Philip Morris’ FDA Gambit: Good for Public Health?

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ABSTRACT

The objective of this study was to determine whether the 2004 USA Dewine–Kennedy Bill is congruent with Philip Morris’ core policy principles for United States Food and Drug Administration (FDA) regulation of tobacco and what impact that would have on the public health. I compared the Dewine–Kennedy Bill with 1999 Philip Morris core policy principles for FDA regulation. Additional supporting data on FDA regulation from 1998 to the present were collected from previously secret tobacco industry documents, relevant newspaper reports from Nexis-Lexis, federal statutes, and federal regulations. The main outcome measure of the study is a comparison, summary, and analysis of the Dewine–Kennedy Bill with Philip Morris’ core principles for FDA regulation, and the result is that the Dewine–Kennedy Bill is compatible with almost all of Philip Morris’ core principles on FDA regulation. In conclusion, The Dewine–Kennedy Bill, at best, was mixed in terms of the enhancement of the public health. On the one hand, proponents of this legislation argued stronger FDA regulatory requirements would have some effect on reducing youth and adult tobacco consumption. On the other hand, tobacco products would have remained a politically and economically viable and legal product consumed by millions of Americans many of whom would have continued to suffer from tobacco-related illnesses and deaths.

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INTRODUCTION

In August 1995, the United States Food and Drug Administration (FDA) issued a proposed rule that would have regulated cigarettes and smokeless tobacco as a drug because “…tobacco products function like drug delivery systems in that they contain a drug, nicotine; (that is) used to deliver the drug to the site at which the drug will be absorbed into the body…”(1,2). The proposed rule also

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would have restricted sales and distribution of tobacco products and established a national counter-marketing campaign to reduce cigarette and smokeless tobacco use by persons under 18 (1,2). By August 1996, the FDA changed the proposed rule to a final rule having the full force and effect of law (2,3).

The tobacco industry vigorously mobilized against the new final rule on two fronts. First, the industry filed suit on October 15, 1996 in federal district court in Greensboro, North Carolina arguing that the FDA had no jurisdiction over tobacco products since they are not drugs or drug delivery devices (4,5). On March 21, 2000, the United States Supreme Court ruled in Food and Drug Administration v. Brown & Williamson Tobacco Company, et al. that Congress did not provide legislative authority to regulate tobacco products (5).

The second front included alternative FDA legislation to regulate the safety of tobacco products while still ensuring adult consumption as a substitute to FDA regulating tobacco as a drug and drug delivery device. FDA regulation of tobacco products as a drug and drug device would have greatly restricted consumer access to purchase tobacco products. In 1997, a group of private product liability attorneys, public health organizations, attorneys general, and the tobacco industry negotiated a global settlement that was designed to settle numerous lawsuits by the states and private plaintiffs against the tobacco industry in return for new regulation over the tobacco industry (6). Under the proposed global settlement, existing FDA rules would have been codified and the FDA would gain new regulatory power over the testing of tobacco smoke, approval of tobacco industry health claims, and new technology that purportedly would reduce harm from health dangers associated with tobacco and non-tobacco additives and ingredients (6). Other new FDA regulatory powers would have included banning tobacco companies from making statements downplaying health risks due to tobacco use, creating tobacco contamination controls, overseeing tobacco handling and inspection, and establishing standards of nicotine levels not considered addictive (6). While the 1998 McCain Bill, when introduced, adopted the provisions of the global settlement and was supported by many public health organizations, some health advocates were concerned that the bill contained some procedural requirements that would compromise FDA’s ability to fully and vigorously regulate tobacco products (many of these problems were
subsequently corrected by amendments to the original legislation) 
(6). However, the 1998 McCain Bill was not enacted, leaving the 
scope and context of how the FDA might regulate tobacco products 
subject to future deliberation.

In 1999, Philip Morris proposed specific core principles for FDA 
regulation of tobacco products. These proposals collectively focused 
upon tobacco harm reduction including the design and performance 
of tobacco products, youth prevention programs, no undue 
economic harm due to regulation of tobacco jobs and sales, and 
no banning of tobacco products for adult consumption (7). Since the 
2000 US Supreme Court decision denying FDA authority to regulate 
tobacco as a drug and drug delivery device, Philip Morris for 
purposes of regulatory and market stability, has proposed that FDA 
be provided with the authority to regulate tobacco products (7–10). 
Other tobacco companies including Lorillard, Brown & Williamson, 
R. J. Reynolds, and American Tobacco Company have strenuously 
opposed the proposed FDA regulatory authority (11–13).

