Policy and Health Implications of Using the U.S. Food and Drug Administration Product Design Approach in Reducing Tobacco Product Risk

Michael Givel*

Department of Political Science, The University of Oklahoma, 455 West Lindsey, Room 217, Norman, Oklahoma 73019, USA

Abstract: Purported risk or harm reduction through product design change of cigarettes has occurred in three phases in the U.S. The first phase from the 1940s to the early 1960s included a gradual rise in filtered cigarettes. The second phase, which began in the early 1960s in response to the landmark 1964 U.S. Surgeon General's report that linked smoking with lung cancer and other diseases, included the introduction of purportedly low tar and nicotine cigarettes. Subsequent research found that both filters and low tar and nicotine cigarettes were ineffective approaches to reducing health risks associated with smoking. Despite this, these product design changes were used in tobacco industry marketing campaigns to allay consumer health concerns and stabilize tobacco markets and sales. Since 2004, a new risk or harm reduction phase has occurred with the backing by Philip Morris as well as major U.S. health groups of U.S. Food and Drug Administration legislation that would require disclosure of tobacco ingredients, ban misleading health claims, prohibit or reduce harmful ingredients, and require prior approval of tobacco design, performance changes, and modified risk tobacco products. However, current scientific literature indicates that there is no scientific consensus and little evidence on what tobacco ingredients are linked to particular morbidities and mortalities and at what levels. This will allow the tobacco industry to implicitly or explicitly claim their products are "safer." Instead, health advocates should advocate for scientifically proven policy measures such as smoke free public places or higher tobacco taxes that control and reduce tobacco markets and consumption.

INTRODUCTION

One major and historical approach in the U.S. to address concerns of tobacco addiction and disease, which annually kills more than 430,000 Americans, has been to redesign tobacco products so that they are purportedly safer and less risky [1-8]. For this paper, using the U.S. Institute of Medicine definition, risk or harm reduction is defined as: "…a product is harm-reducing if it lowers total tobacco-related mortality and morbidity even though the use of that product may involve continued exposure to tobacco-related toxicants" [9].

In the U.S., the first phase of this risk approach included the gradual rise in manufacture by the tobacco industry of filtered cigarettes from the 1940s to the early 1960s [3, 5, 10]. This approach did not reduce the health risks associated with tobacco use because of ineffective filters, but was a marketing approach designed to allay consumer health concerns and maintain a stable tobacco market [4, 5, 9, 11, 12].

Beginning in 1964 in response to the landmark U.S. Surgeon General report that linked smoking with lung, lip, and laryngeal cancer and chronic bronchitis, a new phase in tobacco industry product design and risk reduction developed in the U.S. with the introduction of reduced tar and nicotine cigarettes [5, 13]. The tobacco industry marketed these new low delivery cigarettes with designations such as "light" or "ultra light" or "low tar." However, research has indicated smokers compensate for reduced nicotine, including through filtered cigarettes, by puffing harder [2-5, 10].

*Address correspondence to this author at the Department of Political Science, The University of Oklahoma, 455 West Lindsey, Room 205, Norman, Oklahoma 73019, USA; Tel: 405-325-8878; Fax: 405-325-0718;
E-mail: mgivel@ou.edu

Since 2004, a new risk reduction phase has occurred with large U.S. health organizations including the Campaign for Tobacco-Free Kids, American Heart Association, American Lung Association, and American Cancer Society as well as Philip Morris continually supporting proposed new U.S. Food and Drug Administration (FDA) regulation of tobacco products [14-17]. As noted in Article 2, Section 36 of the Findings section of the proposed 2007 FDA legislation, the purpose of FDA to regulate tobacco is:

> Unless tobacco products that purport to reduce the risks to the public of tobacco use actually reduce such risks, those products can cause substantial harm to the public health to the extent that the individuals, who would otherwise not consume tobacco products or would consume such products less, use tobacco products purporting to reduce risk. Those who use products sold or distributed as modified risk products that do not in fact reduce risk, rather than quitting or reducing their use of tobacco products, have a substantially increased likelihood of suffering disability and premature death. The costs to society of the widespread use of products sold or distributed as modified risk products that do not in fact reduce risk or that increase risk include thousands of unnecessary deaths and injuries and huge costs to our health care system [18].

