In Search of the Less Hazardous Cigarette

Michael S. Givel

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LESS HAZARDOUS CIGARETTE

Michael Givel

Since the 1950s, despite considerable and long-term tobacco industry and government efforts, attempts to develop a less risky cigarette that reduces harmful ingredients, generally or specifically, have failed. Moreover, even under ideal conditions with adequate scientific testing, the efficacy of purportedly reducing the severe health effects cannot be scientifically verified for up to 20 years after introduction of a product on the market. A key and central provision in the 2009 U.S. Food and Drug Administration (FDA) legislation is to reduce the risk or harm of cigarettes. Because creating a less risky cigarette is not currently possible, this renders the efficacy of the 2009 FDA legislation highly uncertain, with a large risk that the proposed program may not reduce harm.

Since 2004, legislation has been introduced four times in Congress to provide the U.S. Food and Drug Administration (FDA) with the ability to regulate tobacco products (1–4). One of the primary goals of the FDA regulation has consistently been to reduce the health risk or harm associated with tobacco use. For instance, a primary finding by Congress in the enacted FDA tobacco legislation also known as the Family Smoking Prevention and Tobacco Control Act of 2009 was as follows (4):

It is essential that the Food and Drug Administration review products sold or distributed for use to reduce risks or exposures associated with tobacco products and that it be empowered to review any advertising and labeling for such products. It is also essential that manufacturers, prior to marketing such products, be required to demonstrate that such products will meet a series of rigorous criteria, and will benefit the health of the population as a whole, taking into account both users of tobacco products and persons who do not currently use tobacco products.
This proposed approach of harm reduction in U.S. regulation of tobacco products raises crucial questions: What has been the scientific progress in developing a less risky cigarette, and what is the likelihood of manufacturing such a product in the future?

Since the 1950s, cigarette manufacturers including Philip Morris, R.J. Reynolds, Brown & Williamson, Liggett and Myers, Lorillard, and British American Tobacco have spent hundreds of millions of dollars and initiated numerous efforts and approaches to develop and market a less hazardous cigarette (5–16). The tobacco industry has used two primary risk- or harm-reduction approaches to curtail the health risks and impacts of cigarette smoking: general reduction approaches and selective reduction approaches (5–16). General reduction approaches curtail all significant smoke ingredients under the philosophy that “less ought to be better,” whereas selective reduction seeks to remove a specific compound to decrease health risks (5, 14, 17).

In addition, the National Cancer Institute spent more than $50 million from 1968 to 1979 to sponsor the initially named Less Hazardous Cigarette Working Group, renamed in 1968 the Tobacco Working Group (18–21). One primary requirement of the Tobacco Working Group was to assess, from a scientific perspective, the possibilities of developing a less hazardous cigarette. In addition, the Tobacco Working Group was required to develop a methodology to assess which people were most at risk for contracting a disease due to tobacco use, as well as to assess possible tobacco cessation drugs. Nevertheless, the Tobacco Working Group focused primarily on developing a less hazardous cigarette (18–21).

In 2001, the prestigious U.S. Institute of Medicine (22) conducted an exhaustive review of public scientific research to determine whether there had been any progress in manufacturing a less risky cigarette. This analysis also examined possible links between the reduction of specific cigarette ingredients and a scientifically verified decrease in tobacco-related morbidity and mortality. In 2007, the Institute of Medicine released a new report calling on Congress “to give the FDA broad regulatory authority over the manufacture, distribution, marketing, and use of tobacco products” (23).

This recommendation, however, is directly predicated on and linked to the efficacy of the vast scientific quest since the 1950s to develop a less risky cigarette. In this article I review previously secret tobacco documents from the 1950s to the present and government documents for the Tobacco Working Group from 1968 to 1979, obtained through a Freedom of Information Act request, as well as court documents and the best available scientific evidence. This analysis provides a historical and scientific assessment and an overview of the current progress to produce a less risky cigarette. I then compare this analysis of the scientific evidence with all pertinent sections of the 2009 FDA tobacco legislation that calls for rigorous criteria and certification to manufacture less risky cigarettes. From this analysis, I determine whether the 2009 FDA legislation is predicated on a high degree of scientific certainty that a less risky cigarette will be produced.
or, instead, may be inconclusive or create unintended consequences not conducive to lessening the harm and risk of cigarettes.

