INTRODUCTION

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Tobacco control is at a crossroads. The principal goal of this well-established public health movement has been the eradication of tobacco use, a deadly habit that causes tremendous harm while providing no real benefit to society. In the United States, cigarette-caused disease leads to 440,000 deaths annually, one-third of which are caused by cancer; of those, 87% are lung cancer deaths.[1] Because an outright ban on cigarettes and other tobacco products remains impractical and politically impossible, alternative methods to reduce the devastating health effects from tobacco use have been employed. Aimed at reducing consumption, these methods have included public education about the health dangers of smoking and tobacco use, encouraging cessation with assistance from nicotine replacement therapy (NRT), and preventing initiation—especially by minors. These methods have been successful: from 1965 to 1990, the percentage of U.S. adult smokers dropped significantly from an astounding 65% to a more manageable 23%.[2]

In the 1990s, tobacco control strategy expanded from its focus on the health effects on the smoker, to counteracting the negative health consequences of nonsmokers' exposure, and to reducing secondhand smoke, also known as environmental tobacco smoke (ETS).[3] Tobacco control legislation and regulation

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1. Am. Cancer Soc'y, Cigarette Smoking, www.cancer.org/docroot/PED/content/PED_10_2X_Cigarette_Smoking.asp (last visited Jan. 29, 2008).

2. Thomas G. Parish, *Financing Smoking-Related Illness and Smoking Cessation in the United States: Can it be Done?*, 2 INTERNET J. ALLIED HEALTH SCI. & PRACTICE (2004), http://ijahsp.nova.edu/articles/Vol2num1/tom_parish_pac_mph.htm; *see also* Ctrs. for Disease Control & Prevention, *Tobacco Use – United States, 1990–1999*, 48 MORBIDITY & MORTALITY WKLY. REP. 985, 989 (1999) (linking the reduction in cigarette consumption to various factors, such as educating the public, cessation programs, and improvement in treatment programs), *available at* http://www.cdc.gov/mmwr/PDF/wk/mm4843.pdf. The imposition of significant federal and state excise taxes on cigarette sales has also played a critical role in lowering tobacco use. *Id.*

3. NAT'L CANCER INST., U.S. DEPT. OF HEALTH & HUMAN SERVS. STRATEGIES TO CONTROL TOBACCO USE IN THE UNITED STATES: A BLUEPRINT FOR PUBLIC HEALTH ACTION IN THE 1990'S, at 20–21 (1991). ETS accounts for approximately 50,000 nonsmoking adult deaths annually, 3,400 from lung cancer and 46,000 from heart disease. Am. Lung Ass'n, Secondhand Smoke Fact Sheet, http://www.lungusa.org/site/pp.asp?c=dvLUK9O0E&b=35422 (last visited Jan. 29, 2008); *accord* Ctrs. for Disease Control & Prevention, Fact Sheet: Secondhand Smoke (2006),

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designed to protect nonsmoking bystanders from ETS has burgeoned from indoor smoking bans in workplaces and schools to comprehensive bans on smoking—and sometimes total tobacco use—in all public places, including bars and restaurants, to places previously considered untouchable by such bans, including outdoor areas, foster homes, and cars carrying children.[4] Such bans not only protect public health by reducing exposure to toxins contained in ETS, they also help reduce tobacco consumption because people who are prevented from smoking at work and in public places are more likely to smoke fewer cigarettes or to quit smoking altogether.[5]

While the decline in smoking prevalence and reduced exposure to ETS are certainly victories that have saved lives and enhanced public health, the current adult smoking prevalence rate, which is nearly 21%,[6] has barely changed since 2004.[7] This begs the question *why*? Could it be that public education on the vagaries of tobacco use has reached its zenith and is no longer capable of effectuating the change in smoking habits necessary to prevent youth initiation and reduce adult smoking prevalence even further? Will NRT and other cessation methods to help smokers quit, which are beneficial to some, remain too costly or ineffectual for others?