In order to accomplish this objective of reducing harm, the proposed 2007 FDA legislation would specifically require disclosure of tobacco ingredients, ban misleading health claims, ban or reduce harmful ingredients, and require prior FDA approval of tobacco design, performance changes, and modified risk tobacco products [14, 15].

1874-4737/08 $55.00+.00 © 2008 Bentham Science Publishers Ltd.

Not for Distribution

In light of this unusual effort that also involves Philip Morris as well as the past two phases that promoted product design initiated to alleviate consumer concerns rather than effectively promote less addiction and disease, this newest phase raises the important question: is this latest risk reduction proposal an adequate approach to effectively reduce tobacco addiction and disease? This article will review current scholarly literature to answer this question.

FIRST PHASE OF PROPOSED FDA REGULATION

In August 1995, FDA issued a Proposed Rule that would have regulated cigarettes and smokeless tobacco products as a "drug and drug delivery device" [19]. Due to this authority, the FDA proposed to make sale of tobacco to minors a violation of federal law by prohibiting retailers from selling tobacco products to anyone under 18, established 20 cigarettes as a minimum package size, banned vending machines in almost all cases, banned self-service displays with a few exceptions, and prohibited mail order redemption of tobacco coupons [20]. In addition the Proposed Rule would have prohibited free samples of tobacco products, prohibited tobacco advertising within 1000 feet of public playgrounds and elementary or secondary schools, limited tobacco advertising to black text on white background thus eliminating imagery attractive to minors, and prohibited tobacco companies from sponsoring any sporting or cultural events with a brand name or logo [20]. Finally, the Proposed Rule would have required tobacco companies to establish a fund for a national counter-marketing campaign. In August 1996, the FDA changed the Proposed Rule to a Final Rule having the full effect and force of the law [21].

Well after this FDA Final Rule in 1996 was issued, the U.S. and 167 other nations signed in 2003 the World Health Organization's Framework Convention on Tobacco Control (FCTC). The FCTC contains policy provisions including Article 11 covering warning labels, Article 12 requiring a national tobacco counter-marketing campaign, Article 13 prohibiting tobacco sponsorships and self-displays, and Article 16 banning sale, promotion, and access of tobacco products to minors that are very similar in scope and intent to the provisions in the FDA Final Rule [21, 22]. As noted in 2003 in the FCTC report by the World Health Organization.

The WHO FCTC represents a paradigm shift in developing a regulatory strategy to address addictive substances; in contrast to previous drug control treaties, the WHO FCTC asserts the importance of demand reduction strategies as well as supply issues [22].

Like the FCTC's focus on reducing demand and consumption, the cumulative intent and effect of the FDA Final Rule was to control both the market and profits of tobacco companies by reducing consumption and sale of tobacco products. These FDA regulatory requirements, which did not focus on product design, represented a significant regulatory threat to the viability and stability of the tobacco market in the U.S.

Due to this threat to the tobacco market and profits, the tobacco industry challenged the new FDA Final Rule on two fronts. First, the industry filed a lawsuit on October 15, 1996 in federal court in Greensboro, North Carolina arguing the FDA had no legislative authorization from Congress to issue the rule [23]. On March 21, 2000 the U.S. Supreme Court ruled that the FDA rule was illegal because the U.S. Congress never mandated that the FDA had jurisdiction to regulate tobacco products as a drug and drug delivery device [23].

SECOND PHASE OF PROPOSED FDA REGULATION

The second front pursued by Philip Morris, beginning in 1999, was to advocate for an alternative FDA regulation. The new regulatory approach supported by Philip Morris, and since 2004, health organizations including the Campaign for Tobacco-Free Kids, American Heart Association, American Lung Association, and American Cancer Society was to regulate product design of tobacco products through a variety of risk reduction approaches including disclosure requirements, banning misleading health claims such as cigarettes are "light" or "low tar" or "ultra-light," prohibiting or reducing harmful ingredients, and requiring previous FDA approval of tobacco design, performance changes, and modified risk tobacco products [14, 15]. The other tobacco companies opposed the new FDA regulation because they feared that prior FDA approval of new and purportedly safer tobacco products would hinder their ability to introduce new tobacco products in the market [14, 15]. They also feared the new FDA regulation would undermine their ability to compete with U.S. market leader Philip Morris in terms of marketing, distribution, and sale of tobacco products [14, 15].

