usfa.fema.gov/downloads/pdf/publications/electronic_cigarettes.pdf [hereinafter U.S. FIRE ADMIN., ELECTRONIC CIGARETTE FIRES].

²³⁰ Konstantinos E. Farsalinos & Riccardo Polosa, *Safety Evaluation and Risk Assessment of Electronic Cigarettes as Tobacco Cigarette Substitutes: A Systematic Review*, 5 THERAPEUTIC ADVANCES IN DRUG SAFETY 67, 69 (2014).

disease.”²³¹ It may also function as a teratogen and can promote cancer growth.²³² CDC notes that “[n]icotine exposure during adolescence, a critical window for brain development, might have lasting adverse consequences for brain development, causes addiction, and might lead to sustained tobacco use.”²³³ In addition, nicotine may be toxic when ingested or exposed to the skin; according to the CDC, “the number of calls to poison centers involving e-cigarette[s] . . . rose from one per month in September 2010 to 215 per month in February 2014”²³⁴ “More than half . . . of the calls” involved children under the age of five.²³⁵ Although the December 2014 death of a one-year-old who ingested liquid nicotine received considerable publicity,²³⁶ a review of data from the California Poison Control System suggests that most of the adverse effects from accidental exposure were short-term and minor.²³⁷

Health experts also express concern over the possible health effects of toxic chemicals in e-cigarette vapor.²³⁸ For example, a study reported in a 2015 letter to the editor of the *New England Journal of Medicine* found that when high voltages are used, “long-term vaping is associated with an incremental lifetime cancer risk . . . 5 times as high . . . or even 15 times as high . . . as the risk associated with

²³¹ WHO FRAMEWORK CONVENTION ON TOBACCO CONTROL, *supra* note 201, at 3. Hajek et al. dispute the claim that nicotine is harmful, except during pregnancy. Hajek, *supra* note 227, at 1802.

²³² WHO FRAMEWORK CONVENTION ON TOBACCO CONTROL, *supra* note 201, at 3.

²³³ Arrazola et al., *supra* note 1, at 381 (citations omitted).

²³⁴ Press Release, Centers for Disease Control and Prevention, New CDC Study Finds Dramatic Increase in E-cigarette-Related Calls to Poison Centers (Apr. 3, 2014), <http://www.cdc.gov/media/releases/2014/p0403-e-cigarette-poison.html>.

²³⁵ *Id.*

²³⁶ See Gillian Mohny, *First Child's Death From Liquid Nicotine Reported as 'Vaping' Gains Popularity*, ABC NEWS (Dec. 12, 2014, 5:40 PM), <http://abcnews.go.com/Health/childs-death-liquid-nicotine-reported-vaping-gains-popularity/story?id=27563788>.

²³⁷ Farsalinos & Polosa, *supra* note 230, at 80.

²³⁸ AM. INDUS. HYGIENE ASS'N., *supra* note 195, at 5.

long-term smoking.”²³⁹ However, the higher exposure rate to formaldehyde was not found when typical voltage rates were used.²⁴⁰

The vapors formed by e-cigarettes contain other chemicals, including propylene glycol, a chemical contained in theatrical smoke,²⁴¹ exposure to which may be associated with asthma, decreased lung function, and airway obstruction.²⁴² E-cigarettes also contain glycerol, which is generally nontoxic but when heated can produce the toxin acrolein, which also is produced by smoking cigarettes.²⁴³ In addition, some studies have found higher concentrations of some heavy metals in the aerosols of e-cigarettes than in the smoke of conventional cigarettes.²⁴⁴ Other studies, however, have reached the opposite conclusion.²⁴⁵ One review of 34 studies found significant variability in findings as to levels of many toxins,²⁴⁶ perhaps because of the “chaotic” e-liquid manufacturing industry.²⁴⁷ In contrast, a review of over 100 studies by Farsalinos and Polosa (the latter of whom has received funding from e-cigarette manufacturers) concluded that e-cigarettes have fewer toxic chemicals and pose fewer clinical risks to users and bystanders than conventional cigarettes, although the authors caution that longer-term clinical studies need to be done.²⁴⁸

There is also a risk of fire caused by the lithium batteries that heat the liquid nicotine. The U.S. Fire Administration reports at least 25 cases in which e-cigarettes have exploded since 2009.²⁴⁹ After

²³⁹ R. Paul Jensen et. al., *Hidden Formaldehyde in E-Cigarette Aerosols*, 372 *NEW ENG. J. MED.* 392, 392 (2015).

²⁴⁰ *Id.* This study has been harshly criticized. See, e.g., Farsalinos, *Verified: Formaldehyde Levels Found in the NEJM Study Were Associated with Dry Puff Conditions. An Update*, *ECIGARETTE RESEARCH* (Jan. 22, 2015, 1:51 PM), <http://www.ecigarette-research.com/web/index.php/2013-04-07-09-50-07/2015/192-form-ver>.

²⁴¹ *AM. INDUS. HYGIENE ASS'N.*, *supra* note 195, at 8.

²⁴² *Id.* at 9; see also Hajek, *supra* note 227, at 1803.

²⁴³ Hajek, *supra* note at 227, at 1803.

²⁴⁴ *AM. INDUS. HYGIENE ASS'N.*, *supra* note 195, at 12.

²⁴⁵ *Id.*

²⁴⁶ Pisinger & Døssing, *supra* note 224, at 250–53.

²⁴⁷ Barboza, *supra* note 217.

²⁴⁸ Farsalinos & Polosa, *supra* note 230, at 79.

²⁴⁹ U.S. FIRE ADMIN., *ELECTRONIC CIGARETTE FIRES*, *supra* note 229, at 3.

several incidents in which e-cigarettes started fires in airplane luggage compartments, the Federal Aviation Administration warned airlines not to store e-cigarettes in checked baggage.²⁵⁰

From public health's population perspective, the key question relates to the impact of e-cigarettes on smoking rates. If e-cigarettes can reduce the overall number of regular smokers, they probably will function as a form of harm reduction, albeit one with its own risks. Conversely, if they lead to increases in rates of smoking or stall reductions in smoking rates, they will likely cause greater mortality and morbidity in the overall population, even if individuals who vape are exposed to less risk than they would face if they smoked.

For the moment, the impact of e-cigarettes on smoking rates is also inconclusive. Several studies have suggested that e-cigarettes may help some individuals kick the habit.²⁵¹ Others suggest e-cigarettes are no more effective in supporting smoking cessation than alternative approaches, such as the nicotine patch.²⁵² After reviewing the literature, Nancy Kaufman and Margaret Mahoney surmise that although some individuals will use e-cigarettes to stop smoking, many will use them to reduce their cigarette consumption, engaging in so-called "dual use."²⁵³ This can provide smokers with the false assurance that their reduced habit is safe, dissuading them from trying to stop smoking. Likewise, by enabling smokers to get their nicotine fix in smoking-prohibited locations, like the workplace, e-cigarettes may reduce the impetus to stop smoking.

Researchers and public health experts are especially concerned about the use of e-cigarettes by minors who have never smoked. Data reported by the CDC show that in 2013 over 250,000 middle and high school students in the U.S. who had never smoked used e-

²⁵⁰ Alan Levin, *FAA Warns E-Cigarettes a Fire Danger in Checked Airline Bags*, BLOOMBERG BUSINESS (Jan. 23, 2015, 3:05 PM), <http://www.bloomberg.com/news/articles/2015-01-23/faa-sends-notice-to-airlines-about-fire-risk-of-e-cigarettes>.

²⁵¹ Pisinger & Døssing, *supra* note 224, at 256.

²⁵² *Id.* (discussing studies showing that e-cigarette use is less effective than the nicotine patch in helping with smoking cessation); Kaufman & Mahoney, *supra* note 210, at 23–24; Hajek et al., *supra* note 227, at 1805 (e-cigarettes can be more effective than other approaches to smoking cessation).

²⁵³ Kaufman & Mahoney, *supra* note 210, at 24.

cigarettes.²⁵⁴ Health experts fear that many of these young people will become addicted to nicotine and end up smoking. A recent study of high school students in Los Angeles seems to affirm that fear. It showed that students who used e-cigarettes were more likely than others to begin smoking within six months or a year.²⁵⁵ Nevertheless, cigarette smoking among youth has declined as e-cigarette use has increased.²⁵⁶ It thus remains unclear whether e-cigarettes will lead to more or less smoking among youth.

The science is also not settled as to the long-term impact of e-cigarettes on norms and attitudes regarding smoking or on the effectiveness of laws regulating e-cigarettes. As discussed below, one of the key strategies of tobacco control efforts over the past 50 years has been to denormalize smoking. This strategy relies on the insight that individuals do not make decisions about whether or not to smoke cigarettes in isolation. Rather, individual decisions are influenced by social patterns and norms.²⁵⁷ Thus, in a world in which smoking is perceived as ubiquitous and glamorous, individuals will often be inclined to smoke if only to “fit in.” In contrast, if smoking is less common and associated with less socially “desirable” people, individuals are less likely to take up the habit.²⁵⁸ As a result, numerous tobacco control strategies seek to “denormalize” tobacco use.²⁵⁹ For example, indoor smoking laws not only reduce exposure to secondhand smoke, they also stigmatize smokers who are forced to separate themselves from others to go outside to smoke.²⁶⁰ Likewise, public service campaigns “emphasize the cosmetic effects of

²⁵⁴ Press Release, Center for Disease Control and Prevention, *supra* note 204.

²⁵⁵ Adam M. Leventhal et al., *Association of Electronic Cigarette Use with Initiation of Combustible Tobacco Product Smoking in Early Adolescence*, 314 JAMA 700, 703 (2015).

²⁵⁶ Arrazola et al., *supra* note 1, at 381.