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http://www.cdc.gov/tobacco/data_statistics/Factsheets/SecondhandSmoke.htm (last visited Jan. 29, 2008).

4. *E.g.*, ARK. CODE ANN. § 20-27-1903 (Supp. 2007) (prohibiting smoking in automobiles carrying children under six years of age who are restrained in car seats); ARK. CODE ANN. § 9-28-413 (Supp. 2007) (prohibiting the Department of Human Services from placing or permitting a child to remain in a foster home where a foster parent smokes unless it is in the child's best interests to be placed in or to remain in the foster home); MD. CODE ANN., HEALTH–GEN. § 24-504 (West Supp. 2007) (prohibiting smoking in indoor areas open to the public, a government-owned or government-operated means of transportation, and indoor places of employment); CALABASAS, CAL., ORDINANCE ch. 8.12.040(B)(4) (2006) (prohibiting smoking in virtually any public area in Calabasas, California, including outdoor areas where nonsmokers are present), *available at* http://www.bpcnet.com/codes/calabasas.

5. Sherry Emery et al., *Characterizing and Identifying "Hard-Core" Smokers: Implications for Further Reducing Smoking Prevalence*, 90 AM. J. PUB. HEALTH 387, 393 (2000) ("[B]oth workplace and home smoking bans have been shown to be associated with quitting behavior [among smokers].").

6. In 2006, the adult rate of smoking was 20.8%, which amounts to approximately 45.3 million adults. Ctrs. for Disease Control & Prevention, *Cigarette Smoking Among Adults—United States, 2006*, 56 MORBIDITY & MORTALITY WKLY. REP. 1157, 1157 (2007) [hereinafter *Cigarette Smoking Among Adults 2006*], *available at* http://www.cdc.gov/mmwr/PDF/wk/mm5644.pdf; Ctrs. for Disease Control & Prevention, *Great American Smokeout – November 15, 2007*, 56 MORBIDITY & MORTALITY WKLY. REP. 1157, 1157 (2007) [hereinafter *Great American Smokeout*], *available at* http://www.cdc.gov/mmwr/PDF/wk/mm5644.pdf. Youth smoking rates in 2004 were around 22.3% for high schoolers and 8.1% for middle schoolers. Am. Cancer Soc'y, *supra* note 1. For more statistics on smoking, see Am. Lung Ass'n, Smoking 101 Fact Sheet, http://www.lungusa.org/site/pp.asp?c=dvLUK9O0E&b=39853 (last visited Jan. 29, 2008).

7. *Compare* Ctrs. for Disease Control & Prevention, *Cigarette Smoking Among Adults—United States, 2004*, 54 MORBIDITY & MORTALITY WKLY REP. 1121, 1121 (2005), *available at* http://www.cdc.gov/mmwr/PDF/wk/mm5444.pdf (20.9% adult smokers in 2004), *with Cigarette Smoking Among Adults 2006*, *supra* note 6 (20.8% adult smokers in 2006).

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The inescapable fact is that some people are simply unable or unwilling to stop smoking, no matter what.[8] Though laudable, the national health objective of attaining a 12% adult smoking rate by the year 2010 is frankly unreachable even years from then.[9] And even if we were to achieve that goal at some time, 12% of the U.S. population still represents a significant number of people suffering a great deal of harm from smoking. Overcoming these obstacles will be a major challenge for public health officials, tobacco control advocates, and lawmakers in the 21st century.

As a public health movement, tobacco control's ultimate goal is finding ways to reduce the harm caused by tobacco use—harm to the individual smoker, the smoking population, and the nonsmoking population. Since the negative health effects of cigarettes were first broadly exposed as early as the 1950s, the response of tobacco companies has been to come up with some technological innovation ostensibly designed to reduce smokers' risks of exposure to the harmful chemicals in tobacco smoke.[10] From filtered cigarettes to so-called light and lower-tar cigarettes, smokers have been fooled into switching to allegedly safer cigarettes.[11] New additions to this false marketing include nicotine-free products such as Vector's Quest cigarette[12] and "lower risk" cigarettes such as R.J. Reynolds' Eclipse® product.[13] Time and again, cigarette manufacturers have marketed products with subtle or blatant reduced harm messages while the smoking population has experienced no real reduction in harm from using these supposedly "safer" products.[14]

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8. Emery et al., *supra* note 5, at 387–88, 393.

