Regulatory Approaches to Ending Cigarette-Caused Death and Disease in the United States

Richard Daynard†

I. INTRODUCTION

Cigarettes result in over 400,000 preventable American deaths each year.¹ In 2011, fewer than twenty percent of adults smoked.² Since the publication of the first U.S. Surgeon General’s Report on Smoking and Health nearly fifty years ago, when smoking prevalence was around forty percent,³ policies such as smoke-free laws, large tax increases, and litigation have collectively contributed to cut smoking prevalence in half.⁴ Unfortunately, no one expects the mix of policies currently proposed, which includes further tax increases, spatial smoking restrictions, somewhat higher minimum age restrictions, adverse publicity, and quitting assistance, to reduce U.S. smoking prevalence below fifteen percent in the foreseeable future.

The rule adopted by the U.S. Food and Drug Administration (FDA) to require hard-hitting graphic warnings on cigarette packages,⁵ as is currently done in dozens of other countries, has thus far been rejected by federal judges who have found that warnings designed to arouse negative emotions violate cigarette manufacturers’ First Amendment rights.⁶ Even if these warnings are eventually implemented, although they may encourage smoking cessation and deter initiation, there is no evidence that they can produce a dramatic drop in smoking rates. Similarly, while the FDA is moving painfully slowly to address the Congressionally-mandated question ⁷ regarding whether menthol as a characterizing cigarette ingredient encourages

---

¹ University Distinguished Professor of Law at Northeastern University School of Law.
⁵ See CDC, supra note 2, at 890.
⁷ See, e.g., R.J. Reynolds Tobacco Co. v. FDA, 696 F.3d 1205, 1221-22 (D.C. Cir. 2012).
uptake or discourages quitting, banning menthol is also unlikely to be a game-changer.  

If these strategies were all we had, we might have to accept that cigarette smoking would be entrenched in American society for the long haul and would continue to exact a heavy toll. Yet surprisingly, over forty percent of survey respondents when asked about banning cigarettes consistently supported that policy, despite a complete absence of public advocacy for it. Over seventy percent would support eliminating the addictive components of cigarettes, including a majority of smokers. While public health advocates need to continue to press forward with existing policies—if for no other reason, to prevent the tobacco industry from finding ways reverse the public health progress made to date—polling data suggest that policymakers and public health leaders can and should—explore “endgame” strategies that would reduce smoking rates to well below ten percent. Several tobacco control advocates have begun discussing such strategies, but while articles have appeared in specialty journals and sessions have been held at the World and National Conferences on Tobacco or Health, there has been little or nothing mentioned about such ideas in the general public health literature, much less implemented in the “real world.”

One fear that may be inhibiting a more thorough exploration of endgame scenarios for cigarettes is that by taking what may be perceived as an “extreme” position, advocates may lose their credibility in pushing mainstream—though still contested—remedies. There appears, however, to be no historical support for this, at least in tobacco control. Smoking bans in restaurants, workplaces, and bars were seen in their time as “crazy” proposals, as were lawsuits against tobacco companies and efforts to raise cigarette taxes in an anti-tax environment. But even skeptical citizens and legislators likely viewed the public health proponents as just doing their job, since the science underlying the health concerns was generally not doubted. Indeed, the publicity surrounding each of these efforts—whether or not it was

Not surprisingly, even the FDA’s use of a Congressionally-authorized scientific panel to make recommendations regarding the fate of mentholated cigarettes has drawn a legal challenge which is moving forward. See Lorillard, Inc. v. United States FDA, No. 11-440 (RJL), 2012 WL 3542228 (D.D.C. July 30, 2012).


successful in any particular instance—reinforced the public’s awareness of the dangers of smoking and secondhand smoke.\textsuperscript{15}

So is there a legally viable endgame strategy that could work in the United States? There are several endgame strategies that will be discussed and two that appear to have particular promise in the United States.

II. SHRINKING CAP-AND-TRADE

One strategy is to carefully control and reduce the supply of cigarettes in the market such that, over time, the reduced supply of the product will compel a reduction in consumption and smoking prevalence.\textsuperscript{16} Legislation to do just this was filed in the U.S. Senate.