In May 2004, United States Senators Mike Dewine (R-Ohio) and 
Edward Kennedy (D-Massachusetts) and United States Representa-
tives Tom Davis (R-Virginia) and Henry Waxman (D-California) 
introduced identical bills in the Senate and House to provide 
legislative authority for FDA to regulate tobacco products (14,15). 
Key provisions included restricting tobacco advertising and prom-
tions; providing for reduction or elimination of harmful ingredients 
in tobacco products; banning labeling including “light,” “mild,” and 
“low-tar” that mislead consumers to believe these type of cigarettes 
are safer; prohibiting health claims of “reduced risk” that have not 
been scientifically verified; requiring ingredient disclosure; and 
requiring larger and more prominent health warnings on tobacco 
products (16). These bills were supported by Philip Morris and many 
health groups including the American Public Health Association, 
Campaign for Tobacco Free Kids, American Cancer Society, 
American Lung Association, and American Heart Association 
(16–18). The 2004 bills were opposed by the rest of the tobacco 
industry (11). In this paper, I examine the question whether the 2004 
Dewine–Kennedy Senate Bill (which was identical to the House 
version) is congruent with Philip Morris’ core policy principles for 
FDA regulation of tobacco and what impact enactment would have 
had on the public health (7).
To compare the Dewine–Kennedy Bill with Philip Morris’s core policy principles for FDA regulation, I utilized Philip Morris’ 1999 core principles for FDA regulation as discovered in the previously secret tobacco documents. More than 40 million pages of documents have been made public as part of the legal settlement in the case of State of Minnesota, et al, v. Philip Morris, Inc., No. C1-94-8565, 2nd District, Minnesota and subsequent litigation against the tobacco industry. The analysis compared each core provision with each section of the Dewine–Kennedy Bill (which was identical to the House version – the Davis–Waxman Bill) (7). In addition, the methodology used to examine the historical background of Philip Morris and the rest of the tobacco industry’s response to FDA regulation was a qualitative and archival analysis from 1998 to the present of previously secret tobacco industry documents. I chose 1998 because this was when the industry’s original support of FDA regulation was codified in 1998 legislation (that ratified the 1997 global settlement agreement) introduced by Senator John McCain (R–Arizona) (6).

Under the terms of the legal settlement, five tobacco companies, a tobacco trade association, and a tobacco company research association have established searchable web sites for documents produced during litigation. This material was accessed in 2004 on the Internet at the University of California–San Francisco Legacy Tobacco Documents Library website at: http://legacy.library.ucsf.edu/

Search terms in which 9146 hits occurred from 1998 to the present and in which 514 relevant documents were produced in .pdf format, included: John McCain, McCain, J, FDA and Kessler, FDA and lawsuit, FDA and regulation, global settlement, Kessler, D, and David Kessler. These search terms were selected because of their wide and general scope and historical importance (all tobacco documents on the University of California–San Francisco Legacy web site were dated prior to November 14, 2003) with respect to the issue of FDA regulation so that the search engine would identify all available documents.

Although all tobacco industry sites were searched, most of the relevant documents appeared on the Philip Morris, RJ Reynolds, and
Lorillard sites. After the documents were obtained, a composite and chronological analysis and summary was created for each document. These results were then aggregated to be read as a whole to ascertain the overall “story” of FDA regulation from 1998 to the present. I also obtained data from 1998 to the present of relevant newspaper reports from Nexis-Lexis, federal statutes, and federal regulations. These documents were then chronologically incorporated with the tobacco documents to ascertain FDA regulation orientations from 1998 to the present.