METHODS

The research for this analysis of the efficacy of the 2009 FDA regulation of tobacco is a detailed qualitative and archival analysis of scientific research conclusions from the early 1950s to 2008, compared with the 2009 FDA legislation to produce a less risky cigarette. The time period of the early 1950s to 2008 was chosen because this represents the period of intensive scientific research to ascertain the viability of a less risky cigarette.

Qualitative and archival data for this research came from more than 50 million pages of previously secret tobacco documents available through a 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. One of the conditions of this legal settlement was that five tobacco companies and a former tobacco research association—American Tobacco Company, Brown & Williamson, Lorillard Tobacco Company, Philip Morris Tobacco Company, R.J. Reynolds Tobacco Company, and the Tobacco Institute—establish online searchable archives of previously secret internal documents discovered during the course of the trial. I conducted thorough and replicable searches of these University of California, San Francisco, tobacco industry archives on the Internet (http://legacy.library.ucsf.edu). To ascertain the most recent tobacco industry conclusions on the efficacy of developing a less risky cigarette, I used broad search terms from 2000 to 2008, including less hazardous cigarette, less ought to be better, reconstituted tobacco sheet, burn less tobacco, air dilution, and cigarette design. I also examined online documents from the period 1968 to 1980 for the National Cancer Institute’s governmental Tobacco Working Group. I used the search terms Less Hazardous Cigarette Working Group and Tobacco Working Group for that period. This search produced 13,381 hits and 104 relevant documents that provided conclusions on the efficacy of developing a less risky cigarette.

I filed a Freedom of Information Act claim with the U.S. Department of Health and Human Services, seeking all records including but not limited to computer, paper, audio, and visual records, from 1969 to 1979, related to the Less Hazardous Cigarette Working Group and the Tobacco Working Group. In response, Health and Human Services, which includes the National Cancer Institute and National Institutes of Health, released 4,760 records. I conducted a search on the LexisNexis search engine for relevant newspaper reports, using the terms Less Hazardous Cigarette Working Group and Tobacco Working Group. I also obtained all peer-reviewed and government reports on the efficacy of less hazardous cigarettes as well as recent federal district court documents from the case of United States of America, Plaintiff and Tobacco-Free Kids Action Fund, American Cancer Society, American Heart Association, American

The pertinent scientific conclusions from all of these studies were then compared with each section and provision of the 2009 FDA legislation to regulate tobacco, as it relates to developing a less risky cigarette. Based on this evaluation, I determined whether the current 2009 FDA legislation to develop a less risky cigarette is based on a high degree of scientific certainty or, instead, may be inconclusive or create unintended consequences that will not lessen the health risk of cigarettes.

RESULTS

Tobacco Industry Efforts to Develop a Less Risky Cigarette

Since the 1950s, the tobacco industry has conducted huge amounts of internal scientific research, spending hundreds of millions of dollars, to ascertain whether it could manufacture a less risky cigarette (5–17, 22, 23). Table 1 provides an overview and summary of the various tobacco industry efforts.

In this research, the tobacco industry has used two primary approaches: general and selective reduction approaches to reduce the health risks of cigarettes (5). The general reduction approach, known as “less ought to be better,” was based on the notion that a general reduction of tobacco ingredients should reduce health risks associated with cigarettes. General reduction approaches used by the industry to curtail all tobacco ingredients have included reconstituted tobacco, more efficient filters, burning less tobacco, and more porous tobacco paper (5, 8, 17). Tobacco industry researchers have historically also used selective approaches by reducing individual harmful ingredients—primarily benz(a)pyrene, nitrosamines, phenols, and ciliostats (chemicals damaging to respiratory tract cilia) (5).

There have been many internal tobacco industry scientific studies to develop and sell a less risky cigarette, such as Premier and Eclipse; so far, tobacco industry sale of purportedly less risky cigarettes on a continual and substantial basis has occurred in two phases (24). The first phase, from the 1940s to the early 1960s, included the use of charcoal-filtered cigarettes (24–27). However, various scientific studies since the 1950s have concluded that charcoal filters are ineffective and do not reduce health risks. Rather, charcoal filters were used by the tobacco industry as a marketing approach to reduce consumers’ health concerns regarding the dangers of smoking (22, 24, 26, 28, 29).