²⁵⁷ WORLD HEALTH ORGANIZATION, *Tobacco Free Initiative (TFI): Tobacco and Youth*, <http://www.who.int/tobacco/control/populations/youth/en/> (last visited Nov. 4, 2015).

²⁵⁸ Kirsten Bell et al., ‘Every Space is Claimed’: *Smokers’ Experiences of Tobacco Denormalisation*, 32 SOC. HEALTH & ILLNESS 914, 915 (2010).

²⁵⁹ Lindsay F. Wiley, *Shame, Blame, and the Emerging Law of Obesity Control*, 47 U.C. DAVIS L. REV. 121, 132 (2013).

²⁶⁰ These laws were initially presented as ways of protecting bystanders from secondhand smoke. See Hardin, *supra* note 195, at 452. However, they have had the effect of stigmatizing tobacco use. See Bayer & Stuber, *supra* note 107, at 47; Deborah Ritchie et al., “*But It Just Has that Sort of Feel About It, A Leper*”—

smoking (yellow teeth, bad breath, smelly clothes and hair, even impotence) or the idea that smoking will lead to rejection by potential romantic partners.”²⁶¹

Public health experts worry—with some reason—that e-cigarettes may serve to renormalize smoking. For example, after decades without cigarette advertising on television, advertisements for e-cigarettes are now appearing with regularity,²⁶² creating the possibility that the advertising industry will be able to (re)create positive images for the act of inhaling tobacco products. Likewise, in jurisdictions in which indoor smoking laws do not apply to e-cigarettes,²⁶³ the appearance of someone inhaling a product that looks a lot like a cigarette is again occurring with some frequency. As it does, inhaling may become a more common and less stigmatized behavior, which may lead more people to feel that it is socially acceptable to smoke conventional cigarettes.

For the moment, however, it is impossible to say whether the above scenarios will occur. Nor do we know the net impact of the various changes that vaping may entail. It is possible that attitudes toward smoking will soften, but that on balance fewer people will smoke cigarettes than will convert to e-cigarettes. If so, we should see a net public health benefit. Alternatively, it’s also quite plausible that more people will become addicted to nicotine than would have in the absence of e-cigarettes and that with the erosion of social norms against smoking, rates of cigarette smoking will eventually climb. And we still don’t know how the technology will evolve. Innovations that increase safety may emerge. Alternatively, new products may provide a more pleasurable and more addictive experience, leading to more nicotine addiction and eventually more smoking. In short, regulators don’t know whether regulatory hurdles will protect or harm public health.

Lack of certainty, however, cannot be the end of the regulatory story. Clearly, the more we know about the health impacts of e-cigarettes, both upon individuals and populations, the more secure we can be in our regulatory decisions. But sitting back and waiting for

Stigma, Smoke-Free Legislation and Public Health, 12 NICOTINE & TOBACCO RES. 622, 622 (2010).

²⁶¹ Wiley, *supra* note 259, at 133.

²⁶² Duke et al., *supra* note 209, at 1.

²⁶³ For a discussion, see *infra* text accompanying note 295.

more information has its own consequences. As we wait for the evidence, the market will continue to develop and mature, and more consumers may become addicted to e-cigarettes or accustomed to seeing vaping in public. Given this possibility, the question of how and whether to regulate while research continues is challenging for public health regulators and theorists.

C. *The Tobacco Control Legal Environment*

The tobacco control laws that have been implemented in the past 50 years illustrate the myriad tools available to regulators regarding e-cigarettes.²⁶⁴ In 1965, a year after Surgeon General Luther Terry issued the first surgeon general's report warning about the health risks of cigarette smoking, Congress passed the Cigarette Labeling and Advertising Act,²⁶⁵ which required warning labels on cigarette packages, while preempting state regulation of cigarette marketing.²⁶⁶ In 1971, the warning labels were strengthened, and Congress banned cigarette advertising on television.²⁶⁷ In 1986, the federal regulatory regime, along with preemption, was extended to smokeless tobacco.²⁶⁸

By the 1990s, evidence of the deleterious effects of secondhand smoke, as well as deliberate efforts by tobacco companies to mislead the public about the dangers of smoking, prompted new regulatory efforts.²⁶⁹ In 1996 the FDA issued broad regulations relating to youth access, marketing, and labeling.²⁷⁰ These regulations were

²⁶⁴ For an overview of cigarette regulation in the U.S., *see generally* Herington, *supra* note 113.

²⁶⁵ Nat'l Comm'n Marihuana & Drug Abuse, *History of Tobacco Regulation*, SCHAFER LIBR.DRUG POL'Y, <http://druglibrary.org/schaffer/library/studies/nc/nc2b.htm> (last visited July 22, 2015); Federal Cigarette Labeling and Advertising Act, 15 U.S.C. §§ 1331–39 (1965 & Supp. I 1966).

²⁶⁶ *Id.* at §§ 1333–34; *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 514 (1992).

²⁶⁷ Public Health Cigarette Smoking Act of 1969, 15 U.S.C. §§ 1333, 1335 (1970).

²⁶⁸ Comprehensive Smokeless Tobacco Health Education Act of 1986, 15 U.S.C. §§ 4401–4408 (1986).

²⁶⁹ These efforts were also spurred in part by a new wave of tort litigation, which uncovered damaging tobacco company documents and moved tobacco companies to be less resistant to regulation. For a discussion, *see* BRANDT, *supra* note 82, at 401–45.

²⁷⁰ 21 C.F.R. § 1140 (2010).

struck down in *Brown & Williamson*, when the Supreme Court concluded that the FDA lacked authority to regulate tobacco under the Food, Drug, and Cosmetic Act (“FDCA”).²⁷¹

In the absence of broad federal regulations, state and local governments adopted a wide range of regulatory interventions.²⁷² In 1990, for example, San Luis Obispo, California, became the first city to enact a comprehensive ban on indoor smoking.²⁷³ As of 2014, 27 states and the District of Columbia had some form of statewide indoor smoking ban,²⁷⁴ and by January 2016, 26 states and territories and 802 localities banned indoor smoking in all non-hospitality workplaces, restaurants, and bars.²⁷⁵ States and cities also led the way with banning cigarette sales to minors,²⁷⁶ prohibiting advertisements on billboards,²⁷⁷ and banning the addition of flavors in cigarettes and cigars.²⁷⁸ State and local governments have taxed cigarettes to increase the cost of smoking (and raise revenue), a strategy especially relevant to youth smoking rates, as young smokers tend

²⁷¹ 529 U.S. 120, 161 (1999).

²⁷² For a discussion of the development and diffusion of local tobacco regulations, see Diller, *supra* note 161, at 1224–31.

²⁷³ *Id.* at 1229.

²⁷⁴ Claire Zillman, *Wait, You Can Still Smoke in an American Office?* FORTUNE (Oct. 23, 2014, 2:05 PM), <http://fortune.com/2014/10/23/smoking-office/>.

²⁷⁵ AMERICAN NONSMOKERS’ RIGHTS FOUNDATION, U.S. 100% SMOKEFREE LAWS IN NON-HOSPITALITY WORKPLACES AND RESTAURANTS AND BARS (Oct. 2, 2015), <http://no-smoke.org/pdf/WRBLawsMap.pdf>.

²⁷⁶ *See e.g.*, Diller, *supra* note 161, at 1231 (“In addition to outdoor advertising restrictions and second-hand smoke regulations, cities have led in adopting a number of . . . tobacco control mechanisms, often focusing on preventing youth access to tobacco, whether directly or indirectly”); Nat’l Comm’n Marihuana & Drug Abuse, *supra* note 265 (“All 50 states [h]ad laws banning sales to minors by 1950.”). Federal law now prohibits the sale of cigarettes to minors. 21 C.F.R. § 1140.14 (2015).

²⁷⁷ Diller, *supra*, note 161, at 1226. In *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525, 551 (2001), the Supreme Court held that such laws were preempted by the Federal Cigarette Labeling and Advertising Act.

²⁷⁸ Diller, *supra* note 161, at 1234.

to be more price-sensitive than adults.²⁷⁹ Together these various regulatory tools are widely credited with helping lower rates of cigarette smoking.²⁸⁰

Litigation has also helped change the environment in which cigarettes are sold and consumed. In the 1990s, several states sued large tobacco companies seeking to recover the health care costs they faced as a result of smoking-related illness.²⁸¹ This litigation was settled by the 1998 Multi-State Master Settlement Agreement, which imposed significant changes in the marketing and advertising of cigarettes and required tobacco companies to pay billions of dollars to the states, the cost of which helped raise the price of cigarettes.²⁸² Shortly thereafter, the federal government sued the tobacco companies under the Racketeer Influenced and Corrupt Organizations Act (“RICO”).²⁸³ A 2014 consent decree in that case required tobacco companies to admit in advertising that they had lied about the effects of smoking.²⁸⁴

In 2009, Congress gave the FDA broad authority over tobacco products with the TCA, which created a new center for tobacco products within the FDA, prohibited the sale of cigarettes and smokeless tobacco to minors, and granted the FDA authority over product marketing and advertising, warning labels, and product ingredients.²⁸⁵ The Act also requires the registration of all entities that own or operate any establishment engaged in the manufacture or processing of tobacco products.²⁸⁶ In addition, the TCA requires

²⁷⁹ Robert L. Rabin, *Reexamining the Pathways to Reduction in Tobacco-Related Disease*, 15 THEORETICAL INQUIRIES L. 507, 513–14 (2014).

²⁸⁰ *Id.*

²⁸¹ For a fuller discussion, see BRANDT, *supra* note 82, at 319–55.

²⁸² See Herington, *supra* note 113, at 14.