RESULTS

Introduction

In 1996, the tobacco industry was adamantly opposed to any new FDA regulation of tobacco products as a drug or a drug delivery device (2). After the FDA issued a final rule in 1996 to regulate tobacco products as a drug and drug delivery device, restrict promotions and sales particularly to youth, and to commence a national youth anti-tobacco counter-marketing campaign, the industry filed suit in federal district court in Greensboro, North Carolina to overturn the rule (2). In 1997, the tobacco industry and product liability attorneys, public health groups, and a group of attorneys general negotiated a global settlement with enhanced FDA powers to purportedly reduce the harm and risk, regulate the safety, and restrict the promotion of tobacco products (6). The global settlement agreement was codified into proposed legislation in 1998 by Senator John McCain. The legislation was defeated.

In March 1999, Philip Morris announced that it would support “a reasonable regulatory regime” that opposed “a new prohibition” by allowing adults the right to choose to smoke and to have “…access to the most up-to-date information regarding smoking and health” (19). In October 1999, Philip Morris, on a new company web site, also announced that the overwhelming scientific evidence indicates that smoking causes disease including “…lung cancer, emphysema, and heart disease” (20). However, Philip Morris did not say whether it agreed with the scientific evidence that smoking causes disease (20).
In a previously secret December 1999 document, Philip Morris further stated (Table 1) what it viewed is a reasonable framework for FDA regulation of tobacco products. This regulatory framework called for reducing youth smoking, banning tobacco sales that were not face-to-face, approving changes in cigarette design and performance, purportedly reducing the harm from smoking, and disclosing fully to consumers health issues associated with smoking. The proposed regulatory framework opposed FDA regulation that resulted in prohibition or lack of marketability of tobacco products to adults, illegal black markets, adverse economic impact on tobacco jobs and sales, can not ban tobacco products or “change the product so as to make it unacceptable or unmarketable to consumers.” Regulation should not result in an illegal black market. Regulation should not hinder industry’s ability to manufacture domestically for international markets. Regulation should not harm tobacco farmers or their communities.

Table 1: Philip Morris core principles on FDA regulation

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<th>Principle</th>
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<tr>
<td>Allow industry freedom to market and communicate to adults about tobacco</td>
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<td>products.</td>
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<td>Utilize 1998 Master Settlement Agreement, federal, state and local, laws to</td>
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<td>reduce youth smoking.</td>
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<tr>
<td>Ban all tobacco sales that are not face-to-face.</td>
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<tr>
<td>Full disclosure to consumers on health issues associated with smoking.</td>
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<tr>
<td>Define changes in design and performance that will reduce risk in smoking.</td>
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<tr>
<td>Take into account economic impact on tobacco jobs and sales.</td>
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<tr>
<td>Can not ban tobacco products or “change the product so as to make it</td>
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<td>unacceptable or unmarketable to consumers.”</td>
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<tr>
<td>Regulation should not result in an illegal black market.</td>
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<tr>
<td>Regulation should not hinder industry’s ability to manufacture domestically</td>
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<td>for international markets.</td>
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<td>Regulation should not harm tobacco farmers or their communities.</td>
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Source: Philip Morris, Core Principles, December 1, 1999, Bates No.: 2065569146(7).

In a previously secret December 1999 document, Philip Morris further stated (Table 1) what it viewed is a reasonable framework for FDA regulation of tobacco products. This regulatory framework called for reducing youth smoking, banning tobacco sales that were not face-to-face, approving changes in cigarette design and performance, purportedly reducing the harm from smoking, and disclosing fully to consumers health issues associated with smoking. The proposed regulatory framework opposed FDA regulation that resulted in prohibition or lack of marketability of tobacco products to adults, illegal black markets, adverse economic impact on tobacco manufacturers, growers, sellers, and distributors, or restricted domestic tobacco exports to other nations with various laws and regulations regarding the sale of tobacco to adults and minors. This proposal ensured that the United States domestic adult and international adult and youth tobacco markets remained intact and that profits derived from customers continued to be protected. It also was in sharp contrast to the FDA rule that would have regulated tobacco as a drug and drug delivery device, which would have severely restricted sales and access to tobacco products by consumers.
**Constructive Engagement**

In March 2000, the United States Supreme Court ruled in the case of *Food and Drug Administration v. Brown & Williamson Tobacco Company, et al.* (4,21,22) that FDA had no jurisdiction to regulate tobacco products. With this announcement, industry opposition to FDA regulation was divided. Philip Morris continued to support FDA regulation, while the rest of the tobacco industry opposed FDA regulation as a threat to their ability to freely market, distribute, and sell tobacco products (10–12,23). In 2000, Steven Parrish, Senior Vice President of Corporate Affairs for Philip Morris, publicly called for federal legislation providing for FDA regulation of tobacco that makes “sense” (9) that reiterated the 1999 core principles (Table 1) of FDA being empowered to prevent youth access, engage in harm or risk reduction, and approve cigarette design and performance that reduces health risks.