The second phase, commencing in 1964 and in reaction to the U.S. Surgeon General’s landmark 1964 report linking cigarette smoking with lung, lip, and laryngeal cancer and other significant pulmonary diseases such as bronchitis, was to manufacture and sell cigarettes with reduced tar and nicotine levels, often in
conjunction with charcoal filters. Often these cigarettes were marketed with labels such as “light” or “ultra light” (24, 26). However, various research studies have indicated that this is an ineffective approach to reducing health risks, because smokers compensate for reduced nicotine by taking more cigarette puffs (25, 26, 28, 30). These claims for reduced tar and nicotine cigarettes have subsequently been banned in many countries, including in the European Union (23).

According to recent assessments by the tobacco industry, what has been the individual and collective progress, so far, in this large-scale, multimillion-dollar industry effort to develop a less risky cigarette? In 2001 R.J. Reynolds noted (8):

Since there is no safe cigarette, what can be done to potentially reduce the risks for adults who choose to smoke? In this section, we discuss options and efforts to potential risk reduction. Of course, the best way to reduce the risks of smoking is to quit.

In a 2005 internal industry memo, R.J. Reynolds also stated (7):

We believe three areas offer the greatest opportunity for developing consumer-acceptable cigarettes that may present less risk to smokers:
1. Continued development of alternative cigarette designs, such as tobacco-heating cigarettes, which offer reductions not achievable through traditional cigarette designs. (See section on Premier and Eclipse)
2. Continued general and specific reductions of specific smoke-constituents in tobacco burning cigarettes. (See sections on Reduced Risk History and Tobacco Specific Nitrosamines)
3. Research of potential products having reduced “tar”/nicotine ratios, to achieve additional general “tar” reductions. (See section on “Tar” and Nicotine)

In 2000, an internal Philip Morris document declared that “there is no safe cigarette” and the company is “...pursuing harm reduction in a responsible way” (10). In 2000, another internal Philip Morris document suggested (15):

To develop and market a cigarette that may reduce the risks of smoking, we must:
• PRODUCT DESIGN: Design a cigarette that significantly reduces the potentially harmful constituents in the inhaled smoke.
• SMOKE ACTIVITY: Provide scientific evidence that this change reduces biological activity in appropriate cellular and laboratory animal models.
• SMOKE EXPOSURE: Measure adult smoker exposure to the smoke from these cigarettes.

