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The Basis of a Comprehensive Regulatory Policy for Reduced Harm Tobacco Products

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THE BASIS OF A COMPREHENSIVE REGULATORY POLICY FOR REDUCED HARM TOBACCO PRODUCTS

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INTRODUCTION

There has been a longstanding, worldwide interest in using regulatory practices to deal with tobacco products.[1] Over the past twenty-five years, there have been many significant advances in areas such as tobacco product taxation,[2] reduction of sales outlets for tobacco products,[3] prevention of sales to minors,[4] advertising and promotion restrictions,[5] package warnings,[6] enforcement of smoke-

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1. *See generally* LUK JOOSSENS, WORLD HEALTH ORG., REGULATION OF TOBACCO PRODUCTS: AN UPDATE ON EUROPEAN DEVELOPMENTS 1999–2001, at 1–10 (2001), *available at* http://www.euro.who.int/document/e74524.pdf; WORLD HEALTH ORG., MONOGRAPH: ADVANCING KNOWLEDGE ON REGULATING TOBACCO PRODUCTS, 59–64 (2001), *available at* http://www.who.int/tobacco/media/en/OsloMonograph.pdf; MITCHELL ZELLER, WORLD HEALTH ORG., REGULATION OF TOBACCO PRODUCTS 2–8 (2000), *available at* http://www.who.int/tobacco/media/en/ZELLER2000X.pdf.

2. AM. LUNG ASS'N, STATE LEGISLATED ACTIONS ON TOBACCO ISSUES: 2005, at vi (2005), *available at* http://slati.lungusa.org/reports/SLATI_05.pdf; RICHARD MCGOWAN, BUSINESS, POLITICS, AND CIGARETTES 79 (1995) ("The measure that government at all levels has employed most frequently to discourage the sale of cigarettes is the cigarette excise tax.").

3. *E.g.*, Smoke-Free Ontario Act, 1994 S.O., ch. 10 § 4 (Ont.), *available at* http://www.health.gov.on.ca/english/public/updates/archives/hu_05/smoke_free_ontario_act.pdf; Tobacco Control Act, S.S., ch.T-14.1 § 8 (2001), *amended by* 2002 S.S., ch. R-8.2 § 97 & 2004 S.S., ch. 51 § 6 (Sask.), *available at* http://www.qp.gov.sk.ca/documents/english/Statutes/Statutes/t14-1.pdf.

4. JESSICA KUEHNE & ERIC LINDBLOM, CAMPAIGN FOR TOBACCO-FREE KIDS, ENFORCING LAWS PROHIBITING CIGARETTE SALES TO KIDS REDUCES YOUTH SMOKE 1 (2007), *available at* http://tobaccofreekids.org/research/factsheets/pdf/0049.pdf ("Efforts to reduce illegal cigarette sales to kids can have a direct impact on roughly three-quarters or more of all cigarettes smoked by kids.").

5. Marc C. Willemsen & Boudewijn de Blij, GLOBALink, Tobacco Control Factsheets: Tobacco Advertising, http://factsheets.globalink.org/en/advertising.shtml (last visited Jan. 17, 2008).

free spaces,[7] and regulation of cigarettes for fire safety.[8] Yet, cigarette smoking continues to be the largest cause of preventable death[9] even in countries like Canada, where per capita cigarette consumption has been driven down by over 60%.[10] Furthermore, the World Health Organization (WHO) estimates that tobacco smoke will have caused nearly one billion deaths this century.[11] Therefore, some key questions remain about the direction of regulatory policy and how we might further reduce tobacco's toll.

I. THE CHALLENGE

It is worth noting that many people consider death and disease from smoking a medical problem[12] and have trouble understanding the need for legal interference. However, there are many ways that (and many reasons why) the law can be used in advancing a public health agenda. It is important to point out that in the history of public health, discovering the cause of a health problem has been a medical or scientific question, but acting on such a discovery raises social, political, and legal issues. Major scientific breakthroughs, like the role of sanitation,[13] immunization,[14] safe food preparation,[15] and effective drug treatments,[16] have created public health breakthroughs that are only fully achieved when policies are changed to reflect

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6. ROB CUNNINGHAM, CAN. CANCER SOC'Y, PACKAGE WARNINGS: OVERVIEW OF INTERNATIONAL DEVELOPMENTS 1 (2007), *available at* http://www.smoke-free.ca/warnings/WarningsResearch/Release_WarningLabels_20070320.pdf.