²⁸³ See 18 U.S.C. §§ 1962(c)–(d)(2012); Robert J. Baehr, *A New Wave of Paternalistic Tobacco Regulation*, 95 IOWA L. REV. 1663, 1673 n.54 (2010).

²⁸⁴ Consent Order Implementing the Corrective Statements Remedy Under Order #1015 and Order #34-Remand at 2, Tobacco-Free Kids Action Fund v. Philip Morris USA Inc., 49 F. Supp. 2d 1 (D.D.C. 2006), http://www.tobaccofreekids.org/content/what_we_do/industry_watch/doj/corrective_statements/2014_06_03_consent_order.pdf.

²⁸⁵ See Family Smoking Prevention and Tobacco Control and Federal Retirement Reform, Pub. L. No. 111-31, 123 Stat. 1776 (2009); see also 21 U.S.C. § 387 (2012); Herington, *supra* note 113, at 14–15.

²⁸⁶ Family Smoking Prevention and Tobacco Control and Federal Retirement Reform, Pub. L. No. 11-31, 123 Stat. 1776, § 905 (2009).

premarket review of *any* new tobacco product, unless the Secretary determines that the product is substantially equivalent to one on the market as of February 2007, the “predicate date.”²⁸⁷ An application for premarket review must contain all information that is published, known, or should be known concerning the health risks associated with the product, the listing of all ingredients, and samples of the product and its proposed labeling.²⁸⁸ The Secretary may deny an application upon finding that the applicant has not shown that the marketing of the product is appropriate for the protection of public health, the making and handling of the product do not conform to good manufacturing practices, or the labeling is false or misleading.²⁸⁹

The Act also regulates the sale and marketing of a modified risk product, which is defined as “any tobacco product that is sold or distributed for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products.”²⁹⁰ In addition, the Act prohibits manufacturers from making health claims not independently verified.²⁹¹

The TCA also made important modifications to the division of authority between the federal government and the states with respect to cigarette regulations.²⁹² Under the TCA, states may not impose any regulations relating to premarket review, misbranding and labeling, good manufacturing standards, modified risk products, and adulteration.²⁹³ States, however, can enact laws “relating to the sale, distribution, possession, information reporting to the State, exposure to, access to, the advertising and promotion of, or use of, tobacco products by individuals of any age, or relating to fire safety standards”²⁹⁴

²⁸⁷ 21 U.S.C. § 387j(e) (2012).

²⁸⁸ 21 U.S.C. § 387j(b)(1).

²⁸⁹ 21 U.S.C. § 387j(c)(2).

²⁹⁰ 21 U.S.C. § 387k(b)(1).

²⁹¹ 21 U.S.C. § 387k(g).

²⁹² The Supreme Court had previously outlined the scope of federal preemption over cigarettes in cases such as *Altria Group, Inc. v. Good*, 555 U.S. 70 (2008), *Lorillard v. Reilly*, 533 U.S. 525 (2001), and *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992).

²⁹³ 21 U.S.C. § 387p(a)(2) (2012).

²⁹⁴ *Id.*

D. Regulatory Options

Once e-cigarettes entered the market, policymakers were forced to consider how they fit into the existing regulatory framework. For states and local governments, a key question is whether existing indoor air laws apply to e-cigarettes. Given the language of such laws, the answer is often “no.” For example, the Attorney General of Kansas concluded that his state’s indoor smoking law did not apply to e-cigarettes because it defined smoking as the “possession of a lighted cigarette, cigar, pipe or burning tobacco in any other form or device designed for the use of tobacco.”²⁹⁵

In recent years, however, several states and many localities have enacted measures to apply their indoor smoking bans to e-cigarettes. As of January 2016, eight states banned vaping in smoke-free venues and sixteen restricted it in some venues.²⁹⁶ Moreover, 475 cities and counties have banned vaping in smoke-free venues, and 310 restricted vaping in other venues.²⁹⁷ As of March 2015, forty-one states banned the sale of e-cigarettes to minors.²⁹⁸ However, five states preempted local regulations.²⁹⁹

States have also had to consider whether to tax e-cigarettes. Because e-cigarettes do not generally fall within the definition of state tobacco taxes, states risk losing tax revenue as e-cigarettes displace

²⁹⁵ Hardin, *supra* note 195, at 453 (quoting Kansas Indoor Clean Air Act, KAN. STAT. ANN. § 21-4009(o) (West 2010)).

²⁹⁶ AM. NONSMOKERS’ RIGHTS FOUND., STATES AND MUNICIPALITIES WITH LAWS REGULATING USE OF ELECTRONIC CIGARETTES (Jan. 1, 2016), <http://www.no-smoke.org/pdf/ecigslaws.pdf>.

²⁹⁷ *Id.* As of January 2015, only one reported case had challenged such laws. In *In re Kuhn v. County of Suffolk*, No. 48869, 2010 Misc. LEXIS 5224 at *1–2 (N.Y. Sup. Ct. Oct. 15, 2010), the court rejected a challenge to a county ordinance banning the use of e-cigarettes in public places.

²⁹⁸ Silvia Fernandez, *Study Reveals E-Cigarette Industry Still Needs Deeper Regulation*, PIONEER NEWS (Mar. 1, 2015), <http://www.piercepioneer.com/study-reveals-e-cigarette-industry-still-needs-deeper-regulation/38456>. New York City has gone further and has banned the sale of e-cigarettes to anyone under the age of 21. *Bloomberg Signs NYC Ban of Tobacco Sales to Anyone Under 21*, CBS NEW YORK (Nov. 19, 2013, 3:00 PM), <http://newyork.cbslocal.com/2013/11/19/bloomberg-to-sign-nyc-ban-of-tobacco-sales-to-anyone-under-21/>.

²⁹⁹ *E.g.*, LA. REV. STAT. ANN. § 14:91.8 (2014); NEV. REV. STAT. § 202.249(4)-(5) (2013); S.C. CODE ANN. § 16-17-504 (2013); IOWA CODE § 453A.56 (2014); OKLA. STAT. ANN. tit. 63, § 1-1527 (2014); *see also* OKLA. STAT. ANN. tit. 37 § 600.10 (2014) (youth access).

cigarette sales.³⁰⁰ To address this, in 2012 Minnesota became the first state to enact a specific tax, at a rate of 95%, for e-cigarettes.³⁰¹ Since then, other governors have called for taxing e-cigarettes, but as of January 2015, no other states have done so.³⁰²

At the federal level, the key question has been whether or not the FDA can or should exert regulatory authority over e-cigarettes. In April 2009, the FDA ordered that a shipment of e-cigarettes imported by NJOY be denied entry into the U.S. on the grounds that they were “adulterated, misbranded or unapproved drug-device combinations under the FDCA.”³⁰³ That same month, another importer, Smoking Everywhere, Inc., asked a federal court to enjoin the FDA from regulating e-cigarettes.³⁰⁴ NJOY joined as an intervenor and filed its own request for a preliminary injunction, which the district court granted, and which the United States Court of Appeals for the District of Columbia affirmed largely on the authority of *Brown & Williamson*.³⁰⁵ According to the court, *Brown & Williamson* made clear that the FDCA provided the FDA with no regulatory authority over tobacco products except when they are marketed for therapeutic purposes.³⁰⁶ That conclusion, the court asserted, was bolstered by the subsequent passage of the TCA, which sought to fill the regulatory gap.³⁰⁷

³⁰⁰ Elaine S. Povich, *States Trying to Tax E-Cigarettes*, GOVERNING (Jan. 23, 2015), <http://www.governing.com/topics/health-human-services/states-trying-to-tax-e-cigarettes.html>. Of course the states also lose revenue when cigarette sales decline through successful public health campaigns. As many have noted, tobacco taxes create a perverse incentive by which states become dependent on continued smoking. Andrew J. Haile, *Sin Taxes: When the State Becomes the Sinner*, 82 TEMP. L. REV. 1041, 1044 (2009).

³⁰¹ Jake Grovum, *States Target E-Cigarettes as Potential Revenue Source*, USA TODAY (Dec. 9, 2013, 11:45 AM), <http://www.usatoday.com/story/news/nation/2013/12/09/stateline-e-cigarette-revenue/3918913/>.

³⁰² *Id.*; *Washington Governor Proposes 95 Percent Tax on Vapor Products, E-cigarettes*, KFOR-TV (Dec. 19, 2014, 11:08 AM), <http://kfor.com/2014/12/19/washington-governor-proposes-95-percent-tax-on-vapor-products-e-cigarettes/>.

³⁰³ *Sottera, Inc. v. FDA*, 627 F.3d 891, 893 (2010).

³⁰⁴ *Id.*

³⁰⁵ *See id.* at 898–99.

³⁰⁶ *Id.* at 894.

³⁰⁷ *Id.* (citing 21 U.S.C. § 387a(c)(1) (2009)).

Under the TCA, a “tobacco product” includes “any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product).”³⁰⁸ Because the nicotine used in e-cigarette cartridges derives from tobacco, e-cigarettes clearly fall within that definition. However, the Act gives FDA regulatory authority over only “cigarettes, cigarette tobacco, roll-your-own tobacco, [] smokeless tobacco and . . . any other tobacco products that the Secretary by regulation deems to be subject to this subchapter.”³⁰⁹ Hence the FDA’s jurisdiction over “any other tobacco products,” including e-cigarettes, depends upon the agency *deeming* the products to be subject to the Act.

Despite calls by the tobacco control community to act quickly, the FDA took no action until April 2014 when it issued the NPRM proposing to deem all tobacco products, with the possible exception of premium cigars and accessories, to be subject to the TCA.³¹⁰ In the NPRM, the FDA explained that the regulations would allow it to take enforcement actions against e-cigarettes that were misbranded or adulterated.³¹¹ In addition, the provisions of the TCA applicable to all tobacco products would apply to e-cigarettes, meaning that e-cigarette manufacturers would have to submit a list of their ingredients to the FDA, would be subject to the TCA’s regulations regarding modified risk descriptors, would be barred from distributing free samples, and would have to submit their products for pre-market review.³¹² In other words, the regulatory regime applicable to cigarettes would largely apply to e-cigarettes.