In 2007, Senator Mike Enzi (R-WY) sponsored the Help End Addiction to Lethal Tobacco Habits Act (HEALTH Act).\textsuperscript{17} This proposal, offered as an alternative to the then-pending Family Smoking Prevention and Tobacco Control Act (FSPTCA), included a cap-and-trade program that would “reduce the adverse health effects of tobacco use through reductions in the annual size of the tobacco market.”\textsuperscript{18} Under the proposal, each cigarette manufacturer would receive an annual allowance from the federal government indicating how many cigarettes it could produce within a given year. The allowance given to each manufacturer would be based on its current production level, and could be traded or sold to another tobacco manufacturer in a fashion similar to cap-and-trade proposals for environmental pollutants.\textsuperscript{19} Under Enzi’s bill, after 2015, it would become unlawful for a cigarette manufacturer to produce more than two-thirds of the brand’s baseline number of cigarettes, which would be established upon implementation, and by 2027, it would be unlawful to produce more than one-tenth of the baseline number of cigarettes.\textsuperscript{20} The bill was referred to the Senate Finance Committee\textsuperscript{21} where it died, and it has not been reintroduced. While this could conceivably be a workable framework for dramatic reductions in U.S. smoking prevalence, it is questionable whether the political support it had upon passage would continue once cigarettes became an ultra-high-price luxury item. Rather than de-normalizing smoking, it might have the perverse effect of glamorizing it. Furthermore, the rationale for cap-and-trade is the limited pollution carrying capacity of the atmosphere, which has no analogue with cigarette smoking.


\textsuperscript{16} One variant of this approach urges that control over the industry should be given to not-for-profit corporations with a mandate to reduce smoking rates. See C. Callard, D. Thompson & N. Collishaw, \textit{Transforming the Tobacco Market: Why the Supply of Cigarettes Should Be Transferred from For-Profit Corporations to Non-Profit Enterprises with a Public Health Mandate}, 14 TOBACCO CONTROL 278 (2005).

\textsuperscript{17} S. 1834, 110th Cong. (2007).

\textsuperscript{18} Id. at § 3001.


\textsuperscript{20} S. 1834, 110th Cong. § 3005 (2007).

\textsuperscript{21} See 21 CONG. REC. S9622-23 (daily ed. July 19, 2007).
III. LICENSE SMOKERS

Another supply-based approach would be to create a “smokers’ license” that would be in the form of a smart card required for any cigarette purchase. Such a card could limit and gradually reduce access to cigarettes over time as part of a cessation program. Presumably, it could also simply expire over time, after which cigarettes would no longer be available to that particular consumer absent a renewal and payment of a significant fee. A financial incentive to surrender one’s license could be the refund of all fees paid to date. Implementing such a program would require a complete reworking of all retail cigarette sales to be smart card compliant, and reconciliation of stock and sales records would need to be precise in order to avoid abuse of the system. The sheer number of sales outlets for cigarettes in the United States is staggering and would make such a plan particularly challenging to implement.

IV. AGRICULTURAL EXIT PLAN

One proposal from Canada is to eliminate tobacco as a cash crop by buying out farmers’ production quotas and implementing a comprehensive public prevention program with funds derived from a levy on tobacco company profits. This proposal would not necessarily reduce tobacco consumption, however, since cigarettes could simply be imported.

V. TWO PROMISING APPROACHES

While no endgame approach would be easy to implement in the United States, and those mentioned thus far present seemingly insurmountable challenges, two viable proposals remain. Both depend on FSPTCA, which President Obama signed in June 2009. One involves action at the federal level, the other action at the state or local levels.

A. NON-ADDICTIVE CIGARETTES

Under the FSPTCA, the FDA has the power to establish “tobacco product standards,” including “provisions, where appropriate, for nicotine yields of the product.” The only limitation on this power is that the FDA may not issue a regulation “requiring the reduction of nicotine yields of a tobacco product to zero.” This is not a major obstacle because the trivial amounts of nicotine present in nightshade vegetables, such as eggplants, would be within the FDA’s nicotine authority under the FSPTCA, and there is no evidence that consumption of nightshade vegetables results in dependence.

23 Id.
26 Id. at § 907 (to be codified at 21 U.S.C. § 387g).
27 Id. at § 907(a)(4)(A)(i) (to be codified at 21 U.S.C. § 387g(a)(4)(A)(i)).
28 Id. at § 907(d)(3)(B) (to be codified at 21 U.S.C. § 387g(d)(3)(B)).
The FDA is required to apply public health criteria in designing its regulations: the Secretary shall consider scientific evidence concerning—

(I) the risks and benefits to the population as a whole, including users and nonusers of tobacco products, of the proposed standard;

(II) the increased or decreased likelihood that existing users of tobacco products will stop using such products; and

(III) the increased or decreased likelihood that those who do not use tobacco products will start using such products.