7. *E.g.*, Mark Levin, *Tobacco Industrial Policy and Tobacco Control Policy in Japan*, 6 ASIAN-PAC. L. & POL'Y J. 44, 51 (2005) (discussing the proliferation of smoke-free spaces across Japan).

8. HILLEL R. ALPERT, TOBACCO CONTROL LEGAL CONSORTIUM, REGULATING CIGARETTES FOR FIRE SAFETY *passim* (2007), *available at* http://www.firesafecigarettes.org/assets/files//RegulatingCigsforFireSafety0507.pdf.

9. CTRS. FOR DISEASE CONTROL, DEP'T OF HEALTH & HUMAN SERVS., TARGETING TOBACCO USE: THE NATION'S LEADING CAUSE OF PREVENTABLE DEATH 2 (2007), *available at* http://www.cdc.gov/nccdphp/publications/aag/pdf/osh.pdf; World Health Org., An International Treaty for Tobacco Control (Aug. 12, 2003), http://www.who.int/features/2003/08/en/.

10. *See* ROB CUNNINGHAM, SMOKE & MIRRORS: THE CANADIAN TOBACCO WAR 16–17 figs.3 & 4 (1996); Canadian Trends in Historical Per Capita Cigarette Consumption (Age 15+), 1921–2005 (on file with author).

11. Ed Cropley, *Smoking Could Kill 1 Billion This Century - WHO*, REUTERS, July 2, 2007, *available at* http://www.reuters.com/article/latestCrisis/idUSBKK252060.

12. *See, e.g.*, Atiya Dhala et al., *Respiratory Health Consequences of Environmental Tobacco Smoke*, 88 MED. CLINICS N. AM. 1535 *passim* (2004) (discussing the major health problems associated with tobacco smoke).

13. GEORGE E. WARING, JR., DRAINING FOR PROFIT AND DRAINING FOR HEALTH 222–23 (New York: Orange Judd & Co. 1893) (1867).

14. *E.g.*, JONATHAN B. TUCKER, SCOURGE: THE ONCE AND FUTURE THREAT OF SMALLPOX 3–4 (2001) (demonstrating that vaccinations eradicated the infectious disease of small pox).

15. *E.g.*, JAMES HARVEY YOUNG, PURE FOOD: SECURING THE FEDERAL FOOD AND DRUGS ACT OF 1906 136–45 (1989) (discussing the health risks posed by adding preservatives to food).

16. *E.g.*, HIV/AIDS PROGRAMME, WORLD HEALTH ORG., ANTIRETROVIRAL THERAPY FOR HIV INFECTION IN ADULTS AND ADOLESCENTS 7, 11–12 (2006).

these advances in knowledge. Using regulatory interventions to prevent diseases caused by smoking is simply following in the footsteps of past public health battles.

Regulatory policies for tobacco products should focus on the ultimate public health goal of the reduction of death, injury, and disease.[17] As with other public health measures (e.g., the control of venereal diseases,[18] alcohol policies,[19] drug issues,[20] and birth control[21]), there is often a strong tendency on the part of some people to take moralistic approaches about the behavior of others rather than taking pragmatic public health approaches aimed at reducing death, injury, and disease. In the case of tobacco and nicotine, there is a strong abstinence-only contingent within the anti-tobacco community that condemns any use of nicotine without apparent concern for issues of relative risk and the potential to move users to far less toxic alternative delivery systems.[22]

If tobacco-caused illness is to be addressed through effective regulatory policy, it is critically important that the focus be on pragmatic measures aimed at reducing death, injury, and disease, rather than simply imposing moral judgments on the actions of others. Indeed, there are four broad pillars of intervention for the purpose of reducing death, injury and disease from any dangerous activity.[23] Interventions can aim to: (1) prevent the onset of a dangerous behavior; (2) encourage cessation of the behavior; (3) seek to reduce the risk the behavior inflicts on third parties; and (4) attempt to reduce risks for those who continue to engage in the behavior.[24]

There is a similarly broad range of strategies that can be used in an effort to apply law to achieve the goal of reduced health impact via these four broad areas of

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17. *See generally* David Sweanor et al., Editorial, *Tobacco Harm Reduction: How Rational Public Policy Could Transform a Pandemic*, 18 INT'L J. DRUG POL'Y 70, 70 (2007) (encouraging public intervention to reduce the risk of death, injury, or disease from tobacco smoke).

