Federal Policy Mandating Safer Cigarettes: A Hypothetical Simulation of the Anticipated Population Health Gains or Losses

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Abstract

If manufacturing a safer cigarette is technically possible—an open question—then mandating that tobacco manufacturers improve the safety of cigarettes would likely have both positive and negative implications for the nation's health. On the one hand, removing toxins may reduce the incidence of smoking-related diseases and premature mortality in smokers. On the other hand, smokers might be less inclined to quit, those who have quit might resume the habit, and youth who have never smoked will have one less reason to avoid tobacco use. To assess the expected population health impacts of a legislative or regulatory mandate, we created the Tobacco Policy Model, a system dynamics computer simulation model. The model relies on secondary data and simulates the U.S. population over time spans as long as 50 years. Our simulation results reveal that even if requiring cigarettes to be safer makes smoking more attractive and increases tobacco use, a net gain in population health is still possible. © 2004 by the Association for Public Policy Analysis and Management.

INTRODUCTION

Cigarette smoking is now widely acknowledged as the single leading preventable cause of death in the United States (US DHHS, 2000). Smoking causes more fatalities each year in this country than AIDS, alcohol, cocaine, heroin, homicide, suicide, motor vehicle crashes, and fires combined (Mokdad et al., 2004). On average, smokers die more than 6 years before non-smokers (Lew and Garfinkel, 1987) from causes such as cardiovascular disease, cancer, and emphysema. In addition, they experience a host of other health problems ranging from poor wound healing (Hollinger et al., 1999) to impotence (Tengs and Osgood, 2001).

Various policy approaches, such as raising excise taxes on tobacco or restricting smoking in restaurants, have been effective in reducing tobacco use. Due in large part to these efforts, smoking rates have been cut in half since 1965 and continue to decline. However, according to the U.S. Surgeon General (US DHHS, 2004), the rate of decline in adult smoking prevalence has slowed in recent years. One of the national objectives for 2010 is to reduce smoking prevalence among adults to 12 percent or less, an objective that has been achieved to date only in the U.S. Virgin

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Islands (CDC, 2004a). In fact, given that 23.8 percent of the adult population smoked in 2001, and 23.5 percent smoked in 2002, "the rate of decline has not been at a sufficient pace to achieve the 2010 national health objective" (CDC, 2004b).

Recently, opinion leaders have begun to seriously discuss a more controversial approach—harm reduction (Hatsukami et al., 2004). Harm reduction refers to minimizing the morbidity and mortality associated with smoking without completely eliminating tobacco use (Stratton et al., 2001). To date, much of the discussion of harm reduction has centered on proposals to regulate the level of nicotine in cigarettes. The American Medical Association (AMA), for example, is an outspoken proponent of this approach (Henningfield et al., 1998). The AMA's reasoning is that because the drug nicotine is the pleasurable and addictive ingredient in cigarettes, reducing the nicotine content of cigarettes would prevent smokers from maintaining their dependence (Benowitz and Henningfield, 1994). Further, nicotine does have some negative health implications, particularly cardiovascular (Benowitz, 1997; McMartin et al., 2002; Mitchell et al., 2002) and the long-term effects of nicotine exposure are uncertain. Nevertheless, it is the toxins in cigarettes, not nicotine, that cause most smoking-induced diseases. While reducing nicotine might dissuade smoking, it would do little to eliminate hazards for those who continue to smoke. Perhaps more worrisome, when addicted smokers are faced with insufficient amounts of nicotine to maintain their addiction, they tend to compensate in various ways, such as smoking more cigarettes, inhaling more deeply, taking larger and more frequent puffs, and smoking the cigarette to a shorter length (Henningfield and Schuh, 1996; Herning et al., 1981; Scherer, 1999; Stephen et al., 1989; US DHHS, 1988). Compensatory smoking has been associated with higher rates of lung cancer and other diseases (Stellman et al., 1997).

Certainly, if it were feasible, a more direct approach to harm reduction would be to simply make cigarettes less hazardous, possibly while maintaining current levels of nicotine. A safer cigarette might be defined as one that results in less morbidity and mortality in those who choose to smoke. "Low tar" cigarettes, introduced in the 1950s, were essentially "safer image" products rather than being truly less hazardous in any meaningful sense (Kaufman et al., 1989; NCI, 2001), thus it remains unclear whether producing safer cigarettes is technologically feasible. Some have suggested that, at a minimum, harmful additives such as acetaldehyde and pyridine, included to enhance nicotine's addictive effects, can be excluded from cigarettes (Douglas, 1998). In addition, companies may be able to remove or reduce some of the major classes of carcinogenic substances such as the nitrosamines, aldehydes, polycyclic aromatic hydrocarbons (PAHs), and trace heavy metals. Reduced exposure to toxins may result in reduced harm, although no direct scientific evidence of this exists at the present time.