Also in early 2000, in conjunction with its FDA regulatory proposal, Philip Morris began a major public relations campaign to:

...reshape the public’s perception of the Company [Philip Morris] in general as being more than just a tobacco company, and of PM USA [Philip Morris] specifically as being the most responsible, effective, and respected developer, manufacturer and marketer of consumer products made for adults (24).

This campaign of constructive engagement occurred because according to Philip Morris:

...there was an unprecedented opportunity right now for the Congress, the tobacco industry, the public health community and others to engage in dialogue to begin shaping a reasonable regulatory framework for cigarettes (24).

A key component of this campaign was obtaining a favorable news story in *The New York Times*. As a 1999 internal Philip Morris document noted:

Our strategy was to get in front of the story, delivering it to key media including *The New York Times*, prior to the actual launch [of the constructive engagement campaign]. Many media reports correctly noted that the [Philip Morris] website
and advertising were both part of a larger effort to engage the public more constructively than the company has in the past. Barry Meier of *The New York Times* was one of the key reporters who was briefed on the advertising and website. Meier’s piece was pivotal in driving and shaping succeeding stories as a number of other media outlets reprinted portions or all of Meier’s column. Meier’s October 13 piece was both balanced and effective in helping us tell one important part of the Philip Morris story: our desire to be more accessible and open to the public about tobacco issues (25).

In concert with favorable news coverage from *The New York Times*, Philip Morris also initiated a widespread advertising campaign showing how the firm was involved in humanitarian concerns including: “hunger, domestic violence, AIDS, education, disaster relief, culture, and the environment (24)”. The campaign also included speeches by Philip Morris executives on how the company is engaging in humanitarian efforts. In addition, a new Philip Morris web site indicated that scientific evidence indicates that smoking causes disease and is addictive (without Philip Morris stating whether it agreed with this evidence). The Philip Morris campaign also encouraged state legislatures to spend a “significant portion” of Master Settle Agreement (MSA) funds on youth tobacco use prevention and run widespread advertisements on youth prevention (24).

*The Other Firms Respond*

While Philip Morris since 1999 has consistently pushed for its “reasonable regulatory” proposal for FDA, the rest of the tobacco industry has consistently opposed Philip Morris’ plan (13,26,27). One reason for this opposition from the rest of the industry is fear that new regulation will lead to even stronger FDA regulations in the future that will hinder marketing, distribution, and sale of tobacco products (27). The other major reason for opposition has been:

...while Philip Morris might talk about the stability of the marketplace, its real motivation, say competing industry lobbyists, is solidifying its market domination and eventually squeezing its competitors out of the business altogether (27).
In May 2004, United States Senators Mike Dewine (R-Ohio) and Edward Kennedy (D-Massachusetts) and United States Representatives Tom Davis (R-Virginia) and Henry Waxman (D-California) introduced identical bipartisan legislation (S2461 and HR4433) to provide authority for FDA to regulate tobacco products (14,15). For the first time since 2000, legislation authorizing FDA regulation of tobacco passed a house of Congress. On July 15, 2004 the Senate passed the Dewine-Kennedy Bill (28,29). HR4433 was not approved by the House.

Supporters of these bills included Philip Morris and many health groups including the American Public Health Association, Campaign for Tobacco Free Kids, American Cancer Society, American Lung Association, and American Heart Association (16–18). These bills were opposed by the rest of the tobacco industry (11). Table 2 compares each section of the Senate version of the bill (which was identical to the House version) and Philip Morris’s core principles for FDA regulation. Sections 1–5, 102–103, 900–902, and 912–916 of the Senate Bill were not included in the analysis because they consisted of qualifying language that covered: the title of the bill, Congressional findings, purpose of the bill, scope and effect, severability, definitions, judicial and congressional review, standards for coordination with other agencies, statement of equal treatment of retail outlets, establishment of advisory committees, creation of user fees, conforming language, and authority for FDA to issue a final rule.