18. ALLAN M. BRANDT, NO MAGIC BULLET: A SOCIAL HISTORY OF VENEREAL DISEASE IN THE UNITED STATES SINCE 1880, at 6 (1985) ("[T]he social and cultural uses of venereal disease as a means of controlling sexuality have greatly complicated attempts to deal effectively with diseases from a therapeutic standpoint.").

19. EDWARD BEHR, PROHIBITION: THIRTEEN YEARS THAT CHANGED AMERICA 21 (1996).

20. MICHAEL MASSING, THE FIX 85–86 (1998).

21. JACK HOLLAND, MISOGYNY 236–37 (2006).

22. Brad Rodu & William T. Godshall, *Tobacco Harm Reduction: An Alternative Cessation Strategy for Inveterate Smokers*, HARM REDUCTION J., Dec. 2006, at 37, http://www.harmreductionjournal.com/content/pdf/1477-7517-3-37.pdf ("In effect, the status quo in smoking cessation presents smokers with just two unpleasant alternatives: quit or die."); Philip Alcabes, Editorial, *Blowing Smoke About Tobacco*, WASH. POST, May 30, 2006, at A17 (comparing the more lenient policy approaches to regulating risky behavior regarding motorcycle helmets and condoms to the no tolerance policy approach dealing with tobacco use); World Health Org., Tobacco Free Initiative, 100% Smoke-free is the Only Answer, http://www.who.int/tobacco/communications/events/wntd/2007/smoke_free/en/index.html (last visited Jan. 19, 2008).

23. Sweanor et al., *supra* note 17.

24. *Id.*

public health intervention. Once again, we can group the strategies into four general areas. The first area deals with accessibility. This area includes measures that impact the relative accessibility of different tobacco products and tobacco dependence treatment products.[25] To reduce the accessibility of tobacco products, the law has been used to adjust the taxes on various tobacco/nicotine products,[26] restrict the locations where various products are sold, prevent sales to minors,[27] ban vending machines,[28] prohibit the distribution of free samples,[29] and increase the accessibility of products that can assist smoking cessation.[30]

A second strategic area is the promotion of informed choice. While there are limitations on consumer sovereignty when dealing with addictive products, the law has still played a huge role in many areas, such as dealing with misleading advertising and promotion,[31] and requiring detailed package health messages and disclosure of product ingredients.[32] The pursuit of informed choice for consumers has also been facilitated through the approval of an ever-wider range of tobacco dependence treatment products for a growing range of indicated uses.[33] In recent years there has also been increased interest in dispelling myths about nicotine itself (many smokers believe it to be a huge health risk) and in ending the misleading information that causes smokers to believe that some alternative products (such as medicinal nicotine and various types of smokeless tobacco) are not significantly less toxic than cigarette smoking.[34]

The third broad area of strategy in achieving health gains through legal measures is obtaining the protection of third parties. As a result of several municipal, state or provincial, and federal laws, as well as various litigation and administrative interventions, governments have enforced a wide range of protections against environmental tobacco smoke (also known as second-hand

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25. Dorothy K. Hatsukami et al., *Reducing Tobacco Harm: Research Challenges And Issues*, 4 NICOTINE & TOBACCO RES. S89, S93 (2002).

26. Michelle Leverett et al., *Tobacco Use: The Impact of Prices*, 30 J.L. MED. & ETHICS 88, 88–89 (2002).

27. KUEHNE & LINDBLOM, *supra* note 4.

28. Jean L. Forster & Mark Wolfson, *Youth Access to Tobacco: Policies and Politics*, 19 ANN. REV. PUB. HEALTH 203, 206 (1998).

29. AM. LUNG ASS'N, *supra* note 2, at vii.

30. *See, e.g.*, Tamar Nordenberg, *It's Quittin' Time*, FDA CONSUMER, Nov.–Dec. 1997, at 19, 20 ("For many smokers who want to quit, willpower alone isn't enough to beat the yearning. For them, smoking cessation products the Food and Drug Administration has approved may reduce the cravings and other withdrawal symptoms.").