If making cigarettes less hazardous proves to be technologically feasible, what means might be used to accomplish this? Reliance on the private market has not resulted in the widespread introduction and adoption of cigarettes that are truly safer. The Food and Drug Administration (FDA) asserted their authority to regulate tobacco, but the U.S. Supreme Court (2000) rejected their assertion concluding that Congress had not granted the FDA that authority. Since then, a number of bills have been introduced in Congress that variously amended the Food, Drug and Cosmetic Act. Most recently, Senator Judd Gregg (R-NH), Chairman of the Senate Committee on Health, Education, Labor, and Pensions and fellow Committee member Senator Mike DeWine (R-OH) introduced The Family Smoking Prevention and Tobacco Control Act, which grants the FDA the authority to regulate the production, distribution, labeling, and marketing of tobacco products. Talks broke down, however,

over a provision that would have stopped the FDA from ordering changes that "directly or indirectly" cause all cigarettes to be eliminated from the marketplace as this seemed to prevent the FDA from requiring the changes to cigarettes that would make them safer.

In lieu of new authority for the FDA, Willam Farone (2002; personal communication) has suggested that the Environmental Protection Agency (EPA) might extend its current maximum allowable exposure levels to cigarettes. Cigarettes contain known carcinogens that, if found at the same level elsewhere in the environment, would be considered in violation of current EPA standards. For example, a single unfiltered cigarette contains 100 μg (micrograms) of formaldehyde, 120 μg of arsenic, and 1400 μg of acetaldehyde, even though the EPA requires that daily exposure to these chemicals not exceed 40 μg, 0.06 μg, and 90 μg, respectively.

Though mandating safer cigarettes has a certain obvious appeal, detractors express concern that if cigarettes are safer, tobacco use may increase (Warner, 2002). Smokers might be less inclined to quit, those who have already quit might be inclined to resume smoking, and youth who have never smoked will have one less reason to avoid tobacco use. The historical emergence and subsequent market dominance of filter cigarettes and, in later years, low-tar cigarettes, offers clear evidence that the public will consume a seemingly safer product in lieu of avoiding tobacco use entirely (Kozlowski et al., 1998; NCI, 2001). Many smokers switched to low-tar cigarettes rather than quit (Shiffman et al., 2001). Finally, although reductions in tar and other toxins could mean fewer cases of smoking-related diseases, nicotine, which would likely remain an active ingredient, is not completely harm-free (Benowitz, 1997; McMartin et al., 2002; Mitchell et al., 2002). On the other hand, after factoring any hazards associated with nicotine, a cigarette that is truly safer, and not merely "safer image," would have the potential to reduce the excess mortality and morbidity experienced by those who continue to smoke.

Because making cigarettes less hazardous would have positive and negative consequences, some scholars have called for a better understanding of the risk/use equilibrium (Kozlowski et al., 2001). The equilibrium might be considered the level at which increased use of a harm-reducing product negates the benefits of its risk reduction to a population. If a risk-reducing product is particularly attractive, it is possible that the excess use it generates will be greater than the benefits of reduced exposure, resulting in a net public health loss. Alternatively, if the reduction in risk is great enough, then despite any increased use, the result could be a net public health gain.

Policymakers face a dilemma. First, it remains uncertain whether cigarettes can, in fact, be made safer in any meaningful way. If improved safety is viable, it will still be impossible to know the larger population health effects of a federal mandate with certainty prior to its implementation. Yet, a decision must nevertheless be made. In fact, taking no action is itself a decision and so choice cannot be avoided. It is in instances like this that computer simulation of the likely impacts can be especially useful. Thus, to aid policymakers we consider the following hypothetical question: *If* cigarettes could be made safer, and *if* policymakers were to mandate their safety, then what might be the public health implications?

METHODS

To estimate the anticipated population health gains or losses from federal policy changes requiring safer cigarettes, we used the Tobacco Policy Model. The model is described briefly here, but in more detail elsewhere (Tengs, Osgood, and Chen, 2001; Tengs, Osgood, and Lin, 2001).