Negotiations for the proposed bill began in November 2001 between Philip Morris and the Campaign for Tobacco-Free Kids. As reported in an in depth news story by *Roll Call* in October 2004:

> Thanks to separate but equally calculated decisions by Philip Morris and the Campaign for Tobacco Free Kids, each has broken ranks with their typical allies, formed a secret alliance and met clandestinely to iron out key sticking points on the legislation.

"It's the most unusual alliance I have seen in a while", said Rep. Henry Waxman, a 15-term Democrat from California and author of the House version of the tobacco bill.

The talks between Philip Morris and the Campaign for Tobacco Free Kids took place on Capitol Hill even as the two sides battled over a $200 billion Justice Department lawsuit in a federal courthouse a few blocks down Pennsylvania Avenue.

The face-to-face negotiating sessions and conference calls were so sensitive that Philip Morris and the Campaign for Tobacco Free Kids refused to tell even their closest allies [24].

The negotiations culminated in 2004 with the introduction by U.S. Senators Edward Kennedy (D-Massachusetts) and Mike Dewine (R-Ohio) in the U.S. Senate of an FDA bill that would primarily modify the product design of tobacco products [14, 15]. This legislation (Table **1**) was also vigorously endorsed and supported by other major health organizations including the American Cancer Society, American Heart Association, and American Lung Association [14, 15]. The 2004 bill was defeated in a committee vote [14, 15]. Since the initial negotiated deal, the same bill, again supported by Philip Morris as well as major health organizations was also defeated in 2005 [14, 15].

Not For Distribution

In 2007, an FDA bill to regulate tobacco, once more supported by Philip Morris as well as major health organizations, was introduced that was very similar to the 2004 and 2005 bills (Table **1**) [14, 15]. The reason provided by Philip Morris for its support of the 2007 FDA bill regulating tobacco included:

Philip Morris USA (PM USA) believes regulation of tobacco products by the Food and Drug Administration (FDA) would establish a comprehensive national tobacco policy that could potentially create a competitive framework within which manufacturers are focused on reducing the harm tobacco use causes. The company believes regulation would also bring predictability and clear standards to the tobacco industry in the United States [25].

Public health group support for the 2007 FDA bill to regulate tobacco was based on the following rationales:

The tobacco companies take advantage of this lack of regulation to do many harmful things. They market their deadly products in ways that attract children, deceive consumers about the harm their products cause and resist changes that could make their products less harmful.

Congress can end this special protection for Big Tobacco by passing legislation to give the FDA authority to regulate tobacco products. The public health community strongly supports identical, bipartisan bills that have been introduced in Congress to give the FDA this authority [26].

Thus, both Philip Morris and major U.S. health organizations supported the proposed FDA bill primarily due to a congruence of support to reduce tobacco harm.

This new FDA legislation as illustrated in Table **1** represents a fundamentally different regulatory approach than the 1996 FDA Final Rule. The 1996 FDA Final Rule would have provided for market control, reduced profits, and provided several public health approaches to reduce disease and addiction. Instead, the new version, since 2004, of FDA regulation is primarily oriented toward product design and the manufacture of purportedly less risky tobacco products. In addition, if enacted due to the political influence of the tobacco industry, which has stopped significant federal tobacco control legislation for years, the FDA bill will quite likely become the cornerstone of U.S. federal tobacco policy for a long time [14, 15].

RISK REDUCTION REGULATION VERSUS MARKET CONTROL

The central issue with respect to this third phase in U.S. product design and risk reduction policy is whether like the first two phases, the intent of this policy is to actually save lives or is it to market cigarettes that reduce consumer concern about the health issues associated with tobacco use? Currently, a review of all scientific research on this issue indicates that there is no scientific consensus and little evidence that removing ingredients from cigarettes will make them "safer" [9, 14, 15, 28-31]. This includes little evidence on what ingredients are linked to particular morbidities and mortalities and at what levels [28]. Unburnt cigarettes contain a complex amalgamation of at least 2000 chemicals and toxicants [9]. When tobacco is burned the chemical reaction results in about 4000 chemicals and toxicants [9]. At present, tests of vitro-toxicity that examine the responses of single cell types to tobacco smoke, cyto-toxicity that examine a culture of different cells or a body organ, and geno-toxicity that examines cell mutation have provided very little evidence on which tobacco constituents are conclusively linked with particular diseases [8, 28-30].