The bill and an amendment to a separate corporate tax bill (Table 2) in the US Senate providing a $12 billion bail out of tobacco farmers closely followed Philip Morris’ preferred policy goals for FDA regulation (30). The bill provided for greater disclosure to consumers of tobacco health issues and risks, allowed FDA to regulate tobacco products to purportedly reduce the risk or harm in smoking, prohibited the banning of tobacco products and reduced nicotine content in tobacco products to 0%, contained anti-black market provisions, and provided for state and local pre-emption of stronger rules in a large variety of FDA regulatory areas. The bill also allowed the industry the freedom to market and sell tobacco products to adults, relied on youth prevention programs such as
Table 2: Comparison of Philip Morris’ core principles on FDA regulation with 2004 Kennedy and Dewine FDA bill

<table>
<thead>
<tr>
<th><strong>Philip Morris core principles for FDA regulation</strong></th>
<th><strong>Individual sections of the 2004 FDA bill</strong></th>
<th><strong>Analysis</strong></th>
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<tbody>
<tr>
<td>Allows industry freedom to market tobacco products to adults.</td>
<td>Not covered.</td>
<td>Allows industry freedom to market tobacco products to adults.</td>
</tr>
<tr>
<td>Utilize 1998 Master Settlement Agreement, federal, state and local laws to reduce youth smoking.</td>
<td>Not specifically covered (Sec. 906 includes youth and adult requirements that restrict tobacco advertising and promotions).</td>
<td>Relies on federal, state, and local laws and general restrictions in bill to curtail advertising and promotion</td>
</tr>
<tr>
<td>Ban all tobacco sales that are not face-to-face.</td>
<td>Authorizes face-to-face sales (Sections 203 and 906).</td>
<td>Permits non-face-to-face sales.</td>
</tr>
<tr>
<td>Full disclosure to consumers on health issues associated with smoking.</td>
<td>Requires disclosure of tobacco ingredients, restricts tobacco advertising and promotions, bans misleading labeling with terms like “light,” “mild,” and “low-tar,” bans health claims of “reduced risk” that are not verified, and requires stronger label warnings (Sections 201, 202, 204, 205, 206, 903, 904, 906).</td>
<td>Same.</td>
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<tr>
<td>FDA should define future changes in design and performance that will reduce risk in smoking.</td>
<td>Prior approval by FDA for: changes in design and performance of new and modified risk tobacco products, good manufacturing requirements, nicotine replacement products, label</td>
<td>Same.</td>
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<tr>
<td><strong>Philip Morris core principles for FDA regulation</strong></td>
<td><strong>Individual sections of the 2004 FDA bill</strong></td>
<td><strong>Analysis</strong></td>
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<td>statements, and tobacco product standards. Bans artificial flavors except menthol. Authorizes FDA to issue orders to reduce risk and recall tobacco products (Sections 903, 905, 906, 907, 908, 910, 911, and 919).</td>
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<td>FDA actions should take into account economic impact on tobacco jobs and sales.</td>
<td>Not covered.</td>
<td>Bill does not cover economic impact to tobacco jobs and sales.</td>
</tr>
<tr>
<td>FDA cannot ban tobacco products or “change the product so as to make it unacceptable or unmarketable to consumers.”</td>
<td>Restricts sales of tobacco products to protect public health. Exempts actions prohibiting sales to persons older than 18. Prohibits banning tobacco products and reducing nicotine level to zero (Sections 906 and 907).</td>
<td>Authorizes continuing sales to adults and no regulatory action entirely eliminating tobacco products and reducing nicotine level to zero.</td>
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<tr>
<td>FDA regulation should not result in illegal black market.</td>
<td>Contains anti-black market provisions (Section 301).</td>
<td>Same.</td>
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<tr>
<td>FDA regulation should not hinder industry’s ability to manufacture domestically for international markets.</td>
<td>Not covered.</td>
<td>Allows export to international markets to nations with varying laws addressing adult and youth smoking.</td>
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the MSA to reduce youth tobacco use, did not require face-to-face sales (which is weaker than the Philip Morris proposal for only face-to-face sales), and allowed exports to international markets of domestically produced tobacco products.