The Tobacco Policy Model

The Tobacco Policy Model is a flexible system dynamics computer simulation model that we developed. The model is designed to calculate the public health gains or losses from any change in the hazards or patterns of cigarette use.

To start the present simulation, we initialized the model with the number of people in the U.S. population in the year 2003. We divided the population into cohorts according to gender, initial age (U.S. Census, 1996) and smoking status (current, former, or never smoker) (CDC, 1995a, b; US DHHS, 1994). The model then simulates annual transitions such as birth, death, aging, net migration, and changes in smoking behavior in the U.S. population over 50 years with transition probabilities varying by age, gender, smoking status, and year.

Three types of annual smoking behavior change are simulated: initiation (the transition from being a never smoker to being a current smoker), cessation (current to former smoker), and relapse (former to current smoker). Data used to estimate annual behavior change probabilities were obtained from various sources (NCHS, 1991; US Census, 1994). Then, using regression methods, we fit separate hazard functions for each type of smoking behavior change by age, gender, and interaction terms.

In our model, gains or losses in an individual's health are measured with quality-adjusted life-years (QALYs). The QALY measure, recommended by the U.S. Task Force on Cost-Effectiveness in Health and Medicine (Gold et al., 1996), combines improvements in length of life and health-related quality of life into a single measure. Quality of life data for current, former, and never smokers of various ages and genders were obtained from the quality of well-being scale (Kaplan, 1993). We estimated mortality hazard functions using mortality data for each gender (US Census, 1996) and smoking status (NCHS, 1994a) and built those into the model so as to simulate improvements in length of life and QALYs.

Calibration

To ensure the accuracy of the model, we calibrated it against reliable external estimates of smoking prevalence (never, current, and former), population size (by age and gender), and life expectancy (by age, gender, and smoking status). We compared each model output with external estimates, and then made adjustments to select model parameters to improve the correspondence. We repeated this exercise until all model outputs were within 3 percent of the external estimate.

To calibrate smoking prevalence, we started the model in 1995, loading it with historical data. We then ran the model forward and observed the predicted prevalence of current smokers, former smokers, and never smokers in 2000. We corrected discrepancies in never smoker prevalence by changing the initiation rate, and discrepancies in current and former smoker prevalence by changing cessation and relapse rates. Our model estimated that 23.6 percent of the adult population would be current smokers in 2000, while 22.5 percent would be former smokers and 53.9 percent never smokers. These estimates compared favorably to estimates from the National Health Interview Survey (CDC, 2000), which reported prevalence as 23.2, 22.2, and 54.6 percent, respectively.

To calibrate population size, we ran the model forward through the year 2050. We compared population counts for years 2025 and 2050 with U.S. Census middle series projections for those years (US Census, 1999). To improve the correspondence between model estimates and Census projections, we made slight

increases to fertility and decreases to mortality. In the end, model estimates of population size for both genders and all age groups differed from Census projections by less than half of 1 percent for the future year 2025 and by less than 2 percent for 2050.

Finally, we compared the simulated life expectancy of current, former, and never smokers to external estimates from the American Academy of Actuaries (2002) and Hatton Financial (2002), revising mortality rates to improve correspondence. Life-expectancy estimates vary by age and gender, but as one example, the model estimated that a 45-year-old female never smoker would live 39.37 additional years and a female current smoker of the same age would live 33.94 additional years. These life-expectancy estimates compare favorably with insurance industry estimates of 39.33 and 33.89 years, respectively.

Scenarios Evaluated

We estimated the QALY gains or losses that might result from the combination of the three effects that we expect to follow any federal mandate of safer cigarettes. The first effect, and the most obvious one, is that if cigarettes can be made safer then those who choose to smoke will live longer. This is primarily because if cigarettes are made safer by removing carcinogens and other hazardous substances, the incidence of fatal cancers and other diseases may decline. However, because the degree of any improvement is uncertain, we simulated a hypothetical reduction in the differential in mortality between current smokers and never smokers by amounts ranging from 0 to 100 percent. To reduce the differential, we simulated an improvement in the survival prospects of smokers, leaving the survival of never smokers unchanged. For example, when we reduced the differential by 50 percent this resulted in current smokers of safer cigarettes having an elevated risk of mortality compared to never smokers that was half of what it would have been had they smoked regular cigarettes. At the extreme, when we reduced the differential by 100 percent, current smokers were assumed to have the same probability of death as never smokers. Clearly, this represents an unreachable upper bound, but it was included to verify the accuracy of our model; QALYs for never smokers should be the same as QALYs for smokers under this hypothetical scenario.