In 2001, Philip Morris, in another internal industry document, provided a flow chart illustrating the process by which a reduced-harm product might be verified and manufactured (31). The protocol for this process to develop a less risky
<table>
<thead>
<tr>
<th>Year(s) introduced or last tested</th>
<th>Tobacco company</th>
<th>Product name or research title</th>
<th>General or selective reduction approach?</th>
<th>Specific description of risk reduction approach</th>
<th>Was approach successful to reduce risk?</th>
</tr>
</thead>
<tbody>
<tr>
<td>1950s</td>
<td>Lorillard</td>
<td>Internal company research</td>
<td>Selective</td>
<td>Reduce levels of benzo[a]pyrene</td>
<td>Yes and no; benzo[a]pyrene levels reduced, but nitrosamine levels also increased</td>
</tr>
<tr>
<td>1954</td>
<td>American Tobacco</td>
<td>Tareyton</td>
<td>Selective</td>
<td>Charcoal filters to reduce phenols</td>
<td>No</td>
</tr>
<tr>
<td>Early 1960s</td>
<td>Lorillard</td>
<td>Kent</td>
<td>Selective</td>
<td>Charcoal filters to reduce phenols</td>
<td>No</td>
</tr>
<tr>
<td>1962</td>
<td>BATco and Brown &amp; Williamson</td>
<td>Internal company research</td>
<td>Selective</td>
<td>Charcoal filters to reduce phenols</td>
<td>No</td>
</tr>
<tr>
<td>1963</td>
<td>BATco</td>
<td>Project Ariel</td>
<td>General</td>
<td>Reduce combustion by ceramic tube length of cigarette</td>
<td>No</td>
</tr>
<tr>
<td>1963</td>
<td>Brown &amp; Williamson</td>
<td>Avalon</td>
<td>Selective</td>
<td>Charcoal filters to reduce phenols</td>
<td>No</td>
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<tr>
<td>1963</td>
<td>Lorillard</td>
<td>York</td>
<td>Selective</td>
<td>Charcoal filters to reduce phenols</td>
<td>No</td>
</tr>
<tr>
<td>1964</td>
<td>Philip Morris</td>
<td>Saratoga</td>
<td>Selective</td>
<td>Charcoal filters to reduce phenols</td>
<td>No</td>
</tr>
<tr>
<td>Year</td>
<td>Company</td>
<td>Product/Technology</td>
<td>Type</td>
<td>Description</td>
<td>Outcome</td>
</tr>
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</tr>
<tr>
<td>1964</td>
<td>Philip Morris</td>
<td>Philip Morris Multifilter</td>
<td>Selective</td>
<td>Charcoal and cellulose acetate filters to reduce phenols and ciliastrats</td>
<td>No</td>
</tr>
<tr>
<td>1964</td>
<td>R.J. Reynolds</td>
<td>Tempo</td>
<td>Selective</td>
<td>Charcoal filters to reduce phenols</td>
<td>No</td>
</tr>
<tr>
<td>1966</td>
<td>BATco</td>
<td>Project Conqueror</td>
<td>Selective</td>
<td>Cigarette designed to reduce ciliastrasis</td>
<td>No</td>
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<tr>
<td>Late 1960s; 1990s</td>
<td>R.J. Reynolds</td>
<td>Multijet Filter—internal company research</td>
<td>General</td>
<td>Reduce smoke particulates</td>
<td>No</td>
</tr>
<tr>
<td>1970</td>
<td>Lorillard</td>
<td>PMO</td>
<td>Selective</td>
<td>Remove phenol methyl oxadiazole</td>
<td>No</td>
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<tr>
<td>Early 1970s</td>
<td>Liggett</td>
<td>ProjectXA; later Omni</td>
<td>General</td>
<td>Used palladium to alter chemical reactions and composition of tobacco smoke</td>
<td>No</td>
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<tr>
<td>Early 1970s</td>
<td>Philip Morris</td>
<td>Internal company research</td>
<td>Selective</td>
<td>Nicotine analog cigarette</td>
<td>No</td>
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<tr>
<td>Early 1970s</td>
<td>Philip Morris</td>
<td>Project Delta</td>
<td>General</td>
<td>Carbon used as reduced heat source</td>
<td>No</td>
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<tr>
<td>1972</td>
<td>Philip Morris</td>
<td>Benson &amp; Hedges Multifilter</td>
<td>Selective</td>
<td>Charcoal filters to reduce phenols</td>
<td>No</td>
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</tbody>
</table>