In the NPRM, the FDA also proposed several additional regulations, including setting 18 as the minimum age for purchase, requir-

³⁰⁸ 21 U.S.C. § 321(rr)(1) (2012).

³⁰⁹ Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 387a (2012).

³¹⁰ Deeming Tobacco Products to be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Regulations on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products, 79 Fed. Reg. 23142 (proposed Apr. 25, 2014) (to be codified at 21 CFR pts. 1100, 1140, 1143).

³¹¹ *Id.* at 23143.

³¹² *Id.* at 23148.

ing health warnings as to addictiveness, and barring vending machine sales except in adults-only facilities.³¹³ It also sought public comments as to whether it should ban the addition of flavorings to the nicotine liquids used in e-cigarettes.³¹⁴ The agency added that it lacked “sufficient data . . . to determine what effects e-cigarettes have on the public health,” and that it sought comments on how such products should be regulated.³¹⁵

Many tobacco control and public health advocates have either supported the proposed regulations or sought even stronger actions.³¹⁶ Some e-cigarette trade associations and manufacturers also supported many of the regulatory steps proposed by the FDA, including barring sales to youth, authorizing the FDA to act against misbranded or adulterated products, and requiring companies to list product ingredients.³¹⁷ Other industry commentators, however, raised concerns about some other aspects of the proposed regulations, especially the imposition of premarket review, which the FDA specifically noted would come into effect if e-cigarettes were deemed to be tobacco products.³¹⁸ Recall that under the TCA, new tobacco products that cannot establish “substantial equivalence” to a product on the market in 2007 (the predicate date) need to go through a full premarket review.³¹⁹ Because e-cigarettes are so new, both the FDA and industry groups concede that it might be impossible to demonstrate substantial equivalence to a product on the market on the predicate date of 2007 for most, if not all, products now sold.³²⁰

³¹³ *Id.* at 23143–44.

³¹⁴ *Id.* at 23144.

³¹⁵ *Id.*

³¹⁶ See Jonathan H. Adler et al., *Bootleggers, Baptists, and E-Cigs*, REGULATION, Spring 2015, at 30–33 (describing the public health community’s “scorn” for e-cigarettes and their advocacy for greater regulation).

³¹⁷ *E.g.*, *id.* at 33 (surveying support for regulation by large tobacco companies, which Adler and colleagues ascribe to a desire to maintain their cartel).

³¹⁸ See *id.* at 35.

³¹⁹ 21 U.S.C. § 387j(e) (2012).

³²⁰ Lorillard Comment Letter, *supra* note 196, at 29; *The FDA & Deeming Regulations of E-cigarettes*, CASAA (Mar. 3, 2013), http://casaa.org/deeming_regulations.html.

In the final regulations, the FDA stated that it had identified some e-cigarettes on the market as of the predicate date. See Deeming Tobacco Products to Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family

In response to the NPRM, many industry groups argued that the premarket review process would stifle innovation and potentially kill the industry because manufacturers simply cannot present the type of evidence required for premarket review, nor does the FDA have evidence necessary to do the assessments required by the statute.³²¹ Recognizing the problem, the FDA proposed using its discretion to give manufacturers a two-year grace period in which to seek premarket review.³²² This would enable manufacturers to continue marketing their products without premarket review for two years after the effective date of the deeming regulations. The FDA claimed, however, that it lacked the discretion to go further and spare e-cigarettes from premarket review using the 2007 date.³²³

In June 2015, a report by the House Appropriations Committee expressed support for most of the deeming regulations, urging the FDA to issue them swiftly.³²⁴ The report further urged the FDA to

Smoking Prevention and Tobacco Control Act: Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products, *supra* note 10, at 81 Fed. Reg. at 28978.

³²¹ Guy Bentley, *FDA Regulations Could Wipe Out 99 Percent of E-Cigarette Industry*, DAILY CALLER, (Aug. 14, 2015, 2:22 PM), dailyaller.com/2015/08/14/fda-regulations-could-wipe-out-99-percent-of-e-cigarette-industry. Jonathan Adler and colleagues argue that large tobacco companies are working to stop disruption innovation by supporting cartelizing the e-cig industry by way of regulation. Adler et al., *supra* note 316, at 30.

³²² Deeming Tobacco Products to be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Regulations on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products, 79 Fed. Reg. 23142, 23144 (proposed Apr. 25, 2014) (to be codified at 21 CFR pts. 1100, 1140, 1143). Products that can establish the existence of a substantially equivalent product on the market on or before 2007 face a substantially less complex and more expedited review process. *Id.*

In the final regulations promulgated while this article was in press, the FDA provided for three different periods of up to 14, 30, or 36 months, depending upon the pathway chosen, for a manufacturer to obtain premarket review and authorization from the FDA. *See* Deeming Tobacco Products to Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act: Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products, *supra* note 10, at 81 Fed. Reg. at 28977–78.

³²³ 79 Fed. Reg. at 23174 (“[W]e do not believe that we have the authority to amend [this grandfathering date],” which is set by statute.).

³²⁴ H.R. REP. NO. 114-205, at 75 (2015).

ban the sale of all tobacco products to minors, and “to make child-resistant packaging and warning labels mandatory for liquids used with electronic-cigarette vaporizers.”³²⁵ The Committee, however, also voiced concerns about the use of 2007 as the predicate date for premarket review for newly deemed tobacco products, stating that it would add to the logjam of applications for review and divert the agency from “its core mission to promote public health, ensure the safe use of these products and prevent underage use and abuse.”³²⁶ While asserting its belief that the FDA had the discretion to change the predicate date, the Committee added language to the appropriations bill to require the FDA to treat the effective date of the deeming regulations as the predicate date for newly deemed tobacco products.³²⁷ This would mean that e-cigarettes that are currently sold could remain in the market without premarket review. New products introduced after the regulations’ effective date could bypass full review by establishing substantial equivalence to products sold before the effective date of the regulations. The bill would also allow products to enter and remain on the market for 21 months after the effective date of the regulations while they undergo review for substantial equivalence.³²⁸

Shortly after the Committee issued its report, the FDA published an Advance Notice of Proposed Rulemaking (“ANPRM”) seeking comments, data, and information regarding whether it should require nicotine warnings and/or child-resistant packaging for liquid nicotine.³²⁹ It remains unclear when the FDA will issue the deeming regulations and what form they will take.

³²⁵ *Id.*

³²⁶ *Id.*

³²⁷ *Id.*

³²⁸ *Id.*

³²⁹ Nicotine Exposure Warnings and Child-Resistant Packaging for Liquid Nicotine, Nicotine-Containing E-Liquid(s), and Other Tobacco Products, Request for Comments, 80 Fed. Reg. 37555 (July 1, 2015) (to be codified at 21 CFR pts. 1100, 1140, 1143).

IV: REGULATING E-CIGARETTES

The three justifications discussed in Part II—impaired agency, harm to others, and self-governance—provide a powerful framework for assessing the normative justifiability of public health laws. The framework differs from other approaches to regulatory decision-making, such as those relying upon cost-benefit or cost-effectiveness analysis, by responding directly to the paternalism critique, basing its support for public health law on either well-established justifications for paternalism (in the case of impaired agency or the harm principle) or the enhancement of liberty itself, in the case of the self-governance rationale.³³⁰ In addition, as explained above, by demanding that each public health law satisfy the conditions of at least one of the three justifications, the framework provides important constraints on limitations on liberty imposed in the name of public health. Thus, the framework provides both robust support and significant restraints on the scope of public health laws. It also offers guidance as to when regulators should proceed in the face of significant scientific uncertainty.

The discussion below applies the framework to some of the oft-discussed regulations of e-cigarettes.³³¹ As the analysis suggests, the three justifications can be read broadly to offer a far wider berth for the regulation of e-cigarettes than many critics of laws regulating NCDs accept. Yet by demanding that each regulation satisfy the conditions of at least one justification, the framework also exposes serious doubts about some regulations that would come into effect under the FDA's proposed deeming regulations in the absence of further congressional action.

³³⁰ Cf. FRANK ACKERMAN & LISA HEINZERLING, PRICELESS: ON KNOWING THE PRICE OF EVERYTHING AND THE VALUE OF NOTHING 8–9 (2004) (arguing that cost-benefit analysis devalues life and nature by treating them as commodities); Robert R.M. Verchick, *The Case Against Cost Benefit Analysis*, 32 *ECOLOGY L.Q.* 349, 360 (2005) (reviewing FRANK ACKERMAN & LISA HEINZERLING, PRICELESS: ON KNOWING THE PRICE OF EVERYTHING AND THE VALUE OF NOTHING (2004)) (“Governance based on welfare maximization stands in tension with the traditional liberal view, which holds that an individual should not be used only as a means to another’s end.”).

³³¹ Because the question of whether e-cigarettes should be taxed in a manner similar to cigarettes raises additional issues, including the raising of revenue and the distribution of tax burdens, the discussion below does not address this possible form of regulation.

A. *Impaired Agency*

Consider first the least contentious type of regulation relating to e-cigarettes: Barring sales to youth. As noted above, use of e-cigarettes by minors is rising, even as teen smoking rates are falling.³³² Whether the two phenomena are causally related is unknown. Nor do we know the long-term *population* impact of youth vaping. E-cigarettes may possibly displace traditional cigarettes and lead to a reduction in population harm. Or, the increasing popularity of e-cigarettes among youth may increase nicotine addiction, renormalize cigarette use, and eventually support an increase in smoking rates.