We also considered that at the moment of any change in federal policy, considerable irreparable damage would already have been done to the health of people who had been smoking for some time, even if they immediately began to smoke safer cigarettes. To simulate this, we assumed that the improvement in the survival prospects of current smokers would be in proportion to the amount of time they smoked safer vs. unsafe cigarettes. We used the smoker's age as a proxy for this amount of time assuming, for example, that current smokers who were older at the time of the policy change smoked unsafe cigarettes for a larger proportion of their life relative to smokers who were younger. Using age as a proxy for time is reasonable because 89 percent of smokers begin smoking before the age of 18 (NCHS, 1994b). We modeled any change in the mortality of smokers as a function of age and, as the simulation progressed over the 50 years, as a function of time since the hypothetical federal policy change. We estimated reductions in the mortality of former smokers in the same fashion.

The second effect that would likely follow the legislation of safer cigarettes is that those who choose to smoke may have not only improved survival, but also lower morbidity rates. We modeled this by reducing the net differential in health-related quality of life between current smokers and never smokers by amounts ranging

from 0 to 100 percent, consistent with the change in mortality. We made the same change for former smokers.

The third possible effect of legislating safer cigarettes is that the prevalence of tobacco use may increase. In our model, prevalence is analogous to a fluid level that increases with any inflow and decreases with outflow. Flows occur due to mortality and smoking behavior change. That is, in the Tobacco Policy Model, prevalence is not entered or manipulated directly; rather, it varies with any change in the rate of inflow from initiation and relapse, and outflow from cessation or death. We assumed that safer cigarettes would make smoking more attractive to current smokers, former smokers, and never smokers and revised the corresponding probabilities of cessation, relapse, and initiation accordingly. When simulating a hypothetical increase in tobacco use, we increased the annual probabilities of initiation and relapse, which vary naturally by age and gender, by amounts ranging from 0 to 100 percent. We also decreased the annual probability of cessation by amounts ranging from 0 to 100 percent. As a starting point, we assumed that all three probabilities would change by the same amount so that, for instance, if cessation decreased by 10 percent, then relapse and initiation would increase by 10 percent, as well. Described later, we varied this assumption in sensitivity analysis. Note that while a 100 percent decrease in cessation will make those probabilities 0, a 100 percent increase in initiation and relapse will not make those probabilities 1.

For each hypothetical change in mortality and morbidity (0, 10, 20, …, 100 percent) combined with a change in tobacco use behavior (0, 10, 20, …, 100 percent) we ran the simulation model for 50 years, estimating the total cumulative QALYs accrued to the entire U.S. population over that period. Note that the scenario where mortality and morbidity were changed by 0 percent and tobacco use behavior was also changed by 0 percent effectively allows us to calculate QALYs under the scenario where everything remains constant absent a change in federal policy. We calculated the gain or loss in QALYs for each combination scenario, relative to this 0 percent change scenario.

Sensitivity Analyses

In the baseline analysis described above, we assumed that initiation, cessation, and relapse would all change by the same percent in response to the introduction of a safer, and thus more attractive, cigarette. In reality, the availability of safer cigarettes may have a more profound influence on the likelihood of some types of smoking behavior change and less influence on others. For example, it may be that the availability of safer cigarettes has little influence on whether youth start to smoke because forces such as the media, peer pressure, and parental influence might have more importance (Gottlieb and Baker, 1986; Killen et al., 1997; Mermelstein, 1999; NCHS, 1994b; Tyas and Pederson, 1998; Unger and Chen, 1999). Relative to initiation, it may be that cessation and relapse will be affected to a greater extent. Thus, we varied our assumptions about the types of behavior change that are most affected to assess the relative importance of our initial assumption on the results. To do this, we investigated two extremes. First, we assumed that the introduction of safer cigarettes would have no influence on initiation but would affect cessation and relapse by amounts ranging from 0 to 100 percent. In a second sensitivity analysis, we assumed that the availability of safer cigarettes would have no influence on cessation and relapse, but would affect initiation by amounts ranging from 0 to 100 percent. By testing these extreme cases, we can determine whether the

results are sensitive to the nature of behavior change, in addition to the amount of behavior change.