Each of these considerations strongly supports a product standard reducing nicotine levels in cigarettes below addictive levels. By making cigarettes non-addictive, the sixty-nine percent of smokers who want to quit will find it much easier to do so and those who cannot eliminate their nicotine dependence may switch to much less toxic non-combusted tobacco products. Current nonsmokers could not become addicted smokers. The lives saved—including those who would otherwise have been smokers or exposed to secondhand smoke—would eventually number in the hundreds of thousands per year.

Additional mandated considerations under FSPTCA are technical feasibility and countervailing considerations. We know non-addictive cigarettes are feasible since tobacco companies have occasionally produced and marketed them. The National Institute on Drug Abuse has also commissioned a large study to determine whether gradual nicotine reductions or “cold turkey” is the preferable strategy. The principal countervailing consideration mentioned in the Act is the possibility of “the creation of a significant demand for contraband or other tobacco products that do not meet the requirements of this chapter and the significance of such demand.” While there would surely be some demand for and supply of contraband nicotine-rich cigarettes, the facts that most smokers want to quit and that a wide range of pharmaceutical aids and non-smoked tobacco products would be legally available (the phasing out of the latter could be handled at a later date) would insure that the existence of contraband would not vitiate the benefits of the regulation.

Obviously, cigarette manufacturers will legally challenge any efforts to adopt such a tobacco product standard. If past litigation by the industry is a guide, a legal challenge is likely to take several years to resolve, but this particular legal attack seems unlikely to succeed. The language of the FSPTCA clearly gives the FDA the

---

29 Id. at § 907(a)(3)(B) (to be codified at 21 U.S.C. § 387g(a)(3)(B)).
30 See CDC, Quitting Smoking Among Adults—United States, 2001-2010, 60 MORTALITY & MORTALITY (WKLY. REP.) 1513, 1513 (2011).
31 See Family Smoking Prevention and Tobacco Control Act § 907(b) (to be codified at 21 U.S.C. § 387g(b)).
32 See David A. Kessler et al., The Food and Drug Administration’s Regulation of Tobacco Products, 335 NEW. ENG. J. MED. 988, 989 (1996) (providing two examples of tobacco products marketed that contained no nicotine.).
34 Family Smoking Prevention and Tobacco Control Act § 907(b)(2) (to be codified at 21 U.S.C. § 387g(b)(2)).
35 See CDC, supra note 30, at 1513.
REGULATORY APPROACHES TO ENDING CIGARETTE-CAUSED DEATH AND DISEASE IN THE UNITED STATES 295

power to adopt such a standard,36 and the legislative history of the provision begins with a 1994 New England Journal of Medicine article urging just such a standard for the purpose of freeing smokers from nicotine addiction and preventing other from acquiring it.37

Another defense that would be utilized by cigarette manufacturers would be to orchestrate a sophisticated public relations campaign. Such a strategy was first adopted by the industry when the smoking and health crisis frightened customers in the 1950s. The industry worked closely with the firm Hill & Knowlton to reassure the public with a fraudulent pledge to conduct research.38 This time, however, manufacturers’ public relations attack would be greatly complicated by their longtime public posture (and still-current litigation position) that smokers “choose” to smoke.39 The fundamental idea with this potential regulatory intervention is to make smoking a genuine matter of choice by taking addiction out of the decision-making process. Cigarette manufacturers’ legislative options are also limited because, while they could surely block legislation directly imposing a non-addictive cigarette product standard, passing legislation to block FDA action is somewhat more difficult. Through friends in Congress, the industry could try to limit FDA funding in ways to prevent the rule from advancing and it would take a firm Executive Administration position supported by strong public health lobbying and public advocacy to keep them from being successful. It can also be anticipated that cigarette manufacturers will seek every opportunity to urge the Executive Administration not to take this step, and to block or delay proposed regulations throughout the FDA’s administrative process. Such tactics would seem more likely to delay rather than deny final rulemaking action by FDA to make combustible tobacco products non-addictive.