31. Richard Craswell, *Taking Information Seriously: Misrepresentation and Nondisclosure in Contract Law and Elsewhere*, 92 VA. L. REV. 565, 588–89 (2006).

32. PETER D. JACOBSON & JEFFREY WASSERMAN, TOBACCO CONTROL LAWS 7 (1997).

33. *See* Nordenberg, *supra* note 30, at 20–23.

34. *See, e.g.*, TOBACCO ADVISORY GROUP, ROYAL COLL. OF PHYSICIANS OF LONDON, PROTECTING SMOKERS, SAVING LIVES 4–5 (2002).

smoke), and have guaranteed broad protections in many countries.[35] Further regulatory measures, such as a requirement for reduced ignition propensity cigarettes, have reduced the risk to third parties from other cigarette-related injuries, like cigarette-caused fires.[36] Interestingly, protection of third parties is already, at least partially, based on the recognition that it is possible to reduce the overall harm caused by tobacco use without necessarily requiring complete cessation.[37]

Finally, broad product regulatory standards can dramatically reduce the risks associated with tobacco use. Aside from the requirement to reduce the ignition propensity of cigarettes and the provision of greater access to smoking cessation products, various jurisdictions are now starting to take a serious look at product standards.[38] This relatively late move to look at the products themselves is seemingly anomalous to product standards that are based on the recognition of a continuum of risk, which have traditionally played one of the greatest roles in reducing many other public health risks.[39] In addition, tobacco products containing nicotine seem ideally suited for such interventions since the risk is virtually all due to the delivery system rather than the nicotine itself.[40] Most users smoke cigarettes

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35. *See, e.g.*, 20 U.S.C. §§ 6081, 6083 (2000) (codifying the Pro-Children Act of 1994 that prohibits smoking in many types of facilities that routinely provide services to children, such as libraries, day care facilities and elementary schools); 49 U.S.C. § 41706 (2000) (barring smoking on all United States airline flights arriving in or departing from the United States); 41 C.F.R. § 102-74.315 (2004) (banning smoking from all offices owned or used by the executive branch of the federal government); 49 C.F.R § 374.201 (2005) (prohibiting smoking on all buses transporting passengers on an interstate service); Levin, *supra* note 7; Jordan Raphael, Note, *The Calabasas Smoking Ban: A Local Ordinance Points the Way for the Future of Environmental Tobacco Smoke Regulation*, 80 S. CAL. L. REV. 393, 393 (2007).

36. ALPERT, *supra* note 8, at 7 ("Almost 27% of the U.S. population and all of Canada will soon be covered by fire-safe cigarette legislation. With other states and countries, including Australia, New Zealand, and members of the European Union, potentially following suit, the trend may lead to total U.S.—and eventually nearly global—coverage."); Health Canada, Reduced Ignition Propensity Cigarettes, http://www.hc-sc.gc.ca/hl-vs/tobac-tabac/legislation/reg/ignition-alllumage/index_e.html (last visited Jan. 18, 2008).

37. TOBACCO ADVISORY GROUP, ROYAL COLL. OF PHYSICIANS OF LONDON, HARM REDUCTION IN NICOTINE ADDICTION 213 (2007), *available at* http://www.rcplondon.ac.uk/pubs/contents/4fc74817-64c5-4105-951e-38239b09c5db.pdf; *see also* MICHAEL BLEWDEN, ACTION ON SMOKING & HEALTH, DISCUSSION DOCUMENT AND POLICY/LITERATURE REVIEW 46 (2007), http://www.sfc.org.nz/pdfs/gravitasreport.pdf (reducing exposure to toxic substances in tobacco products protects both the smoker and third party).

38. *E.g.*, C. EVERETT KOOP & DAVID A. KESSLER, FINAL REPORT OF THE ADVISORY COMMITTEE ON TOBACCO POLICY AND PUBLIC HEALTH app. 3 at A4 (1997) (recommending that all nicotine delivery devices, whether produced by tobacco companies or by pharmaceutical companies, should be evaluated and regulated by the FDA using a consistent set of standards).

39. *See, e.g.*, Press Release, U.S. Food & Drug Admin., Pharmaceutical cGMPs for the 21st Century: A Risk-Based Approach (Aug. 21, 2002), http://www.fda.gov/oc/guidance/gmp.html (discussing the Food and Drug Administration's risk-based approach to product quality regulation).