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<table>
<thead>
<tr>
<th>Year(s) introduced or last tested</th>
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<th>Was approach successful to reduce risk?</th>
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</thead>
<tbody>
<tr>
<td>Mid-1970s</td>
<td>BATCo and Brown &amp; Williamson</td>
<td>FACT</td>
<td>General</td>
<td>Low gas cigarette</td>
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<td>1980</td>
<td>Philip Morris</td>
<td>Internal company research</td>
<td>Selective</td>
<td>Cigarette designed to reduce nitrosamines</td>
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<td>Early 1980s</td>
<td>R.J. Reynolds</td>
<td>Premier</td>
<td>General</td>
<td>Carbon reduced heat source and filter</td>
<td>No; lack of consumer acceptance</td>
</tr>
<tr>
<td>1980s</td>
<td>Philip Morris</td>
<td>Accord</td>
<td>General</td>
<td>Electrically heated cigarette</td>
<td>No</td>
</tr>
<tr>
<td>1982</td>
<td>Philip Morris</td>
<td>Internal company research</td>
<td>Selective</td>
<td>Reduce nitrosamines using air-cured Bright tobacco</td>
<td>No</td>
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<tr>
<td>1989</td>
<td>Philip Morris</td>
<td>Next De-Nic and Benson &amp; Hedges De-Nic</td>
<td>Selective</td>
<td>Significant nicotine reduction</td>
<td>No</td>
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<tr>
<td>Year</td>
<td>Company</td>
<td>Program/Innovation</td>
<td>Type</td>
<td>Description</td>
<td>Outcome</td>
</tr>
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<td>-----------------------------------------------------------------------------</td>
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<tr>
<td>Late 1980s</td>
<td>Brown &amp; Williamson</td>
<td>Project Airbus</td>
<td>General</td>
<td>Reduce combustion by ceramic tube length of cigarette</td>
<td>No</td>
</tr>
<tr>
<td>1994</td>
<td>R.J. Reynolds</td>
<td>EW/Winston Select</td>
<td>General</td>
<td>Carbon scrubber and low nitrogen blend of tobacco</td>
<td>No; lack of consumer demand</td>
</tr>
<tr>
<td>1996</td>
<td>R.J. Reynolds</td>
<td>Eclipse</td>
<td>General</td>
<td>Carbon reduced heat source and reconstituted tobacco paper</td>
<td>No; relative lack of consumer acceptance</td>
</tr>
<tr>
<td>1998</td>
<td>R.J. Reynolds</td>
<td>Internal company research</td>
<td>Selective</td>
<td>Reduce nitrosamines</td>
<td>No</td>
</tr>
<tr>
<td>2001</td>
<td>Brown &amp; Williamson</td>
<td>Advance</td>
<td>Selective</td>
<td>Reduce nitrosamines</td>
<td>No</td>
</tr>
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</table>


Note: BATco is British American Tobacco Company.
cigarette included premarket research of consumer acceptability, special harm-reduction tests on humans, and short-term (12 to 36 months) and long-term social epidemiological health studies (5 to 20 years).

A 2003 internal Brown & Williamson document stated (11):

Research into many of the same areas (general and selective reduction approaches) has also been conducted over the years by the external scientific community. While much is known about product modification and health risks of cigarette smoking, we still do not know how smoking might contribute to disease. Neither our research nor that of the external scientific community has provided unequivocal and certain guidance about what modifications could be made in cigarettes to reduce the risk of smoking.

In 2006, in an Amended Final Opinion in U.S. District Court for the District of Columbia in the case of United States of America, Plaintiff and Tobacco-Free Kids [et al.] Interveners, v. Philip Morris USA, Inc. et al., Defendants (which is now under appeal), the court ruled the following (5):

The cigarette company Defendants have made many efforts and used many different scientific approaches over the last forty years, to develop and market less hazardous cigarettes. These Defendants knew that there was an enormous market for such cigarettes and an enormous profit to be made by whichever company was first to achieve success. For that reason, they invested hundreds of millions of dollars, as well as the time and creativity of hundreds of scientists and technical assistants, to reach that goal. They still failed.

**Tobacco Working Group**

In addition to private industry research, in 1966, President Lyndon Johnson created a National Cancer Institute task force to investigate the link between cigarettes and lung cancer (21). In response, the Less Hazardous Cigarette Working Group, later renamed the Tobacco Working Group, was established and first met on March 11, 1968 (21, 32, 33). Membership on this committee throughout its 11-year existence included various representatives from the tobacco industry, government officials, and academics (21, 32, 34–38). Most (74%) of the approximately $50 million spent by the Tobacco Working Group was devoted to research to develop a less risky cigarette (21, 39, 40). More specifically, most of the research was conducted on mice and some on dogs to ascertain possible inhalation health effects due to tobacco smoke. In particular, much of the research focused on tumorigenic activity due to tobacco smoke on mouse skin (41–45). Other testing examined cigarette filters to possibly reduce ciliotoxicity, cytotoxicity, and inhibition of alveolar macrophages (46). All of these study results either showed no significant reduction in risk or were inconclusive and inconsistent on whether product modification increased or decreased the health risk of
cigarettes for humans (18, 21). By 1979, Joseph Califano, Secretary of the Department of Health, Education, and Welfare under President Jimmy Carter, ended funding for the Tobacco Working Group (18, 21). His rationale, reflecting a growing consensus by national health groups, was a need to emphasize smoking research that focused on cessation and prevention.