B. SMOKE-FREE MILLENNIAL GENERATION

The second, and completely complementary, viable U.S. cigarette endgame strategy looks to state and local authority preserved by the FSPTCA. Under a section entitled “Preservation of State and Local Authority,”40 the Act affirms (twice) the authority of “a State or political subdivision of a State . . . to enact, adopt, promulgate, and enforce any law, rule, regulation, or other measure with respect to tobacco products . . . including a law, rule, regulation, or other measure relating to or prohibiting the sale, distribution, possession, exposure to, access to . . . or use of tobacco products by individuals of any age.”41 While this authority probably existed prior to the FSPTCA, its existence cannot be doubted today. This provides an opportunity for states, and even smaller governmental units, to adopt the Smokefree Millennial Generation proposal, a brilliant strategy devised by a mathematics professor and tobacco control advocate in Singapore, which is under active

41 Id. at § 916(a)(1) (to be codified at 21 U.S.C. § 387p(a)(1)).
consideration in Singapore, Tasmania. Unlike the other endgame strategies considered herein, the simplicity of this proposal is part of its appeal and power: no person born after December 31, 1999 shall be sold cigarettes.43 This proposal has many strengths: (1) the Millennials—now 13 at the oldest—will never start smoking, and will never have to figure out how to quit; (2) almost no one, including smokers, wants their children to smoke; (3) the proposal has only a marginal impact each year on retailers and tobacco farmers, reducing political opposition; (4) it is easy for retailers to enforce; (5) not long into the implementation period, smoking will begin to look less to Millennials and to older smokers like a tragic affliction of the no-longer-young; (6) the proposal is thematically compatible with the potential FDA effort to prohibit addictive levels of nicotine in cigarettes (i.e. prevent addiction and premature deaths); and (7) it provides a useful focus for state and local public health officials and advocates to do something game-changing, rather than sitting on the sidelines waiting for a federal solution from Washington.

The major argument against it is likely to be that, in the United States, would-be smokers could simply go to an adjoining jurisdiction to buy their cigarettes. While this is true, the fact that states have sharply raised their cigarettes taxes and have experienced large revenue increases and smoking prevalence reductions demonstrates the limited impact of border-crossing and smuggling, even on addicted smokers.44 The impact should be even less on Millennials, who are not addicted, have limited cross-border mobility, have no current interest in smoking, and are in an era where less than ten percent of teenagers are daily smokers.45 The tobacco industry’s public opposition would raise again the specter of Joe Camel, the vilified marketing campaign that helped define them as needing replacement. The tobacco industry’s public opposition wo could not make a legal challenge based on preemption or dormant Commerce Clause theories, and a hundred-year-old Supreme Court case upholding Tennessee’s ban on cigarette sales against a Due Process challenge should still be good law.46

VI. CONCLUSION

Despite the halving of smoking rates over the past fifty years, cigarette smoking continues to kill more than 400,000 Americans each year.47 Regular incremental progress continues, but it is unlikely in the foreseeable future to dislodge cigarette smoking from its position as the leading preventable cause of death in the United States. Nonetheless, dramatically reducing smoking and the cycle of addiction, 42 Deborah Khoo et al., Phasing-Out Tobacco: Proposal to Deny Access to Tobacco for Those Born from 2000, 19 TOBACCO CONTROL 355, 355-56 (2010); see also Palash R. Ghosh, Tasmania Seeks to Create Tobacco-Free Generation by Banning Cigarette Sales to Anyone Born After 2000, INT’L BUS. TIMES (Aug. 22, 2012), http://www.ibtimes.com/tasmania-seeks-create-tobacco-free-generation-banning-cigarette-sales-anyone-born-after-2000-752901.

43 Khoo et al., supra note 42, at 356.

44 See MATTHEW C. FARRELLY ET AL., STATE CIGARETTE EXCISE TAXES: IMPLICATIONS FOR REVENUE AND TAX EVASION 6-8 (2003), available at http://www.rti.org/pubs/8742_excise_taxes_fr_5-03.pdf (finding total revenue increased as excise taxes increased despite decrease in smoking prevalence and smuggling in response to these tax increases).


46 See Austin v. Tennessee, 179 U.S. 343, 361-63 (1900).

47 CDC, supra note 1, at 1226.
disease, and death associated with it is something that can be largely accomplished by the end of the decade. Different solutions may work better for different countries, but two complementary ways to make this happen in the United States—nicotine reduction and the smoke-free millennial generation proposal—deserve serious and urgent consideration.