40. Sweanor et al., *supra* note 17, at 71.

for the nicotine, but they die from the smoke.[41] Given the potential gains from reducing the risks of the delivery system combined with the successes to date from other tobacco control strategies, it is very likely that product regulation will become the key area of legal intervention in the years ahead.

It is within an overall context of comprehensive regulatory policies aimed at reducing the harms of tobacco use that we need to consider how best to apply harm reduction principles to tobacco/nicotine products.[42] Ignoring harm reduction is simply not a viable option as there is no question that it is possible to provide massively less toxic alternative products. The continuum of risk for tobacco products is very pronounced, with the Royal College of Physicians of the United Kingdom estimating that cigarettes are in the range of ten to one thousand times more hazardous than various non-combustible tobacco products.[43] Some markedly less hazardous non-combustion nicotine delivering products are already on the market,[44] while others can be expected very soon, and most of the major tobacco companies (along with many pharmaceutical and "alternative health" companies) are entering the alternative nicotine market.[45]

Another important change in the world of tobacco—one often overlooked by anti-tobacco campaigners—is that as tobacco companies have come to acknowledge the addictive and deadly nature of cigarettes,[46] they have arguably gained credibility and positioned themselves to take a seat at the table when discussing what can be done to alleviate the harm. This is similar to when a company that is a large carbon emitter accepts the scientific evidence on global warming. This acceptance gives the company credibility when it says that it wants to be "part of the solution."[47] Governments will have an obligation to listen to what

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41. *Id.*

42. For an in-depth discussion of harm reduction principles, see Gerry V. Stimson, Editorial, *"Harm Reduction—Coming of Age": A Local Movement with Global Impact*, 18 INT'L J. DRUG POL'Y 67 (2007).

43. TOBACCO ADVISORY GROUP, *supra* note 34, at 5. The term non-combustible tobacco refers to smokeless tobacco products. SCOTT D. BALLIN, TOBACCO AND TOBACCO PRODUCTS 5 (2006), *available at* http://www.tobaccoatacrossroads.com/tobacco/11.pdf.

44. *E.g.*, Sweanor et al., *supra* note 17, at 71 (discussing the widespread use of "snus" (a smokeless tobacco product) in Sweden and the corresponding low level of tobacco-related disease).

45. John M. Broder, *Experts Envision Battle Between Drug and Tobacco Companies*, N.Y. TIMES, Oct. 1, 1997, at A14.

46. *See, e.g.*, Philip Morris USA, Smoking & Health Issues: Cigarette Smoking and Disease, http://www.philipmorrisusa.com/en/health_issues/cigarette_smoking_and_disease.asp (last visited Jan. 18, 2008) ("Philip Morris USA . . . agrees with the overwhelming medical and scientific consensus that cigarette smoking causes lung cancer, heart disease, emphysema and other serious diseases in smokers.").

47. *E.g.*, bp.com, BP and Climate Change, http://www.bp.com/genericsection.do?categoryId=6905&contentId=7030746 (last visited Jan. 19, 2008); ExxonMobil.com, Climate and Emissions, http://www.exxonmobil.com/Corporate/energy_climate.aspx (last visited Jan. 19, 2008) ("Recognizing

these companies have to say about alternative methods of nicotine delivery, and they will need to think of how to deal with the fact that there is a very strong basis in science for believing that the harm caused by current cigarettes can be massively reduced by alternative nicotine delivery systems. Anti-tobacco campaigners who refuse to discuss harm reduction will merely be ensuring that they are not part of the ongoing dialogue that will shape this key area of policy.

II. LESSONS FROM THE PAST

Preventing a billion deaths through intelligent policy interventions is not an unattainable goal. Not only do we see the examples of the eradication or extensive control of communicable diseases and the role of sanitation,[48] but there is also the relatively recent example of the "Green Revolution" led by Norman Borlaug and funded by philanthropic organizations in the United States.[49]

There have also been numerous examples of other transformations in the provision of goods and services as harm reduction approaches were applied to regulation. The enactment of regulations aimed at protecting consumers from hazardous food,[50] drugs,[51] and medical services[52] are prime examples of what could potentially happen to the tobacco/nicotine market. The history of goods and services shows that nothing arrives "regulated." Rather, over time there is an inter-relationship between changes in various businesses and changes in the regulations affecting these businesses.[53] Tobacco products were left behind as other products and services "morphed" into the modern businesses of today. As evidenced by the current debate in tobacco harm reduction, the tobacco industry is now also starting to "morph."