Summary of Industry and Government Attempts to Develop a Less Risky Cigarette

Despite the large-scale and long-term tobacco industry and government efforts to develop a marketable and less risky cigarette, this has not occurred (5–18, 22, 23). This has been the case whether the approach was to generally or selectively reduce tobacco ingredients such as ciliastats or nitrosamines (Table 1). Moreover, even under ideal conditions with adequate scientific testing, as indicated in 2001 by Philip Morris, the efficacy of purportedly reducing the health effects cannot be scientifically verified for up to 20 years after introduction of the product on the market (31). This also has not occurred.

Recent External Scientific Investigation on Developing a Less Risky Cigarette

Since 2001, there have been several external and non-tobacco industry studies and analyses assessing the scientific possibilities of developing and selling a less risky cigarette (16, 22, 24, 47–59). Much of the analysis has been associated with considerable controversy over the efficacy and viability of government regulation to initiate and oversee the manufacture of less risky cigarettes (16, 24, 48–55). Some recent external peer-reviewed research and findings have also found scant or no evidence that removing cigarette ingredients in part or in whole will facilitate the manufacture of less risky cigarettes (22, 24, 57–64).

In 2001, the prestigious U.S. Institute of Medicine concluded that a burnt cigarette includes about 4,000 ingredients (22). Currently, the report noted, scientific examinations of vitrotoxicity, cytotoxicity, and genotoxicity provide almost no evidence on the basis of which tobacco ingredients are conclusively linked to specific morbidities and mortalities. Furthermore, testing of live exposure to complex mixtures of chemicals has received almost no examination. The Institute of Medicine report also indicated that scientifically unconfirmed linkages to carcinogenesis could include nitrosamines, aromatic amines, free radicals that cause oxidation damage, and a myriad of other carcinogens contained in burning cigarettes. The Institute of Medicine also concluded (22):

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 (various rates of puffing cigarettes) and actual exposure and by inter-individual or population differences.

In its 2007 report *Ending the Tobacco Problem: A Blueprint for the Nation*, the Institute of Medicine reaffirmed this key finding (23):

Since the 1980s, tobacco companies have experimented with novel tobacco- and cigarette-like products designed to reduce the toxicity of smoking and the level of secondhand smoke emissions. These products have taken various forms over the years, including cigarette-like devices that heat rather than burn tobacco and, more recently, cigarettes with reduced carcinogen emissions. Harm reduction products, also referred to as PREPs (potential reduced-exposure products), are potentially beneficial, but there is not yet enough scientific evidence to determine their effectiveness in reducing harm from smoking (IOM 2001 [22]).

Nevertheless, the 2007 Institute of Medicine report, in its Recommendation 24, called for “Congress [to] confer upon the FDA broad regulatory authority over the manufacture, distribution, marketing, and use of tobacco products” with one priority being to “reduce the risks of using tobacco products to the users and to others” (23). The report further explained (23):

The regulation of tobacco product characteristics can be seen as having two primary goals (IOM 2001 [22]). One is to reduce the harm from the continued use of tobacco products. This might be achieved by reducing the toxic emissions from cigarettes or the toxic constituents of smokeless tobacco. Reducing toxic exposures would potentially lower the risk and severity of disease in people who continue to smoke. It is essential, however, that the federal government assures that consumers are informed about what is and what is not known about the risks of using products that result in reduced toxic exposures (reduced-exposure products). Moreover, regulators must take steps to reduce the likelihood that the availability of reduced-exposure products will increase initiation or reduce the number of users who quit. The danger that the marketing of reduced-exposure products could lead to an increase in smoking prevalence by altering risk perceptions about smoking is one of the greatest challenges that the FDA will need to address.

*Current Science on Less Risky Cigarettes Compared with Proposed FDA Regulation of Tobacco*

Given the current science and the need to test the health effects of purportedly less risky cigarettes for up to 20 years, what is the likelihood that the policy goals
stated by the Institute of Medicine and embodied in the 2009 FDA legislation to regulate cigarettes may be mismatched or create unintended consequences that will not lessen the health risk of cigarettes? Whether the cigarette risk reduction provisions in the 2009 FDA tobacco regulatory legislation, which was supported by large majorities in the U.S. House and Senate, would produce a less risky cigarette is currently unknown (4, 65).