Harm or Risk Reduction

At the heart of Philip Morris and the health organizations’ approach was a regulatory framework calling for a reduction in youth tobacco use and the creation and regulation of purportedly safer or less risky tobacco products that reduced harm. Harm reduction is defined as tobacco products and ingredients “that lower total tobacco caused morbidity and mortality, even though these products might involve continued exposure to one or more tobacco-related toxicants”.

(31,32) For instance, the removal of the toxic substance coumarin

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<tr>
<td>FDA regulation should not harm tobacco farmers or their communities.</td>
<td>Not in FDA legislation. Companion amendment provides $12 billion bailout of tobacco farmers</td>
<td>Same.</td>
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<tr>
<td>Not covered.</td>
<td>Pre-empt states and local governments from regulating product standards, pre-market approval, adulteration, misbranding, labeling, registration, good manufacturing standards, increasing minimum age to use tobacco to above 18, and reduced risk products (Sections 201, 203 and 917)</td>
<td>State and local pre-emption not enunciated as core principle. However, historic goal of tobacco industry is to counter stronger state and local regulations and taxes.</td>
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Sources: Philip Morris, Core Principles, December 1, 1999, Bates No.: 2065569146(7); HR 4433 (108th Congress) (15); and S2461 (108th Congress) (14).
from tobacco products or the use of non-burning tobacco might be considered a harm reduction approach. (33) However, among tobacco control scholars and policy analysts, there is a wide divergence of opinion over the efficacy, suitability, and even desirability of various or all harm reduction approaches to reduce morbidity and mortality. (31,32,34–36) Yet, Philip Morris and some health advocates were now calling for less risky tobacco products or harm reduction as embodied in the new FDA legislation and subsequent regulations. Any new federal rule covering less risky tobacco products and harm reduction would have required a fairly high degree of rationality and scientific certainty in order to be effective. Since there is now a high degree of uncertainty over the need and effectiveness of various harm reduction approaches, this left any new FDA rule subject to time consuming, widely varying, politically motivated, and potentially inaccurate interpretations as to what constitutes harm reduction.

Youth Tobacco Use and Access Prevention

The other major Philip Morris policy goal embodied in the Dewine–Kennedy Bill of reducing youth access and youth products was equally uncertain as to efficacy, suitability, and desirability (37–39). Philip Morris in its core principles, calls for utilizing the MSA and other federal, state, and local laws as a means to reduce youth tobacco use (7). The Dewine–Kennedy Bill called for general advertising and promotion restrictions for adults and youth without specifically addressing youth access leaving open regulatory uncertainty as to the manner and effectiveness of youth advertising restrictions and requirements that would be authorized by FDA. In addition, only a few states including California, Arizona, Minnesota, Massachusetts, Maine, Mississippi, Oregon, and in the past Florida have engaged in effective and vigorous youth counter-marketing and anti-tobacco education programs with the MSA settlement money (38,40,41).

The other major purported means to reduce youth consumption of tobacco is to reduce youth access to tobacco products. As Ling and her colleagues observed: “Unfortunately, while these programmes do make it difficult for teens to purchase cigarettes, on the whole they do not affect teen smoking prevalence (37)”. Jones and colleagues
found that a number of factors contribute to this including students: illegally purchasing tobacco products from stores, borrowing tobacco products from others, using vending machines, and giving other persons funds to purchase tobacco products (37,42). In addition, Ling and colleagues note that youth access programs are widely supported by the tobacco industry “because they reinforce the industry’s key marketing message that ‘smoking is for adults,’ which arguably makes smoking more attractive for teens” (37).

Summary

Judged from the perspective of regulating tobacco as a drug and drug delivery device as originally proposed in the 1996 FDA rule, was the Dewine–Kennedy Bill, which is compatible with almost all of Philip Morris’ core principles on FDA regulation, an enhancement of the public health? On the one hand, proponents of this legislation argued stronger regulatory requirements would have had an effect on reducing youth and adult tobacco consumption and harm and risk through such approaches as stronger warning labels and the removal of misleading health claims. On the other hand, tobacco would have remained under the proposed FDA regulation a politically and economically viable and legal product consumed by millions of Americans, many of whom would have continued to suffer from tobacco-related illnesses and deaths.