Table 1. Analysis of Key Provisions of 2004, 2005, and 2007 FDA Tobacco Regulation Bills

Major Tobacco Control Provisions in 2004, 2005, and 2007 FDA Bills
Required tobacco ingredient disclosure requirements (Section 904)
Prior approval for modified risk tobacco products (Section 911)
Prior approval for tobacco design changes (Sections 906-907 and 910)
Restricted tobacco advertising and promotions (Section 906)
Banned misleading health claims and labels such as "mild" or "light" or "superlight" or low tar (Sections 903, 906, and 911)
Bans additives except menthol (Section 907)
Required stronger warning labels* (Sections 201-206)
Prohibited banning tobacco products and reducing nicotine level to zero (Section 907)
Anti-black market smuggling requirements (Section 301-302)
Preempted states from regulating product standards, pre-market approval, adulteration, misbranding, labeling, registration, good manufacturing standards, increasing minimum to use tobacco to above 18, and reduced risk products (Sections 906 and 917)

***** During U.S. Senate Health, Education, Labor, and Pension (HELP) Committee mark-up hearings on July 25, 2007, the HELP Committee strengthened the warning label requirement by making graphic color warnings of major diseases mandatory rather than discretionary, which is similar to current Canadian warning label requirements.
Sources: H.R. 4433, 108th Congress, 2nd Session; and S. 625, 110th Congress, 1st Session [18, 27].

In addition as also noted in 2001 in a prestigious U.S. Institute of Medicine report:

Further, the study of mixtures (i.e. the real life scenario of simultaneous exposure to many chemicals and chemicals and classes) has received insufficient attention, and exposures to tobacco constituents as complex mixtures would provide the most compelling evidence for the prediction of a successful PREP (potential reduced exposure product) [9].

Probable but as yet scientifically unconfirmed constituents, in tobacco that might cause carcinogenesis include: N-nitrosamines, aromatic amines, free radicals that cause oxidation damage as well as other severe carcinogens such as 1,3-butadiene [9, 28]. Another important factor in the development of lung cancer includes the phenomena of smokers compensating for lower nicotine levels in cigarettes by puffing with more frequency and thus increasing the amount of constituents inhaled [9]. Current research has also not been conclusive with respect to the linkage between tobacco smoke and other diseases including acute cardiac events, atherosclerosis, chronic obstructive pulmonary disorder, asthma, other respiratory infections, sudden infant death syndrome, congenital malformation, cognitive and behavioral deficits in childhood, rheumatoid arthritis, oral diseases, diabetes, renal diseases, dermatological conditions, Parkinson's disease, and preeclamsia [2, 9, 28, 30].

Not for Distribution

Table 2. A Comparison of the 2001 Institute of Medicine Report with the Key Provisions of the 2004, 2005, and 2007 FDA Tobacco Regulation Bills

2001 Institute of Medicine Regulatory Principles	Provisions in 2004, 2005, and 2007 FDA Bills	Analysis
Disclose quantitative data on tobacco ingredients (Principles 1 and 8)	Require tobacco ingredient disclosure requirements (Section 904)	Same
Assess tobacco toxicants and tobacco products; must reduce risk (Principles 2,3, 4, 6, 7 and 9)	Prior approval for modified risk tobacco products (Section 911)	Same
Assess tobacco toxicants and tobacco products; must reduce risk (Principles 2,3, 4, 6, 7 and 9)	Prior approval for tobacco design changes (Sections 906-907 and 910)	Same
Regulate tobacco advertising and promotion for non-misleading statements (Principle 5)	Restrict tobacco advertising and promotions (Section 906)	FDA bill provides for broader restriction of advertising and promotion such as restricting tobacco advertising 1000 feet from a public playground or elementary or secondary school
Prohibit misleading health labels (Principles 3, 4 and 5)	Prohibit misleading health labels such as "mild" or "light" or "superlight" or low tar (Sections 903, 906, and 911)	Same
Assess tobacco toxicants and tobacco products; must reduce risk (Principles 2,3, 4, 6, 7 and 9)	Bans additives except menthol (Section 907)	FDA bill weaker due to allowance of menthol, an important ingredient in Marlboro cigarettes among others
Prohibit misleading health claims (Principles 4 and 5)	Prohibit misleading health claims (Sections 903, 906, and 911)	Same
Not covered	Require stronger warning labels (Sections 201-206)	Only covered in FDA bill
Assess tobacco toxicants and tobacco products; must reduce risk (Principles 2,3, 4, 6, 7 and 9)	Prohibit banning tobacco products and reducing nicotine level to zero (Section 907)	FDA bill weaker due to exceptions to reduce risk
Not covered	Anti-black market smuggling requirements (Section 301-302)	Only covered in FDA bill
Not covered	Preempt states from regulating product standards, pre-market approval, adulteration, misbranding, labeling, registration, good manufacturing standards, increasing minimum to use tobacco to above 18, and reduced risk products (Sections 906 and 917)	FDA bill weaker because allows federal preemption of stronger state laws
Sufficient administrative power to regulate (Principle 10)	Sufficient administrative power to regulate (Sections 101 and 103)	Same
Allowance of tobacco exposure and risk reduction drugs (Principle 11)	Allowance of tobacco exposure and risk reduction drugs (Section 919)	Same