Two hundred years ago, there was little to distinguish between a charlatan and a medical professional.[54] Over one hundred and fifty years ago, there was little differentiation between processed foods that delivered nutrition and those that delivered deadly infections.[55] One hundred years ago, there was no clear division between science-based pharmaceutical products and "other substances, faked, or

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the risk of climate change, we are taking actions to improve efficiency and reduce emissions in our operations.").

48. *See supra* notes 13–16 and accompanying text.

49. JOEL L. FLEISCHMAN, THE FOUNDATION 115–24 (2007) (discussing the effects of the Green Revolution and crediting it to saving a billion lives since the mid-1960s).

50. YOUNG, *supra* note 15, at 262–64.

51. PHILIP J. HILTS, PROTECTING AMERICA'S HEALTH: THE FDA, BUSINESS AND ONE HUNDRED YEARS OF REGULATIONS 95 (2003).

52. ROY PORTER, QUACKS: FAKERS & CHARLATANS IN MEDICINE 206 (2000).

53. *E.g.*, NaturalGas.org, The History of Regulation, http://www.naturalgas.org/regulation/history.asp (demonstrating that regulating natural gas is the product of 30 years of regulatory evolution).

54. *See* PORTER, *supra* note 52, at 193.

55. YOUNG, *supra* note 15, at 291–93.

mixed with dangerous ingredients."[56] Fifty years ago, consumers were not able to make adequate purchase decisions based on automobile safety because there were no well-defined automobile safety standards.[57]

A pattern emerges when looking at how other industries have changed, and the tobacco/nicotine market seems to be experiencing these patterned changes as well. In general, as products or services become established, there is a proliferation of new products as various companies seek a marketplace advantage.[58] As the examples above demonstrate, science also advances and allows the ability to distinguish between products on the basis of a continuum of risk. This in turn creates an opportunity to use regulatory standards to shape the overall marketplace. Social reformers may then be influenced by the changes in the marketplace and scientific understanding, and may move from an abstinence-only approach to an approach aimed at maximum reduction in death, injury and disease.

III. THE WAY FORWARD

Reducing risks for continuing users of tobacco/nicotine products without requiring abstinence should be integrated into public health campaigns.[59] The application of harm reduction principles to public health issues has a very long and successful history,[60] and failure to apply these principles to tobacco policy would be a public health failure of enormous significance. We know the projected death toll from smoking based on current studies.[61] From increased scientific understanding, we also know more about the nature of nicotine addiction, and that people often smoke as a form of self-medication to cope with numerous conditions (schizophrenia, depression, anxiety, etc.).[62] Based on this knowledge, it is clear that abstinence-only campaigns are not only unsupported by science, but also constitute a denial of human rights.[63]

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56. HILTS, *supra* note 51, at xi.

57. PETER ASCH, CONSUMER SAFETY REGULATION 21, 127 (1988).

58. *See, e.g.*, Neelie Kroes, Comm'r for Competition, Eur. Comm'n, Industrial Policy and Competition in Law and Policy, Address at the Developments in European Law Dedicated to CFI President Bo Vesterdorf, *in* 30 FORDHAM INT'L L.J. 1401, 1410 (2007).

59. Alcabes, *supra* note 22.

60. Stimson, *supra* note 42, at 67–68.

61. *E.g.*, Cropley, *supra* note 11.

62. Louisa Degenhardt & Wayne Hall, *The Relationship Between Tobacco Use, Substance-Use Disorders and Mental Health: Results from the National Survey of Mental Health and Well-Being*, 3 NICOTINE & TOBACCO RES. 225, 231–34 (2001).

63. *See* L. T. Kozlowski & B. Q. Edwards, *"Not Safe" is Not Enough: Smokers Have a Right to Know More Than There is No Safe Tobacco Product*, 14 TOBACCO CONTROL, at ii3, ii3 (2005) (arguing that abstinence-only messages violate the right to health relevant information, which is a human right that is based on the principles of autonomy and self-determination and is supported by the Universal Declaration of Human Rights).