The significant scientific uncertainty poses a problem for attempts to justify the regulation of youth access based on the harm principle. We just don't know whether youth vaping harms others. But in the case of youth, the harm principle is not a necessary justification. The impaired decision-making rationale suffices. Because teenage brains are insufficiently developed, and minors are impressionable, we accept that they are not consistently able to exercise the type of informed agency the paternalism critique seeks to protect. For this reason, there is broad agreement that paternalistic laws are appropriate to protect minors.³³³ In the case of e-cigarettes, this agreement supports laws limiting youth access, including regulations requiring childproof packaging (which would protect very young children from poisoning hazards) and laws barring youth sales, including by banning vending machine sales in establishments not limited to adults.³³⁴ This is so even though barring youth access may harm public health by decreasing the availability and use of e-cigarette as compared with traditional cigarettes.

³³² See *supra* text accompanying notes 203–207.

³³³ This is not to say that youth bans are paternalistic. Because such laws operate more directly on the seller of e-cigarettes than the youth the laws seek to protect, it is plausible to argue that, strictly speaking, these laws are not paternalistic. See *supra* text accompanying notes 60–63.

³³⁴ This is what the FDA has proposed in its so-called deeming regulations. See Deeming Tobacco Products to be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Regulations on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products, 79 Fed. Reg. 23142, 23144 (proposed Apr. 25, 2014) (to be codified at 21 CFR pts. 1100, 1140, 1143).

Interestingly, the existence of scientific uncertainty strengthens the justification for regulations aimed at preventing youth from using e-cigarettes. Respect for individual autonomy may oblige us to allow (informed) adults to make their own decisions in the face of scientific uncertainty. But the uncertainty adds enormous complexity to the decision to vape, requiring the individual to weigh short-term pleasures against unknown long-term risks.³³⁵ Because teens may be especially challenged in assessing long-term risks,³³⁶ the idea that they can make fully informed and carefully reasoned decisions regarding unknown dangers is unsustainable. For this reason we do not ordinarily permit minors (without a showing of maturity) to make decisions about their medical care, and we treat them as especially vulnerable subjects in human research trials.³³⁷ The addictiveness of e-cigarettes only compounds the impairment of agency. We know young people significantly overestimate their ability to stop smoking.³³⁸ This suggests that they are unlikely to be

³³⁵ Although it is safer for any individual to vape than to smoke, the scientific uncertainty that exists remains critical to a rational agent's decision to use e-cigarettes, and thus adds to the reasons we are justified in acting paternalistically on behalf of minors. First, we don't yet know the long-term effects of e-cigarettes on individuals, both as to their direct health impacts and as to the potential to increase the risk of smoking. Second, a rational agent may want to know the population impacts of e-cigarettes. Will use of e-cigarettes increase rates of smoking among others in their community? But as noted above, the answers to these questions remain unknown.

³³⁶ Alexander Persoskie, *How Well Can Adolescents Really Judge Risk? Simple, Self Reported Risk Factors Out-Predict Teens' Self Estimates of Personal Risk*, 8 JUDGMENT & DECISION MAKING 1, 4 (2013) (finding that a small subset of risk factors significantly outpredict teens' self-estimates of risk).

³³⁷ See Kimberly M. Mutcherson, *Whose Body Is It Anyway? An Updated Model of Healthcare Decision-Making Rights for Adolescents*, 14 CORNELL J.L. & PUB. POL'Y 251, 253 (2005) ("In the health care context, the law has traditionally erred on the side of protecting young people from themselves . . . and vesting most decision-making authority in parents or other guardians. For the most part, with important exceptions, people under the age of eighteen may not make binding decisions about their own medical care.").

³³⁸ Tara Mantler, *A Systematic Review of Smoking Youths' Perceptions of Addiction and Health Risks Associated with Smoking: Utilizing the Framework of the Health Belief Model*, 21 ADDICTION RES. & THEORY 306, 313 (2013) ("[T]he results of this systematic appraisal suggested youth were optimistic about their cigarette addiction, health risks, and consequences of smoking, and rationalized smoking by thinking perceived barriers to quitting outweigh perceived benefits.").

able to fully assess their ability to stop vaping if and when they want to.

Critically, the impaired agency rationale for banning the sale of e-cigarettes to minors is based on the fact that youth lack full decision-making capacity, rather than the dangerousness of e-cigarettes. In other words, we can justify banning sales of e-cigarettes and e-liquid to minors, as suggested by the ANPRM, not because we know bans will protect their health, but because youth may not be able to assess what they would like to do if they were fully informed and mature in the face of scientific uncertainty. But banning youth sales might end up harming their health (if they smoke instead). On the other hand, as long as we envision a ban on the sale of e-cigarettes or e-cigarette liquids to minors as a public health law, we need at least a plausible reason for believing it will protect health. To put it another way, if the weight of the evidence showed that banning youth sales would harm minors' health, a ban could not be justified as a *public health* law that compensated for the impaired decision-making of youth. But given the scientific uncertainty, restrictions on youth sales may be warranted to compensate for the teens' impaired decision-making.

The impairment of agency rationale also provides support for some regulations not specifically aimed at youth. As noted above, the decision-making of otherwise competent adults can be impaired by informational deficits.³³⁹ In such cases, the impaired agency rationale supports laws that provide individuals with information material to their decision-making, or prevent them from making choices they would not make were they fully and accurately informed.

In the case of e-cigarettes, this rationale supports the FDA asserting authority to undertake enforcement actions against manufacturers that make unsupported and therefore misleading therapeutic claims for e-cigarettes.³⁴⁰ The rationale also suggests regulators

³³⁹ See *supra* text accompanying notes 82–96.

³⁴⁰ See *Sottera, Inc. v. FDA*, 627 F.3d 891 (D.C. Cir. 2010). After several years of inaction, in the spring of 2015 the FDA issued its first warning letters relating to e-cigarettes. Anthony “Tony” Pavel & Jonathan A. Havens, *FDA Issues First E-Cigarette Warning Letters*, NAT'L L. REV. (Apr. 15, 2015), <http://www.natlaw-review.com/article/fda-issues-first-e-cigarette-warning-letters> (“The [FDA] is not waiting to finalize the ‘deeming rule’ before taking enforcement action against [e-cigarette] and e-liquid companies.”).

should have the authority, which the FDA would attain under the deeming regulations, to act against misbranded or adulterated e-cigarettes.³⁴¹ Clearly laws that protect people from false information do not undermine the liberty of those protected (though such laws do limit the liberty of those who sell misbranded products).³⁴²

The same reasoning would apply to a law requiring e-cigarette manufacturers to disclose their ingredients. Enormous heterogeneity now exists in the ingredients found in e-cigarette liquids.³⁴³ Because it is impractical for consumers to uncover product information on their own, a law requiring the disclosure of product ingredients would support consumers' decision-making.³⁴⁴ The deeming regulations would do precisely that, requiring manufacturers to report their ingredients to the FDA,³⁴⁵ which would then be required to make the ingredients public.³⁴⁶

The impaired decision-making justification also supports the requirement for warning labels regarding the addictiveness of e-cigarettes, as proposed in the NPRM.³⁴⁷ Although the addictive nature

³⁴¹ See Deeming Tobacco Products to be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Regulations on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products, 79 Fed. Reg. 23142, 23148 (proposed Apr. 25, 2014) (to be codified at 21 CFR pts. 1100, 1140, 1143). This argument could potentially be made to justify premarket review, as that requirement could be viewed as a regulatory compensation for the consumers' inability to know if the product is safe. For a discussion as to why the harm principle does not justify premarket review, see *infra* text accompanying notes 360–61.

³⁴² See Mariner, *supra* note 62, at 1826.

³⁴³ Christoph Hutzler et al., *Chemical Hazards Present in Liquids and Vapors of Electronic Cigarettes*, 88 ARCHIVES TOXICOLOGY 1295, 1304 (2014) (“Our data . . . confirm the presence of a wide range of flavors and additives in e-cigarette liquids [including] some potentially allergenic compounds . . .”).

³⁴⁴ Laws requiring the disclosure of truthful, non-misleading information in a commercial context do not generally violate the First Amendment. See *Zauderer v. Office of Disciplinary Counsel of Sup. Ct. of Ohio*, 471 U.S. 626, 638 (1985); *Am. Meat Inst. v. USDA*, 760 F.3d 18, 21 (D.C. Cir. 2014).

³⁴⁵ 21 U.S.C. § 387a(a)(1) (2012); *Guidance for Industry: Listing of Ingredients in Tobacco Products*, FDA (Nov. 2009), <http://www.fda.gov/downloads/TobaccoProducts/GuidanceComplianceRegulatoryInformation/ucm192053.pdf>.

³⁴⁶ 21 U.S.C. § 387d(a), (e); *Harmful and Potentially Harmful Constituents in Tobacco Products and Tobacco Smoke: Established List*, 77 Fed. Reg. 20,034 (Mar. 31, 2015).

³⁴⁷ See Deeming Tobacco Products to be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco

of traditional cigarettes is well-known,³⁴⁸ e-cigarettes are relatively new products. Users should know they are addictive in order to make an informed choice.³⁴⁹ For much the same reason, the impaired agency rationale would appear to support regulations requiring warnings about the known potential dangers of e-cigarettes or e-liquids, as suggested by the ANPRM. The rationale would also support a regulation requiring manufacturers and sellers to inform consumers that the long-term and population-wide health risks and benefits of these products are not yet known. In a sense, the scientific uncertainty is itself information that people should know about, lest they mistakenly conclude that the absence of health warnings means e-cigarettes have been proven safe.³⁵⁰ To date, the FDA has not proposed such a warning.