RESULTS

Table 1 shows the cumulative change in QALYs (in millions) to the U.S. population over a 50-year period as a function of alternate levels of cigarette safety that might prove possible and degrees of change in smoking behavior that might occur. To orient the reader, the rows in this table represent different hypothetical percent reductions in the mortality and health-related quality of life differential between current smokers and never smokers (and between former smokers and never smokers). For example, the 50 percent row represents the scenario where cigarettes were safer such that age- and gender-specific excess mortality risk in current smokers is cut in half. Columns represent different degrees of smoking behavior change that might occur. For example, the 30 percent column represents the scenario where never smokers increase their age- and gender-specific natural annual probabilities of starting to smoke by 30 percent. In addition, current smokers of every age and gender would have a 30 percent decrease in the annual probability of quitting and former smokers would have a 30 percent increase in the probability of relapsing.

It is clear from Table 1 that the magnitude and direction of the hypothetical change in the health of the U.S. population relative to the status quo will depend on the level of risk reduction offered by safer cigarettes and the degree of behavior change that this encourages. For example, if cigarettes are safer such that the excess mortality in smokers relative to never smokers is decreased by 20 percent, and if behavior also changes by 20 percent, then a gain of 18 million QALYs over the 50-year period might be expected. Alternatively, if the mortality differential is reduced by 10 percent and behavior changes by 20 percent, then a loss of 15 million QALYs may occur.

An approximate threshold is evident in Table 1 between the shaded areas, where losses in QALYs are expected, and un-shaded areas, where gains are expected. This

Table 1. Cumulative change in quality-adjusted life-years (in millions) over 50 years depending on the reduction in the hazards of smoking and the change in tobacco use behavior.

		Behavior Change										
		0%	10%	20%	30%	40%	50%	60%	70%	80%	90%	100%
Decrease in Mortality	0%	0	–24	–48	–73	–99	–127	–156	–186	–220	–256	–297
	10%	31	8	–15	–39	–64	–90	–118	–148	–180	–216	–256
	20%	62	40	18	–5	–29	–54	–81	–109	–141	–175	–214
	30%	93	73	52	30	8	–17	–42	–70	–100	–134	–171
	40%	125	106	86	66	44	21	–3	–30	–59	–91	–128
	50%	157	139	121	102	81	59	36	11	–18	–49	–84
	60%	190	174	156	138	119	98	76	52	25	–6	–40
	70%	223	208	192	175	157	138	116	93	68	39	5
	80%	257	243	229	213	196	178	158	136	111	83	51
	90%	292	279	266	251	235	218	199	179	155	128	97
	100%	327	316	303	290	275	260	242	222	200	174	145

"Behavior change" refers to a change in smoking behavior, that is, initiation, cessation, and relapse. A behavior change of x% would imply an x% increase in initiation and relapse combined with an x% decrease in cessation.

demarcation represents the threshold where the mortality and behavior change impacts are such that they cancel each other out, meaning no change in QALYs are expected relative to the status quo. The results in Table 1 also reveal that if cigarettes can be made safer such that excess mortality in smokers is decreased by 70 percent or more, then a gain in QALYs is expected regardless of the level of behavior change. This is evident from the positive sign in all cells in and below the 70 percent row.

Table 2 shows the change in smoking prevalence at the end of 50 years as a function of varying levels of cigarette safety and extent of change in smoking behavior. For example, if cigarettes are safer such that the excess mortality in current smokers is reduced by 20 percent and if the annual probability of initiation and relapse increase by 20 percent while the probability of cessation decreases by 20 percent, then the prevalence of current smokers would increase from 23.20 to 28.43 percent of the population, or a 5.23 percentage point increase after 50 years. It is clear from the results in Table 2 that smoking prevalence is very sensitive to the change in smoking behavior but insensitive to the level of cigarette safety (change in mortality). For example, if a 100 percent change in smoking behavior occurred (100 percent increase in initiation and relapse combined with a 100 percent decrease in cessation) with no change in cigarette safety, smoking prevalence would increase by approximately 29.69 percentage points in 50 years. Conversely, with a 100 percent reduction in the hazards of smoking and no change in behavior, the prevalence of current smokers in the population would be estimated to increase by less than one percentage point.

The gains and losses in QALYs shown in Table 1 were obtained assuming that the degree of change in initiation, cessation, and relapse following the introduction of safer cigarettes are identical. In Table 3a and 3b we show the results of sensitivity analyses where this assumption is relaxed. Table 3a shows the anticipated population health impacts assuming that the annual probability of cessation decreases by amounts ranging from 0 to 100 percent and the probability of relapse increases by the same amount, but the probability of initiation remains unaffected. Table 3b

Table 2. Estimated percentage increase in the prevalence of current smokers in 50 years depending on the reduction in the hazards of smoking and the change in tobacco use behavior.