Sources: Institute of Medicine, 2001; and 2004 and 2007 Family Smoking Prevention and Tobacco Control Acts [9, 18, 27].

With respect to the current scientific knowledge of distinct tobacco smoke constituents linked to diseases, parts of which has been confirmed by other recent studies [2, 29, 30], the 2001 Institute of Medicine report concluded.

In order to effectively evaluate the toxic effects of tobacco smoke and identify the primary causal agents, the toxic components of PREPs [potential reduced exposure products] and comparison products must be identified and be disclosed. For the most part, the data are insufficient to accurately describe the relationship of tobacco use and disease formation at the level of detail that would establish all causal agents involved or the exact dose-response relationship. The characteristics of this relationship vary among diseases and are affected by differences in compensation and actual exposure and by inter-individual or population differences [9].

The Institute of Medicine report also recommended eleven regulatory principles (Table **2**) to nationally implement a harm reduction approach when it is scientifically known to have a substantial chance of success. A comparison of the Institute of Medicine principles with the key provisions of the proposed FDA legislation to regulate tobacco products indicates fairly similar risk or harm reduction regulatory approaches (Table **2**). In essence, despite the important current scientific conclusions that harm reduction for cigarettes are not verified, FDA tobacco regulation is being proposed through a harm reduction regulatory framework. Since the science behind this harm reduction regulatory approach is not currently authenticated, what this approach currently also represents is a fairly weak and symbolic policy designed to appear to reduce tobacco harm when there is no current evidence that this will occur.

CONCLUSION

During the first two phases of changes in cigarette product design for "safer" cigarettes in the U.S. including adding

Not For Distribution

filters and manufacturing purportedly lower tar and nicotine cigarettes, the tobacco industry's primary motivation for this effort was allaying consumer concerns about health risks of tobacco use. This effort was also undertaken in tandem with marketing supposedly safer cigarettes and thus stabilizing and even enhancing tobacco markets and profits.

In the latest phase of product design, the proposal for design of a purportedly safer cigarette (which will likely become the cornerstone of U.S. federal tobacco policy for a long time) is a regulatory effort by a federal agency rather than self-regulation by the tobacco industry as was done with filters and purportedly lower tar and nicotine cigarettes. Despite the new emphasis on federal agency regulation, the same central issue remains with respect to manufacturing purportedly safer cigarettes with little evidence that such an effort will make cigarettes safer. And like the first two phases of product design to make a purportedly safer cigarette, this latest effort will allow tobacco companies to explicitly or implicitly claim that they are a more responsible industry because their products are now "safer". The major health organizations are also adding to this claim of greater responsibility through their collaboration and support of the proposed FDA legislation. Product design to make cigarettes purportedly safer in the form of a fairly symbolic policy also presents an implicit and explicit assumption that the cigarette market and profits will be maintained. Since product design is not known at this point to work and diverts crucial political organizing energy and resources from policies that do work, what is the alternative? The reason declines in tobacco use prevalence in which more than 20% of Americans still use tobacco have stalled is that there has been a failure to enact at the federal level the major scientifically verified demand side FCTC policies that are known to reduce tobacco prevalence [32, 33].