It is far less certain whether the impaired agency justification supports laws subjecting e-cigarettes to the full panoply of TCA regulations pertaining to the marketing of traditional cigarettes, including premarket review with a 2007 predicate date (which might effectively act as a ban on brands sold by smaller manufacturers), or regulations of advertisements on televisions or billboards.³⁵¹ Cer-

Control Act; Regulations on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products, 79 Fed. Reg. 23142, 23163 (proposed Apr. 25, 2014) (to be codified at 21 CFR pts. 1100, 1140, 1143).

³⁴⁸ See U.S. DEP'T OF HEALTH & HUMAN SERV., HOW TOBACCO SMOKE CAUSES DISEASE: THE BIOLOGY AND BEHAVIORAL BASIS FOR SMOKING-ATTRIBUTABLE DISEASE 105 (2010); U.S. DEP'T OF HEALTH AND HUMAN SERVS., THE HEALTH CONSEQUENCES OF SMOKING: NICOTINE ADDICTION: A REPORT OF THE SURGEON GENERAL (1988).

³⁴⁹ See, e.g., Jolls & Sunstein, *supra* note 87, at 216.

³⁵⁰ As suggested above, the existence of scientific uncertainty may play out somewhat differently with minors, whose decision-making capacity is presumed to be impaired. For competent adults, the impaired agency justification simply supports laws that compensate for the decisional deficiency, such as the lack of knowledge of scientific uncertainty. For minors the deficiency runs deeper; we can question their ability to make judgments that respect their own choices even when information is complete. Scientific uncertainty adds a measure of complexity that provides further support for limiting minors' agency (by banning their purchase of the product).

³⁵¹ Health authorities often attempt to debias by engaging in counteradvertising. This form of debiasing can raise ethical issues regarding the government's

tainly, concern about the impaired decision-making of youth provides some justification for regulating the marketing of e-cigarettes, especially when the advertising is directed at minors. Moreover, even when directed at adults, marketing regulations can serve as a form of debiasing that seeks to overcome advertisers' ability to manipulate consumers' cognitive errors, such as the optimism bias, which may lead them to underestimate the risk of addiction.³⁵² Likewise, premarket review can be viewed as a regulatory compensation for consumers' inability to know whether the e-cigarettes they use are safe, as is the case with pharmaceuticals.

Nevertheless, there are several reasons why the impaired agency justification does not currently support restrictions on the marketing of e-cigarettes that go beyond prohibiting deceptive advertising, banning advertisements aimed at youth, and mandating ingredient listings and product warnings. Most critically, because of the scientific uncertainty about the long-term and net effects of e-cigarettes, regulators are not in a position to know that either premarket review or advertising regulations would help individuals exercise the choices they would make if they were fully informed and fully rational. This is for two reasons. First, rational people can and do make different decisions about how to proceed in the face of uncertainty. Thus regulators cannot be confident that product or advertising bans would help consumers achieve the outcomes they would want if they were fully informed about the scientific uncertainty. Second, even if we accept that individuals value their health, and would factor negative health effects of e-cigarettes into their decision-making, the scientific uncertainty bars assurance that advertising restrictions or premarket review would further individual health goals. To the contrary, it is possible that such regulations would undermine health by reducing individuals' use of e-cigarettes in lieu of traditional cigarettes.³⁵³ If so, premarket review and advertising restrictions would

attempt to manipulate people. Jolls & Sunstein, *supra* note 87, at 232. Informational campaigns, however, are not forms of regulation, and are thus outside the scope of this analysis.

³⁵² For a discussion on how advertising exploits cognitive biases, see Paul Horwitz, *Free Speech as Risk Analysis: Heuristics, Biases, and Institutions in the First Amendment*, 76 TEMP. L. REV. 1, 53–55 (2003).

³⁵³ This is so even in the case of nonsmokers. Especially in the case of young adults, we cannot know if they would be more likely to begin smoking if they did not feel that e-cigarettes provided a safer alternative.

not put into place the outcome individuals would seek in the absence of the informational deficiencies.

Finally, the limits external to the impaired agency justification offer an additional argument against restricting the advertising of e-cigarettes. Recall that in addition to the justifications for public health laws, we need to consider the nature of the individual interests restrained. This normative principle is reflected in constitutional law, which demands a higher degree of justification for laws that infringe upon protected rights, including freedom of speech. Under current doctrine, laws regulating truthful and non-misleading commercial speech are permissible only when they can be shown to directly advance a substantial state interest.³⁵⁴ Although there are many reasons from a population perspective to question the Supreme Court's current application of the doctrine,³⁵⁵ its core principle remains compelling: laws that infringe upon speech in the name of protecting health should protect health.³⁵⁶ Given the current evidence, laws that broadly restrict e-cigarette advertising cannot meet that test.

B. *The Harm Principle*

The harm principle offers the most well-established justification for public health laws. Most infectious disease laws rest upon it. So do many laws that target NCDs.³⁵⁷ For the time being, however, we do not know that e-cigarettes harm population health so as to justify banning their sale to adults, or severely limiting the market, as would happen through premarket review, especially if 2007 remains

³⁵⁴ Cent. Hudson Gas & Elect. Corp. v. Pub. Serv. Comm'n, 447 U.S. 557, 564 (1980).

³⁵⁵ Current doctrine places high hurdles on public health laws regulating commercial speech. For a discussion and critique of current law, see Kevin Outterson, *Higher First Amendment Hurdles for Public Health Regulation*, 365 NEW ENG. J. MED. e13 (2011).

³⁵⁶ There are reasons to believe that the Court now applies the *Central Hudson* test so strictly that almost no regulation of advertising can pass muster. From a public health perspective, and indeed, based upon the justifications set forth above, that's highly problematic. See *id.* at e13(2). Laws regulating commercial speech require more justification than those that infringe upon lesser liberties (such as the right to smoke indoors); given the state of the evidence, advertising restrictions cannot at this time meet that test.

³⁵⁷ Lawrence O. Gostin, *Public Health Law in a New Century: Part III: Public Health Regulation: A Systematic Evaluation*, 283 JAMA 3118, 3118 (2000).

the predicate date.³⁵⁸ Although the risk of poisoning and fires (especially aboard airplanes) may warrant targeted regulations,³⁵⁹ the evidence suggests e-cigarettes do not pose the type of proximal harm to bystanders, i.e., secondhand smoke, created by cigarettes.³⁶⁰ Rather, by reducing cigarette consumption, e-cigarettes may reduce third-party exposure to secondhand smoke, or even fire. If so, regulations impeding access to e-cigarettes may harm public health. Likewise, regulations such as the premarket review that would restrict entries into the e-cigarette market might harm health either by increasing the price of e-cigarettes relative to cigarettes or by slowing innovations by smaller manufacturers that might reduce the risks associated with e-cigarettes. Note that this is so even if e-cigarettes are not harmful to individual users.

Many public health advocates nevertheless worry that widespread use of e-cigarettes may undermine tobacco control efforts and ultimately increase rates of smoking.³⁶¹ This possibility must be taken seriously. When we think about harm to others we need to consider not only the proximal harm, but also the ways in which the social environment influences health risks across populations. Thus *if*, as public health advocates fear, the widespread use of e-cigarettes

³⁵⁸ See *supra* text accompanying notes 318–29.

³⁵⁹ See *supra* text accompanying notes 233–237; 249–250. To address the risk of poisoning due to liquid nicotine, Congress recently passed the Childhood Nicotine Poisoning Prevention Act of 2015, Pub. L. No. 114-116, 130 Stat. 3 (2016) (to be codified at 15 U.S.C. 1477a). This act requires that all liquid nicotine be packaged in accordance with the standards set forth in 16 C.F.R. 1700.15 and 16 C.F.R. 1700.20 which relate to child resistant packaging.

³⁶⁰ See *supra* text accompanying note 248.

³⁶¹ Toni Clarke, *E-Cig Use Soared, Cigarette Use Fell Among U.S. Youth in 2014*: CDC, REUTERS (Apr. 16, 2015, 3:04 PM), <http://www.reuters.com/article/2015/04/16/us-ecigarettes-cdc-data-idUSKBN0N723O20150416> (stating that data of increased e-cigarette usage among middle and high school students “sparked alarm among tobacco control advocates who fear e-cigarettes will create a new generation of nicotine addicts who may eventually switch to conventional cigarettes”).

renormalizes smoking and increases cigarette consumption, a population-based approach to the harm principle would justify regulations restricting adult access to or use of e-cigarettes.³⁶²

For now, however, the science does not support such conclusions.³⁶³ The application of the population perspective's capacious interpretation of the harm principle demands respect for the perspective's own limits. In other words, if the justification for a regulation rests on the harm principle, the scientific evidence must provide a strong (although not necessarily conclusive) basis for believing the regulation will reduce harm.

This is not to say the risks public health advocates worry about are wholly implausible or should be ignored. As suggested above, e-cigarettes present numerous risks, and it is quite possible the evidence will eventually show that their net risks to population health outweigh their net population benefits. Moreover, because nicotine is addictive, and marketing is fierce, use very well may become entrenched before the evidence is in, making it harder to regulate e-cigarettes if and when they are shown to be harmful at a population level. Still, if a public health regulation is to rest on the harm principle, there must be strong reason to believe the regulation will prevent harm to others. That case has yet to be made for most proposed regulations of e-cigarettes.

C. *Self-Governance*

In the midst of scientific uncertainty, the self-governance rationale offers the most robust justification for regulating e-cigarettes. Because public health laws are the manifestation of populations' positive liberty to secure their own health, populations may adopt a precautionary approach and regulate e-cigarettes even though the evidence of harm is not yet settled. Alternatively, popu-

³⁶² Premarket review may also be justified to prevent the introduction of adulterants or especially dangerous ingredients and designs. Given the state of the evidence, however, we cannot know that premarket review will benefit rather than harm public health.