This new regulatory framework was likely to remain in place for a relatively long period unless, perhaps, Philip Morris changed its perspective on what constituted core principles for FDA regulation. With the passage of this legislation Philip Morris also stood to gain public relations goodwill as is embodied in its constructive engagement campaign. The stronger regulatory emphasis would undoubtedly have meant that there would have been a renewed push by tobacco companies to sell this product overseas to youth and adults.

Discussion

Scholars of United States regulatory policy have noted that during the 1930s New Deal era, there was a regulatory period known as the associational regulatory regime characterized by the promotion of economic stability (43). In the 1960s and 1970s, a new regulatory
era emerged known as the societal regulatory regime characterized by the prevention of hazards to the public health and environment due to advanced capitalist economic production (43). The efforts from 1996 to 2000 by FDA to regulate tobacco products as a drug and drug delivery device are a clear illustration of the societal regulatory regime. Philip Morris’ core principles for FDA regulation as embodied in the Dewine–Kennedy Bill changed the focus of this regulatory effort to primarily an associational regulatory regime in tandem with a weaker societal regulatory regime with a main purpose of maintaining tobacco as a viable and legal product, particularly for adults.

Key to the success of Philip Morris’ FDA regulatory campaign embodied in the Dewine–Kennedy Bill was a public relations approach called constructive engagement, which was primarily designed to improve Philip Morris’ corporate image and the market desirability of its products like Marlboro cigarettes. As the smaller tobacco companies pointed out, this new FDA regulatory approach that Philip Morris and the major health advocates espoused would have likely decreased the market share or viability of Philip Morris’ smaller competitors and increase Philip Morris’ market share (11).

Both the Philip Morris campaign and Dewine–Kennedy Bill were designed to ensure regulatory and economic stability in contrast to the past uncertainty of FDA regulating tobacco products as a drug and drug delivery device. This economic stability would have been maintained because the FDA policy and legislative approach advocated by Philip Morris and many health groups ensuring that tobacco products would not be banned and that nicotine would not be removed from tobacco products ensured a steady adult market into the foreseeable future. This approach, of course, would quite likely have also blocked any future attempts by FDA to treat tobacco products and nicotine as a drug and drug delivery device (unless new legislation was enacted by Congress), which would have greatly restricted the supply and marketability of tobacco products. The legislative agreement by the major health groups of this new Philip Morris regulatory scheme also ensured that the highly debatable and potentially time-consuming approaches from the perspective of public health harm reduction and youth prevention would have become the cornerstones of federal FDA tobacco policy.
The enactment of FDA legislation meeting Philip Morris’ core regulatory principles also would have meant that adult tobacco use including associated illnesses and deaths would have, using optimistic scenarios, been reduced to a certain extent and then stabilized and institutionalized at the federal level. This is contrary to the goals of the major health groups supporting this legislation, who generally have called for reducing tobacco use for the entire population as much as is feasible or possible. Without advocating through wide publicity and public pressure inside and outside of Congress for legislation and regulations that would move FDA regulation closer to the original FDA goal of regulating tobacco as a drug and drug delivery device, this federal legislation, at best, provided an incremental approach to tobacco control. Without such insider and outsider advocacy, in the interim and probably for the long term, this meant that progress toward reducing tobacco use and tobacco-related disease as much as possible through FDA regulation would have been stalled.

Philip Morris’ FDA gambit meant that some harm from tobacco products might be reduced. However, tobacco would remain a legal and stable commodity, particularly for adults, and would continue to cause significant illness and death. The threat of future FDA legislation patterned after Philip Morris’ core principles has not diminished. After the defeat of the 2004 Dewine–Kennedy Bill, Philip Morris publicly announced in January 2005 that it still seeks at an unspecified future time FDA regulation of tobacco. As Philip Morris spokesperson Bill Phelps stated:

It is also important for us to listen to the public’s perception of what we should be doing in regard to public health. That is why we were the only company to support FDA regulation. We intend to fully live up to the expectations of our community (44).

The crucial policy message and lesson of the 2004 Kennedy–Dewine Bill for public health advocates in the United States, which is also appropriate in other countries particularly where relationships between tobacco producers and marketers are even more closely linked to government regulation than in the United States, is be extremely vigilant and do not be drawn in by an apparent willingness of the industry to “change its ways.”
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