The answer is a regulated marketplace for nicotine delivering products that is based on a pragmatic risk reduction strategy. It must combine efforts focused on prevention, cessation and protection with serious efforts aimed to reduce risks for continuing nicotine product users.[64] Such an approach has the ability to maximize health gains and minimize the risks of any unintended consequences, like less toxic tobacco products encouraging or prolonging smoking. Applying such a risk-minimizing approach to nicotine delivery products also follows the examples set over many years in the regulation of a myriad of other goods and services.[65]

We are dealing with a category of products that can be set out along a very pronounced continuum of risk. There is a large risk differential between the use of cigarettes and alternative nicotine delivery products.[66] Further, this risk differential may even be greater than some well-known reduced-harm mechanisms, like safety features in automobiles, the use of protective sports equipment in contact sports, and airline safety enhancements.[67] The most pronounced difference in nicotine delivery products is whether a product requires lung inhalation of combustion products to deliver nicotine or if the product is a less toxic non-combustion product.[68] Even with non-combustion products there is a significant range of risks,

64. For more information regarding an alternative cessation strategy for continuing smokers, see Rodu & Godshall, *supra* note 22.

65. *See supra* text accompanying notes 50–53.

66. *See* David T. Levy et al., *The Relative Risks of a Low-Nitrosamine Smokeless Tobacco Product Compared with Smoking Cigarettes: Estimates of a Panel of Experts*, 13 CANCER EPIDEMIOLOGY, BIOMARKERS & PREVENTION 2035, 2038 (2004) (finding that the use of low-nitrosamine smokeless tobacco poses only 5% to 10% of the risk of smoking, or, in other words, a 90% reduction in relative risk in comparison with smoking); Carol E. Gartner et al., *Assessment of Swedish Snus for Tobacco Harm Reductions: An Epidemiological Modeling Study*, 369 LANCET 2010, 2012 (2007) (finding little difference between the health-adjusted life expectancy between smokers who quit all tobacco use and those who switched to snus). For more information regarding studies that have concluded that smokeless tobacco use poses a lesser risk to users in comparison to cigarettes, see Rodu & Godshall, *supra* note 22.

67. Improvements in automobile safety, such as the use of seat belts, have reduced the risk of fatal injury during accidents by about 50%. NAT'L HIGHWAY TRAFFIC SAFETY ADMIN., SAFETY BELTS AND TEENS 2003 REPORT (2003), *available at* http://www.nhtsa.dot.gov/people/injury/airbags/buasbteens03/index.htm. Use of discretionary protective equipment while playing sports has resulted in only an approximately 9% decrease in the overall rate of lower extremity injury and a 19% decrease in the rate of game injury for all athletes. Jingzhen Yang et al., *Use of Discretionary Protective Equipment and Rate of Lower Extremity Injury in High School Athletes*, 161 AM. J. EPIDEMIOLOGY 511, 515 (2005). Because of new warning devices and other safety enhancements adopted by the airline industry, the risk of a passenger dying on an airline jet flight from 2000 through 2005 was one flight in 22.8 million, a 60% drop from the 1990's. Alan Levin, *Airways Are the Safest Ever*, USA TODAY, June 30, 2006, at 1A.

68. Karl Fagerstrom, *The Nicotine Market: An Attempt to Estimate the Nicotine Intake from Various Sources and the Total Nicotine Consumption in Some Countries*, 7 NICOTINE & TOBACCO RES. 343, 343–44, 349 (2005).

but manufacturers have the ability to further reduce risks to consumers through such measures as the reduction of tobacco-specific nitrosamines.[69]

CONCLUSION

Product regulation can have various purposes. Regulations can be designed to ban or standardize products, give a relative advantage to some politically favored product, or reduce harm from the use of certain products. Regulations can sometimes simultaneously pursue more than one of these goals. But if the goal is reduction of death, injury and disease, product regulation must be narrowly focused on reduction of harm. Regulators should replace the abstinence-only paradigm with a pragmatic science-based public health approach that includes risk reduction strategies for continuing users. With this approach, we can achieve a great advance for global health.

69. *See* Levy et al., *supra* note 66, at 2038 (explaining that results from the article's study suggest that low-nitrosamine smokeless tobacco products may be less hazardous than conventional cigarettes).