³⁶³ Clarke, *supra* note 361 (quoting the director of the Center for Smoking Cessation at Duke University acknowledging that data of increased e-cigarette usage among youths "is equally amenable to the interpretation that e-cigarettes are diverting young people away from cigarettes").

lations may adopt a harm-reduction strategy and allow the proliferation of e-cigarettes, even though we do not yet know whether it will work. If we take self-governance seriously, these choices are ultimately for affected populations to make.

The self-governance rationale, however, does not necessarily support all regulations of e-cigarettes. Regulations resting on the self-governance justification must comport with the limitations implied by that justification. Unfortunately, there is no magic formula for determining if and when regulations can plausibly be asserted as the product of self-governance. If we simply assume all duly enacted regulations meet the test, the justification becomes meaningless. Yet if we were to say that only those regulations that result from popular referenda qualify, we would handcuff populations' ability to adopt a precautionary principle, or to seek the types of regulations (such as import bans) that can be carried out only at the federal level. Nevertheless, if the justification for any specific law rests on self-governance, the claim of self-governance must be plausible.

There is strong reason to believe many regulations of e-cigarettes satisfy this test. For example, in cities such as Philadelphia³⁶⁴ and New York,³⁶⁵ city councils have voted to extend their public smoking laws to e-cigarettes. In many jurisdictions these laws have been enacted after considerable public debate. Proponents of some of the regulations have explicitly noted that the science is not in, but have argued for erring on the side of safety.³⁶⁶ Other communities

³⁶⁴ Dan Stamm & Vince Lattanzio, *Philadelphia City Council Bans E-Cigarettes in Public Places*, NBC10.COM, (Mar. 27, 2014), <http://www.nbcphiladelphia.com/news/health/E-Cigarette-Ban-Philly-252610201.html>.

³⁶⁵ Scott Neuman, *New York City Extends Smoking Ban to E-Cigarettes*, NPR (Dec. 19, 2013, 7:04 PM), <http://www.npr.org/blogs/thetwo-way/2013/12/19/255582225/new-york-extends-smoking-ban-to-e-cigarettes>.

³⁶⁶ For example, Philadelphia City Councilman William K. Greenlee stated, "I know they say, 'Because we don't know enough, don't do anything . . . I'm saying, 'Because we don't know enough . . . we should take necessary precautions.'" Troy Graham, *E-cigarette Restrictions Pass Council*, PHILLY.COM (Mar. 28, 2014, 5:58 AM), <http://www.philly.com/philly/blogs/heardinthehall/E-Cigarette-Restrictions-Pass-Council.html>.

have made the opposite decision.³⁶⁷ Either way, such choices by local elected bodies warrant respect if we are to take self-governance seriously.³⁶⁸

Some forms of state and federal legislation explicitly addressing e-cigarettes may also be justified, although less robustly, on the basis of self-governance. Given the many flaws in our political system, there are serious reasons to question whether ordinary legislative acts, especially those not arising from engaged social movements, should qualify as acts of self-governance.³⁶⁹ Laws enacted without full and open debate are especially problematic from a self-governance perspective. Still, we cannot presume *prima facie* that legislative actions, even when not justified on the basis of the harm principle or impaired agency, are invalid (as the paternalism critique does), lest we disable populations from expressing their values and using the political system to secure their own health. Many health problems cannot be addressed at the local level; any presumption that state or federal legislation is invalid would restrict populations' positive liberty of self-governance. Hence a legislature's decision to regulate e-cigarettes to protect public health may be justifiable even if it exceeds the scope of the impaired decision-making or harm principle justifications, and even if the legislative process is, as is usually the case, less than ideal.³⁷⁰

From a self-governance perspective, administrative action is far more problematic, especially when undertaken in the absence of clear legislative direction. Administrative action beyond the scope of either the harm principle or the impaired agency justification is

³⁶⁷ The website of Consumer Advocates for Smokefree Alternatives Association (CASAA) lists several examples in which proposed regulations were not enacted by city councils. *Successful CASAA Campaigns*, CASAA, http://casaa.org/Successful_Campaigns.html (last visited June 1, 2015).

³⁶⁸ A recent study offered a sobering caveat, finding that so-called astroturf groups, supported by industry, originated a significant portion of the tweets opposing Chicago's e-cigarette law as it was being debated by the city council. Jenine K. Harris et al., *Tweeting for and Against Public Health Policy: Response to the Chicago Department of Public Health's Electronic Cigarette Twitter Campaign*, 16 J. MED. INTERNET RES. e238 (2014).

³⁶⁹ See *supra* text accompanying note 150–160.

³⁷⁰ Importantly, the regulation of e-cigarettes does not appear to raise concerns regarding stigmatization. See *supra* text accompanying notes 155–56.

troubling in the absence of strong grassroots support. In such situations we may worry that health officials are acting in their own view of what is good for a population, rather than carrying out the population's wishes.

In the case of e-cigarettes, polls suggest strong public support for some regulatory action. A 2014 poll by the Center for Prevention at Blue Cross and Blue Shield of Minnesota found that 79% of Minnesotans supported prohibiting indoor use of e-cigarettes in places where smoking is prohibited.³⁷¹ Other polls have likewise found strong support for health warnings and banning the sale of e-cigarettes to minors.³⁷² However, a 2014 Rasmussen poll found that only 51% of adults thought e-cigarettes should be regulated by the FDA in the same manner as traditional cigarettes,³⁷³ and a 2013 poll by libertarian-leaning Reason-Rupe found that 62% of Americans thought e-cigarette use should be permitted in public places.³⁷⁴

Given these polls, it would be hard to conclude that an FDA decision to promulgate the deeming regulations went against the public's wishes. However, the polls do not show overwhelming public support for some of the specific provisions included within the deeming regulations (such as premarket review) that exceed the

³⁷¹ Center for Prevention, *Poll: Minnesotans Strongly Support Prohibiting E-Cigarettes Use Indoors*, BLUE CROSS BLUE SHIELD MINNESOTA (Feb. 26, 2014), <http://www.centerforpreventionmn.com/newsroom/press-releases/poll%20minnesotans%20strongly%20support%20prohibiting%20ecigarette%20use%20indoors>. The poll also found strong support for measures aimed at preventing e-cigarette use by youth. *Id.*

³⁷² See, e.g., C.S. Mott Children's Hospital, *44 Percent of Adults Worry E-Cigarettes will Encourage Kids to Start Smoking Tobacco* (Dec. 18, 2013), <http://www.mottchildren.org/news/archive/201312/44-percent-adults-worry-e-cigarettes-will-encourage-kids> (reporting that 65% of respondents support health warnings and 86% support banning sales to minors); Tobacco Free Kids, *Tobacco Free Kids National Survey* (Feb. 2015), http://www.tobaccofreekids.org/content/press_office/2015/2015_04_14_poll_questions.pdf (reporting high levels of support for disclosures and regulations protecting youth).

³⁷³ *51% Believe E-Cigarettes Should be Regulated by Federal Government*, RASMUSSEN REPORTS (Apr. 29, 2014), http://www.rasmussenreports.com/public_content/lifestyle/general_lifestyle/april_2014/51_believe_e_cigarettes_should_be_regulated_by_federal_government.

³⁷⁴ Emily Ekins, *62 Percent Think E-Cigarette Use in Public Should be Allowed Despite Expected FDA Regulations*, REASON.COM (Dec. 19, 2013, 12:43 PM), <http://reason.com/poll/2013/12/19/62-percent-think-e-cigarette-use-in-pub2>.

scope of the impaired agency and harm principle justifications. Moreover, little evidence exists of widespread public engagement with the issue, as with debates over indoor smoking laws.³⁷⁵ It is true, as previously discussed, that many tobacco control groups have become deeply involved in the issue of e-cigarettes. And the large number of comments submitted in response to the NPRM evinces considerable public and industry interest.³⁷⁶ In addition, the FDA has held a series of public workshops to obtain information on e-cigarettes and public health.³⁷⁷ Still, there remains scant evidence of a strong grassroots movement demanding federal restrictions on the sale of e-cigarettes.³⁷⁸ And in some states, legislative proposals to

³⁷⁵ Baehr, *supra* note 283, at 1673–75.

³⁷⁶ Under the Administrative Procedures Act, notice and comment rulemaking provides the public with the opportunity to participate in and influence the rule-making process. 5 U.S.C. § 553 (2012). In this sense, it affords populations with some opportunity to self-govern. See David J. Arkush, *Direct Republicanism in the Administrative Process*, 81 GEO. WASH. L. REV. 1458, 1486 (advocating for a deliberative democracy approach to notice and comment rulemaking); Mark Seidenfeld, *The Role of Politics in a Deliberative Model of the Administrative State*, 81 GEO. WASH. L. REV. 1397, 1427 (2013). However, whether affected populations actually can influence the rulemaking process is questionable. See Seidenfeld, *supra* note 376, at 1434–35 (discussing the inherent limitations of notice and comment rulemaking). In our less than ideal polity, the same can be said of the legislative process. Still, for theoretical reasons if none other, the political legitimacy of administrative agencies remains more questionable than that of elected bodies. See Arkush, *supra* note 376, at 1467–72 (reviewing the history of legitimacy concerns relating to administrative agencies); Mark Seidenfeld, *A Civic Republican Justification for the Bureaucratic State*, 105 HARV. L. REV. 1511, 1516–28 (1992) (reviewing the “shaky” constitutional foundations of the administrative state).

³⁷⁷ A Public Workshop – Electronic Cigarettes and the Public Health, FDA.GOV, <http://www.fda.gov/TobaccoProducts/NewsEvents/ucm414814.htm> (last visited Mar. 25, 2016).