Demand Side Tobacco Reduction Approaches

These FCTC demand oriented requirements include: Canadian-style warning labels with large type and graphic color warning labels of major diseases, higher tobacco taxes, tobacco cessation programs, effective tobacco countermarketing efforts, and smoke-free requirements for public places [15, 22]. Recent research has shown that graphic Canadian style-warning labels depicting all five major diseases due to smoking has resulted in smokers being much more likely to recognize all major disease risks. This has further motivated a greater percentage of these smokers to quit tobacco use when compared to motivation to quit due to non-graphic and colorful warning labels in the U.S., Australia, and the United Kingdom [34-36]. Over 100 peer-reviewed studies have concluded that cigarette tax increases of 10 percent decrease cigarette consumption from 2.5 to 5.0% [37-40]. Tobacco cessation programs including cessation quitlines have also been effective in assisting smokers in ceasing tobacco use [41, 42]. The most effective cessation approach in helping patients to quit has been a combination of a pharmacological approach such as nicotine replacement therapies or Bupropion with behavioral approaches including intensive counseling [42]. Effective anti-tobacco countermarketing campaigns such as the Truth Campaign in Florida have also been shown to influence a higher percentage of smokers to not start using or to consider quit smoking [43]. Much of the research on smoke-free laws for public places has also concluded that smoke-free laws for public places also reduce tobacco use [44-46]. For instance, recent research has found that between 1988 and 1994 about 12.7 percent of the 76.5 million fewer smokers in the U.S. was due to smoke-free workplace laws [47, 48]. Smoking prevalence is 6 percent less among employees who work in smoke-free workplaces than for the general population [47, 48].

These regulatory approaches require market controls over the tobacco industry with an ultimate goal of reducing tobacco consumption and thus tobacco markets and sales. This approach is inherently more effective in reducing addiction and disease than the product design approach, which to date has not been conclusively and scientifically verified to reduce risk. Even if the product design approach were to include rigorous scientific tests and conclusions, it still would have a negative effect on adopting FCTC demand side tobacco reduction approaches. This would happen due to a direct result of pre-emptive clauses such as prohibiting states to regulate tobacco adulteration in the proposed FDA tobacco regulation legislation and indirectly due to consumers and politicians assuming smoking is safer.

SUMMARY

What has now transpired, since 2004, in the U.S. in advocacy for FDA regulation to address product design to purportedly reduce tobacco risk presents is an important lesson for future advocacy efforts both in the U.S. and throughout the world. There should be no policy compromises based on unproven scientific measures to reduce tobacco consumption. Instead, health advocates should be prepared to wage ongoing and astute political efforts, which means often conflicting politically with the tobacco industry over proven policy measures that reduce tobacco consumption, markets, and profits.

Key Learning Objectives:

- Describe and explain why the introduction of filters in the first phase of cigarette product design change, which lasted from the 1940s to the early 1960s in the U.S. was ineffective in reducing cigarette health risks.
- Describe and explain why the introduction of low tar and nicotine cigarettes in the second phase of cigarette product design change, which began in 1964 in the U.S. was ineffective in reducing cigarette health risks.
- Assess and articulate how the first two phases of cigarette product design change in the U.S. were used by the tobacco industry in marketing campaigns to misleadingly alleviate consumer health concerns regarding smoking.
- Understand the key features, including the reduction or prohibition of harmful ingredients, of the proposed U.S. Food and Drug Administration (FDA) regulation of tobacco products associated with the third phase of cigarette product design change, which began in 2004.
- Analyze and explain the current scientific consensus that there is little evidence that cigarette product design change will make cigarettes safer.
- Understand how demand side smoking reduction approaches including: Canadian-style warning labels, higher tobacco taxes, tobacco cessation programs, effective counter-marketing efforts, and smoke-free restrictions for public places are scientifically verified and effective approaches to reduce smoking prevalence.

Not For Distribution

Future Research Questions:

- Will future scientific testing with respect to reducing or prohibiting cigarette ingredients continue to show that there is little evidence that a cigarette can be made safer?
- If FDA legislation to regulate tobacco products is enacted, how effective will FDA be in implementing the new law?
- What broad underlying ideologies and interests are associated with the proponents and opponents of the proposed FDA legislation to regulate tobacco?
- Will the new FDA legislation to regulate tobacco allow tobacco companies to claim they are more socially responsible companies?
- What policy strategies, actions, and approaches by health advocates will be taken in the future to advocate for scientifically verified demand side tobacco control programs?

REFERENCES

[1] Borland R. A Strategy of Controlling the Marketing of Tobacco Products: A Regulated Market Model. Tob Control 2003; 12:374-82.