9. 2 U.S. DEP'T OF HEALTH & HUMAN SERVS., HEALTHY PEOPLE 2010, at 27-10 (2d ed. 2000), *available at* http://www.healthypeople.gov/Document/pdf/Volume2/27Tobacco.pdf; Asaf Bitton et al., *Reducing Smoking Prevalence to 10% in Five Years*, 286 JAMA 2733, 2733 (2001); David Mendez & Kenneth E. Warner, *Adult Cigarette Smoking Prevalence: Declining as Expected (Not as Desired)*, 94 AM. J. PUB. HEALTH 251, 252 (2004); David Mendez & Kenneth E. Warner, *Smoking Prevalence in 2010: Why the Healthy People Goal Is Unattainable*, 90 AM. J. PUB. HEALTH 401, 403 (2000).

10. Mitch Zeller, Remarks at the University of Maryland School of Law Symposium: Safer Tobacco Products: Reducing Harm or Giving False Hope? (Apr. 20, 2007) (transcript available in the Legal Resource Center for Tobacco Regulation, Litigation and Advocacy at the University of Maryland School of Law).

11. *See* United States v. Philip Morris USA, Inc., 449 F. Supp. 2d 1, 912–13 (D.D.C. 2006) (establishing that cigarette companies knowingly deceived consumers into believing that low-tar cigarettes were less hazardous than full-flavor cigarettes).

12. Press Release, Matthew L. Myers, President, Campaign for Tobacco-Free Kids, Vector's Claims About "Nicotine-Free Cigarettes" Underscores Need for Congress to Grant FDA Authority over All Tobacco Products (Jan. 30, 2003), *available at* http://www.tobaccofreekids.org/Script/DisplayPressRelease.php3?Display=593&zoom_highlight=vectr.

13. Press Release, Campaign for Tobacco-Free Kids, New Scientific Study Contradicts R.J. Reynolds' Claims that Eclipse is a "Reduced-Risk" Cigarette (Oct. 4, 2000), http://www.tobaccofreekids.org/Script/DisplayPressRelease.php3?Display=305.

14. *See* DOROTHY HATSUKAMI & STEPHEN HECT, UNIV. OF MINN. TRANSDICIPLINARY TOBACCO USE RESEARCH CTR., HOPE OR HAZARD? WHAT RESEARCH TELLS US ABOUT "POTENTIALLY REDUCED-EXPOSURE" TOBACCO PRODUCTS 4–5 (2005), *avalaible at*

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Given the lack of success in obliterating tobacco use, proponents of true reduced harm products have begun to tout smokeless tobacco products as a suitable, "healthier" alternative to the combustible cigarette.[15] Focused on "snus," a smokeless product popular in Sweden and now being test marketed in the U.S., the debate about the health properties of smokeless tobacco vis-à-vis cigarettes is a rancorous one, and puts public health and tobacco control advocates in an awkward position. How can one promote use of a product, albeit one less dangerous than cigarettes, that nevertheless may cause cancer and kill people who use it?[16] The dynamics of this debate reach a zenith when the possibility of potentially reduced harm combustible tobacco products enters the fray. To promote the use of a cigarette of any kind simply seems beyond the role of public health and tobacco control advocates.

This leaves public health professionals and those in the tobacco control movement with critical questions in terms of goals and policies: Do we as a community persist with the abstinence-only approach despite knowing that we may not move much lower than a 20%—one in five adults—smoking prevalence? Do we wave the white flag and simply accept the excessive toll of serious disease and death that will continue to befall the hard-core smoking population in generations to come? Or do we seek to somehow ameliorate the harm to this population by fostering the manufacture of safer, consumer-acceptable products to those for whom quitting is not an option? If we choose the latter, how do we ensure that the tobacco industry, which has traditionally deceived the public about the dangers of its products, acts with integrity in developing and marketing safer products? How should the federal and state governments act to protect consumers against confusing, misleading, or blatantly false claims? What is the role of litigation in the reduced harm arena?