³⁷⁸ The most visible grassroots groups may be those who oppose laws that treat e-cigarettes as comparable to cigarettes. For example, CASAA, which claims to have over 113,000 members, has argued against the deeming regulations. *The FDA & Deeming Regulations of E-cigarettes*, *supra* note 320; *CASAA Podcast Update November 2, 2015*, CASAA (Nov. 4, 2015) <http://blog.casaa.org/2015/11/casaa-podcast-update-november-2-2015.html>. Whether CASAA is a genuine grassroots group, or a so-called astroturf group, is debatable. The organization’s bylaws, for example, permit up to 1/3 of its members to be from industry, *About CASAA*, CASAA (Feb. 2015), http://casaa.org/About_CASAA.html. Similar groups exist at the state level. See, e.g., WISCONSIN SMOKE-FREE ALTERNATIVES COALITION, SMOKING ORDINANCES AND ELECTRONIC

require the licensing of vaping businesses have drawn considerable opposition.³⁷⁹ Even some public health advocacy groups have noted that e-cigarettes may reduce harm and have questioned stringent regulatory approaches, even with respect to minors.³⁸⁰

The lack of a clear legislative mandate adds doubt as to whether the deeming regulations can rest solely on the self-governance justification. Certainly, the regulations do not depend upon the type of open-ended delegation that proved fatal to the FDA in *Brown & Williamson*.³⁸¹ Rather they rest on the TCA, which specifically empowers the agency to regulate new tobacco products by promulgating deeming regulations.³⁸² Moreover, the TCA's premarket review provisions show that Congress recognized the possibility of new tobacco products,³⁸³ including modified harm products.³⁸⁴ Perhaps most important, Congress explicitly authorized the FDA to review all new and modified risk products and bar their entry into the market unless the agency found them appropriate for public health.³⁸⁵ For this reason, it can be argued that with the TCA Congress chose a precautionary approach.

That conclusion, however, is contestable because the TCA is silent about the most critical question: under what circumstances should the FDA deem a tobacco product subject to the regulations? In other words, the TCA provides relatively clear guidance on the choice between a precautionary and harm-reduction approach for

CIGARETTES (2014), <https://tobacco.ucsf.edu/sites/tobacco.ucsf.edu/files/u9/smoking-ordinances-and-electronic-cigarettes.pdf>.

³⁷⁹ See e.g., Barbara Brosher, *Proposed E-Cigarette Regulations Creating Controversy*, IND. PUB. MEDIA (Jan. 9, 2015) <http://indianapublicmedia.org/news/proposed-ecigarette-regulations-creating-controversy-76774/> (explaining that vape stores and their customers say bans on e-cigarettes “punish[] adults who are using the devices to quit smoking and give[] people less of an incentive to make the switch”).

³⁸⁰ Liz Szabo, *States Racing to Regulate E-Cigarettes*, USA TODAY (Feb. 7, 2015), <http://www.usatoday.com/story/news/2015/02/07/state-e-cigarette-bills/22364765/>.

³⁸¹ *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120 (1999).

³⁸² Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 387a(b) (2009).

³⁸³ *Id.* at §387j.

³⁸⁴ *Id.* at § 387k.

³⁸⁵ *Id.* For a discussion of the provision's history, see Jim Solyst, *Toward a Comprehensive Policy on Nicotine Delivery Products and Harm Reduction*, 67 FOOD & DRUG L. J. 393, 396–98 (2012).

products subject to its regulation, but leaves it to the agency alone to decide whether and under what circumstances new products should be subject to the Act.

The 2015 actions of the House Appropriations Committee offer at least that Committee's views on the choices facing the FDA. By endorsing the imposition of minimum age purchase requirements and health warnings, and the restriction of vending machine purchases (which prevents minors from circumventing the minimum age requirement),³⁸⁶ the Committee effectively supported the provisions of the deeming regulations that can be justified by the impaired agency rationale. But the Committee also expressed disapproval of requiring premarket review with a 2007 predicate date, stating that it would subject "newly regulated categories of tobacco products—some of which have the potential to play an important role in harm reduction, and some of which hardly existed in commerce before that date—[to] a more onerous approval process than cigarettes."³⁸⁷ The Committee also added language to the appropriations bill for the FDA that would force the agency to use the effective date of the regulations, rather than 2007, as the predicate date.³⁸⁸ The Committee thus rejected a precautionary approach.

On its own, the Committee's report does little to either shore up or undermine the applicability of the self-governance justification for the deeming regulations. Of course, if the proposal had become law, the self-governance justification would become much more secure for the modified regulatory structure the Committee proposed; but as noted previously, the regime that the Committee bill would have put into place does not require the self-governance rationale for its normative legitimacy.³⁸⁹ It is possible that the Committee's action will spark the type of open public debate that would bolster the claim that self-governance supports premarket review. However, in the absence of such debate or new legislation, it is difficult to

³⁸⁶ See H.R. Rep. No. 114-205, at 74. The Child Nicotine Poisoning Prevention Act of 2015, Pub. L. No. 114-116, 130 Stat. 3 (2016), explicitly states that it shall not be read to affect the Department of Health and Human Services' authority to regulate liquid nicotine or e-cigarettes, including any authority under the TCA, the NPRM or ANPRM.

³⁸⁷ H.R. Rep. No. 114-205, at 74.

³⁸⁸ *Id.* at 75.

³⁸⁹ See *supra* text accompanying notes 386–88.

justify the premarket review provisions under any of the three justifications of the framework. And because the deeming regulations as a whole necessarily entail premarket review, the regulations as a whole sit on a tenuous normative foundation.

All this suggests that until the evidence of harm to others is more settled, regulations of e-cigarettes that surpass those justified by impaired agency should derive from legislative rather than administrative bodies. Local legislatures may in fact be the preferable institution for regulating e-cigarettes, as they may be better-equipped to reflect the views of affected populations on the choice between harm reduction and the precautionary principle. Moreover, by allowing significant variation among regulatory schemes, local laws may also facilitate research on the effect of specific e-cigarette regulations on cigarette use. In contrast, by establishing a nationwide regulatory regime that would preempt some local laws³⁹⁰ the deeming regulations would reduce intra-jurisdictional variation, compromising the development of novel regulatory approaches as well as research on their effectiveness.³⁹¹ This may prolong the scientific uncertainty. Perhaps more important, by imposing a nationwide regulatory regime for e-cigarettes before there is widespread public debate and dialog about them, the regulations may forestall the very type of active community engagement that underlies the self-governance regulation.

CONCLUSION

A. *Rethinking the Deeming Regulations*

The choices regulators face regarding e-cigarettes are not easy. Given the state of the science, it is unclear whether the imposition of the tobacco control regulatory regime on e-cigarettes will help or harm population health. And given the lack of public debate and

³⁹⁰ 21 U.S.C. § 387p(a)(2) (2012).

³⁹¹ Researchers could still study the impact of the deeming regulations by comparing smoking rates before and after the regulations' implementation. See Scott Burris et al., *Moving from Intersection to Integration: Public Health Law Research and Public Health Law Systems and Services Research*, 90 MILBANK Q. 375, 392 (2012) (recommending "evaluation [of] health effects and costs associated with . . . regulations . . . before and after implementation").

legislative action, except at the local level, it is unclear how affected populations want regulators to act in the face of this uncertainty.

The constraints imposed by the TCA only add to the FDA's dilemma. The impaired agency rationale provides strong support for a wide range of regulations that are seemingly quite popular, including ingredient listing, warning labels as to the product's addictiveness, and banning sales to minors. The harm principle also supports granting the agency authority to act against adulterated e-cigarettes and require childproof packaging. Given the state of the evidence, however, none of the three responses to the paternalism critique support applying the TCA's premarket review provisions to e-cigarettes.

Unfortunately, although the TCA gives FDA broad authority, the agency cannot pick and choose among many of its provisions. If e-cigarettes are deemed to be subject to the Act, the premarket review provisions will go into effect, either with a 2007 predicate date or, if the FDA changes its views and believes it has more discretion, with a later date. Either way, premarket review will impose a precautionary approach with potentially serious ramifications for the development of the e-cigarette market, one with at least the potential for adverse (or positive) health consequences.

In an ideal world, the public would debate the issue, and Congress would solve the regulatory dilemma by giving the FDA clearer guidance on how to proceed. In the absence of legislation, however, continued delay may be the FDA's most supportable action. Although such delay risks the growth of the e-cigarette market, it provides the opportunity for the agency to attain a clearer picture about the population health effects of e-cigarettes and their regulation. It also permits populations to become more fully engaged in the discussion of how to proceed amid scientific uncertainty. In other words, delay allows populations to exercise their right of self-governance to protect their health.

B. *Justifications for Public Health Law*

Although public health scholars and advocates may be tempted to cast aside the paternalism critique as overblown and inappropriately applied, they do so at their own peril. Even when public health laws are not paternalistic, the critique has proved to be rhetorically

powerful. It resonates with a public that distrusts government and values individual liberty.

In response to the critique, public health legal scholars have offered three broad classes of normative justifications: impaired agency, the harm principle, and, most robustly, self-governance. When applied with a public health perspective, they offer support steeped in the liberal tradition for a wide range of public health laws. They also help explain why the distinction between the old and new public health is misleading. Indeed, the justifications apply with equal force to both infectious-disease laws and regulations targeting NCDs.

But all justifications have their limitations. If public health advocates are to successfully counter the paternalism critique, they must recognize that the conditions upon which they seek to justify public health laws—impaired agency, harm to others, or self-governance—need to be met. Respect for the positive liberties of health and self-governance requires respect for the decisions that engaged populations render in the face of uncertainty. If public health advocates want to claim the mantle of self-governance, they must take it seriously.