[2] Dunsby J, Bero L. A Nicotine Delivery Device Without the Nicotine? Tobacco Industry Development of Low Nicotine Cigarettes. Tob Control 2004; 13:363-9.

[3] Hammond D, Collishaw N, Callard C. Secret Science: Tobacco Industry Research on Smoking Behaviour and Cigarette Toxicity. Lancet 2006; 367:781-7.

[4] Pollay RW, Dewhirst T. The Dark Side of Marketing Seemingly "Light" Cigarettes: Successful Images and Failed Fact. Tob Control 2002; 11(Suppl I): i18-i31.

[5] Wigand J. Cigarette Testing Methods, Product Design, and Labelling: Time to Clean Up the "Negative Baggage." Tob Control 1998; 7(4): 336-7.

[6] Callard C, Thompson D, Collishaw N. 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. Tob Control 2005; 14:278-83.

[7] Slade J. Brave New World in Tobacco Product Design. Cancer Epidemiol Biomark Prev 1998; 7:965-6.

[8] Centers for Disease Control and Prevention. Fact Sheet: Cigarette Smoking-Related Mortality (updated September 2006).

[9] Institute of Medicine. Clearing the Smoke: Assessing the Science Base of Tobacco Harm Reduction. Washington, D.C.; 2001.

[10] Bero L. Implications of the Tobacco Industry Documents for Public Health and Policy. Ann Rev Public Health 2003; 24:267-88.

[11] Pauly J, Mepani A, Lesses J, Cummings K, Streck R. Cigarettes With Defective Filters Marketed for 40 Years: What Philip Morris Never Told Smokers. Tob Control 2002; 11(Suppl I): i51-i61.

[12] Kozlowski L, O'Connor R. Cigarette Filter Ventilation Is A Defective Design Because of Misleading Taste, Bigger Puffs, and Blocked Vents. Tob Control 2002; 11(Suppl I): i40-i50.

[13] United States Surgeon General. Smoking and Health, Report of the Advisory Committee to the Surgeon General of the Public Health Service. Washington, D.C.: United States Department of Health, Education, and Welfare, Public Health Service; 1964. Report No.: Public Health Service Publication No. 1103.

[14] Givel M. Philip Morris' FDA Gambit: Good For Public Health? J Public Health Policy 2005; 26:450-68.

[15] Givel M. FDA Legislation: Time to Shift U.S. Federal Anti-tobacco Advocacy Tactics. Tob Control 2007; 16(4): 217-8.

[16] McDaniel P, Malone R. Understanding Philip Morris's Pursuit of US Regulation of Tobacco. Tob Control 2005; 14:193-200.

[17] McDaniel P, Smith E, Malone R. Philip Morris's Project Sunrise: Weakening Tobacco Control By Working With It. Tob Control 2006; 15:215-23.

[18] Family Smoking Prevention and Tobacco Control Act S-625. 2007.

[19] Federal Register. Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco Products to Protect Children and Adolescents 1995:41313-75.

[20] United States Department of Health and Human Services--Office of General Counsel. Executive Summary of the Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents. Washington, D.C.; August 1, 1996.

[21] Federal Register. Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco Products to Protect Children and Adolescents. 1996:44395-445.

[22] World Health Organization. WHO Framework Convention on Tobacco Control. Geneva: World Health Organization; 2003.

[23] Food and Drug Administration v. Brown & Williamson Tobacco Company *et al*. Supreme Court Reports: United States Supreme Court 2000.

[24] Mullins B. How Philip Morris' Tobacco Foes Tied the Knot. Roll Call. October 5, 2004.

[25] Philip Morris U. Legislation & Regulation: FDA Regulation of Tobacco Products. [Accessed December 4, 2007]; Available from: http://www.philipmorrisusa.com/en/legislation_regulation/fda/regulation_tobacco_products.asp

[26] Campaign for Tobacco Free Kids. FDA Authority Over Tobacco: Legislation Will Protect Kids and Save Lives. [Accessed December 3, 2007]; Available from: http://tobaccofreekids.org/reports/fda/

[27] Family Smoking Prevention and Tobacco Control Act. HR 4433. 2004.

[28] Pankow J, Watanabe K, Toccalino P, Luo W, Austin D. Calculated Cancer Risks For Conventional and Potentially Reduced Exposure Product' Cigarette. Cancer Epidemiol Biomarkers Prev 2007; 16:584-92.