In the FDA tobacco regulation bill (4), Section 901 authorizes the FDA to regulate cigarettes. Section 904 requires tobacco manufacturers to submit a list of tobacco product ingredients including the content and form of nicotine, marketing practices, additives, and health, toxicological, behavioral, and physiological data to evaluate product safety. Section 907 further clarifies what ingredients may be examined by prohibiting all additives except menthol, provides for the reduction of nicotine and other harmful constituents, but prohibits reducing nicotine to zero as well as the banning of specific tobacco products. Sections 910 and 911 require that new tobacco products or modified tobacco products receive pre-market FDA approval for safety and protection of the public health. The criteria to ascertain whether a product is less risky is based on costs and benefits to the population as a whole and whether existing users will stop using a tobacco product, not commence the use of a tobacco product, or switch to a safer product. This will be determined by “well-controlled investigations.” All of these requirements in the proposed FDA tobacco legislation have not been verified by the numerous scientific investigations to develop a less risky cigarette over the past 40 years or so. Therefore, the efficacy of such a regulatory approach is uncertain, with a large risk that this program may not adequately reduce the risk of cigarette smoking.

DISCUSSION

Despite the current provisions in the 2009 Family Smoking Prevention and Tobacco Control Act—supported by large majorities in the U.S. House and Senate and by President Barack Obama—to reduce the risk and harm of cigarettes, such an approach is not rationally connected to any current scientific research that demonstrates the possibility of creating a less risky cigarette with a high degree of certainty to reduce morbidity and mortality (2, 3, 65). To implement the 2009 FDA tobacco regulatory legislation, President Obama’s FDA commissioner has appointed nine voting and three nonvoting members to a Tobacco Product Scientific Advisory Committee. The committee currently is charged with making reports and recommendations on tobacco-related topics (66). Examples include examining the health effects of menthol in cigarettes, of dissolvable tobacco products, and of changing nicotine levels in cigarettes, and analyzing new cigarette products that purportedly reduce the health risks of tobacco products. Furthermore, despite passage of the 2009 FDA legislation, even if a less risky product were to be tested through either a general or a selective reduction approach, social epidemiological and medical evaluations would take up to 20
years to confirm the presence or absence of the long-term health risks of such a risk reduction approach. This effort would entail significant long-term government and regulatory resources, which may or may not benefit individual smokers. In the meantime, morbidity and mortality among smokers would continue.

The flaw in the FDA tobacco regulatory legislation is that the policy instrument based on determining product quality standards, technical production standards, and performance standards is not rationally linked to known scientific research or studies. In fact, with the dismal track record in developing a marketable and less risky cigarette of any type, the current FDA tobacco regulatory legislation is oriented toward possible future discoveries of a less risky cigarette. In essence, the role of research and development of a less risky cigarette will be transferred from private tobacco companies and partially socialized through the FDA regulatory authority to oversee and approve such research and development. This regulatory approach, while maintaining the private profit mechanism for tobacco companies, shifts the onus of certifying less risk to the federal government.

The 2009 FDA tobacco regulatory legislation is predicated on an unverified assumption that the policy intent of the legislation to produce less risky cigarettes is solidly linked to the desired policy outcome to actually approve less risky cigarettes. Unfortunately, because there is no known scientifically verified less risky cigarette, the FDA tobacco regulation is currently and primarily policy symbolism. Policy symbolism is generally understood to be a proposal or proposition that advances a goal (such as developing less risky cigarettes) while actually accomplishing something different. Given the required 20-year period of long-term testing to verify the health effects of a cigarette product modification, that “something” would be maintenance of the status quo in the distribution of current cigarette brands. This would include, in particular, cigarette brands that contain menthol and do not reduce nicotine to zero. Given the lack of scientific certainty about the manufacture of a less risky cigarette, cigarette modifications or the introduction of new brands would be subject to significant and probably long-term restrictions and testing before they could enter the marketplace. This situation would favor the current market leaders in the tobacco industry and would not reveal, for quite a long period, whether a less risky cigarette is feasible—much to the detriment of current and future smokers.

REFERENCES


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Direct reprint requests to:

Michael Givel
Department of Political Science
The University of Oklahoma
455 West Lindsey, Room 205
Norman, OK 73019

mgivel@ou.edu