On April 20, 2007, the University of Maryland School of Law hosted a first-of-its-kind symposium on the issue of reduced harm tobacco products, an event in which all perspectives were welcomed and debated respectfully. More than

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http://www.tturc.umn.edu/documents/hope_or_hazard-3.pdf (explaining that there is no convincing evidence to support the claims that some tobacco products result in reduced harm exposure to toxins or reduced risk of tobacco-related disease).

15. INST. OF MED., CLEARING THE SMOKE 82, 92–93 (Kathleen Stratton et al. eds., 2001).

16. *E.g.*, Neil A. Accortt et al., *Chronic Disease Mortality in a Cohort of Smokeless Tobacco Users*, 156 AM. J. EPIDEMIOLOGY 730, 736 (2002) (concluding "that smokeless tobacco use is a safer alternative than continued cigarette smoking" based on evidence from a study of smokeless tobacco users); Juhua Luo et al., *Oral Use of Swedish Moist Snuff (Snus) and Risk for Cancer of the Mouth, Lung, and Pancreas in Male Construction Workers: A Retrospective Cohort Study*, 369 LANCET 2015, 2019 (2007) (finding that oral use of snus may be associated with an increased risk of pancreatic cancer); Am. Cancer Soc'y, Smokeless Tobacco and How to Quit, http://www.cancer.org/docroot/PED/content/PED_10_13X_Quitting_Smokeless_Tobacco.asp (last visited Feb. 27, 2008) (explaining that the use of smokeless tobacco, including snus, "can cause cancer of the mouth and pancreas and many other health problems . . . .").

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seventy-five members of the tobacco control community throughout the U.S. gathered to hear prominent experts and advocates from the fields of public health, science, communications, and law discuss varying perspectives on the issue of *"Safer" Tobacco Products: Reducing Harm or Giving False Hope?* The over-arching issue addressed was the possibility and desirability of allowing manufacturers of so-called potentially reduced harm tobacco products to market and sell these products as genuine alternatives to cigarettes so as to minimize the negative health consequences to inveterate smokers, rather than as alternative tobacco products actually designed to secure large profit margins for Big Tobacco.

The articles from the symposium published in this issue of the *Journal of Health Care Law & Policy* tackle the issues raised above. Micah Berman writes about current and potential legal challenges to reduced harm claims, specifically addressing the marketing of smokeless tobacco. Mr. Berman concludes that the cigarette companies' entrance into the smokeless tobacco market is a major development with potential negative public health repercussions. He therefore urges public health advocates to work together to respond appropriately to this development. Christopher Banthin and Richard Daynard delve deeper into the legal arena, explaining the role of litigation in preventing false reduced-harm claims and using the ongoing litigation over the marketing of light and lower-tar cigarettes as a case study. Mr. Banthin and Dr. Daynard discuss how federal preemption of state law claims would be impacted by the passage of legislation pending in Congress that would finally give the Food and Drug Administration authority to regulate tobacco products. David Sweanor and Rachel Grunberger provide a unique perspective, perhaps born of Mr. Sweanor's work in progressive Canada, in arguing that the abstinence-only approach must yield to the more rational reduced-harm approach. Mr. Sweanor and Ms. Grunberger implore the public health community to acknowledge that part of the population will always use tobacco, yet caution that adequate regulation is vital to ensure the best result. Finally, in a piece based on her keynote speech at the symposium, Dr. Cheryl Healton powerfully reminds us of the disastrous consequences of an abstinence-only approach in the context of HIV/AIDS prevention, warning advocates not to repeat that failed public health strategy in the tobacco control realm.

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