[29] Sumner W. Estimating the Health Consequences of Replacing Cigarettes With Nicotine Inhalers. Tob Control 2003; 12:124-32.

[30] Kozlowski L, Strasser A, Giovino G, Erickson P, Terza J. Applying the Risk/Use Equilibrium: Use Medicinal Nicotine Now For Harm Reduction. Tobacco Control 2001; 10:201-3.

[31] Stratton K, Shetty P, Wallace R, Bondurant S. Clearing the Smoke: The Science Base for Tobacco Harm Reduction--Executive Summary. Tob Control 2001; 10:189-95.

[32] Trosclair A, Caraballo R, Malarcher A, Husten C, Pechacek T. Cigarette Smoking Among Adults: United States. Morbidity and Morta Wkly Rep 2005:509-13.

[33] Rock V, Malarcher A, Kahende J, Asman K, Husten C, Caraballo R. Cigarette Smoking Among Adults: United States, 2006. Morb Mortality Wkly Rep 2007:1157-61.

[34] Givel M. A Comparison of the Impact of U.S. and Canadian Cigarette Pack Warning Label Requirements on Tobacco Industry Profitability and the Public Health. Health Policy 2007; 83(2-3): 343-52.

[35] Hammond D, Fong G, McDonald P, Cameron R, Brown K. Impact of Canadian Warning Labels on Adult Smoking Behavior. Tob Control 2003; 12:391-5.

[36] Hammond D, Fong G, McNeill A, Borland R, Cummings K. Effectiveness of Cigarette Warning Labels In Informing Smokers About the Risks of Smoking: Findings From the International Tobacco Control (ITC) Four Country Survey. Tob Control 2006; 15(Suppl III): iii19-iii25.

[37] Chaloupka FJ, Cummings KM, Morley C, Horan J. Tax, Price and Cigarette Smoking: Evidence from the Tobacco Documents and Implications for Tobacco Company Marketing Strategies. Tob Control 2002; 11(90001): 62i-72.

[38] Licari M, Meier K. Regulatory Policy When Behavior Is Addictive: Smoking, Cigarette Taxes, and Bootlegging. Polit Res Q 1997; 50:5-24.

[39] Peterson D, Zeger S, Remington P, Anderson H. The Effect of State Cigarette Tax Increases on Cigarette Sales, 1955 to 1988. Am J Public Health 1992; 82(1): 94-6.

[40] Thomson C, Fisher L, Winickoff J, *et al*. State Tobacco Excise Taxes and Adolescent Smoking Behaviors in the United States. J Public Health Manag Pract 2004; 10(6): 490-6.

[41] Stack N. Smoking Cessation: An Overview of Treatment Options With a Focus on Varenicline. Pharmacotherapy 2007; 27(11): 1550-7.

[42] Stead L, Perera R, Lancaster T. A Systematic Review of Interventions for Smokers Who Contact Quitlines. Tob Control 2007; 16(Supplement 1): i3-i8.

[43] Hersey J, Niederdeppe J, Ng S, Mowery P, Farrelly' Messeri M, How State Counter-industry Campaigns Help Prime Perceptions of Tobacco Industry Practices to Promote Reductions in Youth Smoking. Tob Control 2005; 14: 377-383.

[44] Chriqui J, Frosh M, Brownson R, *et al*. Application of a Rating System to State Clean Indoor Air Laws (USA). Tob Control 2002; 11(1): 26-34.

Not for Distribution

[45] Jacobson P, Wasserman J. The Implementation and Enforcement of Tobacco Control Laws: Policy Implications for Activists and the Industry. J Health Polit Policy Law 1999; 24(3): 567-98.

[46] McMullen K, Brownson R, Luke D, Chriqui J. Strength of Clean Indoor Air Laws and Smoking Related Outcomes in the USA. Tob Control 2005; 14(1): 43-8.

[47] Chapman S, Borland R, Scollo M, Brownson R, Woodward S. The Impact of Smoke-free Workplaces on Declining Cigarette Consumption in Australia and the United States. Am J Public Health 1999; 89: 1018-23.

[48] Gilpin E, Farkas A, Emery S, Ake C, Pierce J. Clean Indoor Air: Advances in California, 1990-1999. Am J Public Health 2002; 92(5): 785-91.

Received: August 17, 2007 Revised: November 11, 2007 Accepted: December 8, 2007

Not For Distribution