	Behavior Change										
Decrease in Mortality	0%	10%	20%	30%	40%	50%	60%	70%	80%	90%	100%
0%	0.00	2.55	5.15	7.82	10.56	13.39	16.32	19.38	22.60	26.01	29.69
10%	0.03	2.58	5.19	7.87	10.62	13.46	16.40	19.47	22.71	26.14	29.85
20%	0.06	2.61	5.23	7.91	10.67	13.52	16.48	19.56	22.81	26.28	30.02
30%	0.08	2.65	5.27	7.96	10.73	13.58	16.55	19.65	22.93	26.41	30.19
40%	0.11	2.68	5.31	8.01	10.78	13.65	16.63	19.75	23.04	26.55	30.36
50%	0.14	2.71	5.35	8.05	10.84	13.72	16.71	19.84	23.16	26.69	30.53
60%	0.17	2.75	5.39	8.10	10.89	13.78	16.79	19.94	23.27	26.84	30.71
70%	0.20	2.78	5.43	8.15	10.95	13.85	16.87	20.04	23.40	26.99	30.90
80%	0.23	2.82	5.47	8.20	11.01	13.92	16.96	20.14	23.52	27.14	31.09
90%	0.25	2.85	5.51	8.25	11.07	13.99	17.04	20.25	23.65	27.30	31.29
100%	0.28	2.88	5.55	8.30	11.13	14.06	17.13	20.35	23.78	27.46	31.49

A behavior change of x% would imply an x% increase in initiation and relapse combined with an x% decrease in cessation.

Table 3a. Cumulative change in quality-adjusted life-years (in millions) over 50 years depending on the reduction in the hazards of smoking and the change in cessation and relapse, assuming initiation remains unchanged.

		Behavior Change										
		0%	10%	20%	30%	40%	50%	60%	70%	80%	90%	100%
Decrease in Mortality	0%	0	–13	–27	–41	–57	–74	–92	–112	–135	–160	–189
	10%	31	18	5	–10	–25	–41	–59	–79	–102	–127	–155
	20%	62	49	36	22	8	–9	–26	–46	–68	–93	–121
	30%	93	81	68	55	40	24	7	–12	–34	–58	–86
	40%	125	113	101	88	74	58	41	22	1	–23	–51
	50%	157	146	134	121	107	92	75	57	36	12	–15
	60%	190	179	168	155	142	127	110	92	72	48	21
	70%	223	213	202	190	176	162	146	128	108	85	58
	80%	257	247	236	225	212	198	182	165	145	122	96
	90%	292	282	272	260	248	234	219	202	182	160	134
	100%	327	318	307	296	284	271	256	240	221	199	173

In this table, a behavior change of x% would imply an x% increase in relapse combined with an x% decrease in cessation. For this sub-analysis it is assumed that initiation remains unchanged.

Table 3b. Cumulative change in quality-adjusted life-years (in millions) over 50 years depending on the reduction in the hazards of smoking and the increase in initiation assuming cessation and relapse remain unchanged.

		Behavior Change										
		0%	10%	20%	30%	40%	50%	60%	70%	80%	90%	100%
Decrease in Mortality	0%	0	–11	–21	–30	–39	–48	–56	–64	–72	–79	–86
	10%	31	21	12	3	–6	–14	–21	–29	–36	–43	–49
	20%	62	53	44	36	28	21	14	7	1	–6	–12
	30%	93	85	77	70	63	56	50	44	38	32	27
	40%	125	118	111	104	98	92	86	80	75	70	65
	50%	157	151	145	139	133	128	123	118	113	109	104
	60%	190	184	179	174	169	165	160	156	152	148	144
	70%	223	219	214	210	206	202	198	194	191	187	184
	80%	257	254	250	246	243	240	237	234	231	228	225
	90%	292	289	286	283	281	278	276	273	271	269	266
	100%	327	325	323	321	319	317	315	314	312	310	309

In this table, a behavior change of x% would imply an x% increase in initiation. For this sub-analysis, it is assumed that cessation and relapse remain unchanged.

shows the anticipated change in QALYs assuming that the annual probability of initiation increases by various amounts ranging from 0 to 100 percent but the probability of cessation and the probability of relapse remain unaffected. It is clear from comparing the results in these two tables with those in Table 1 that if only some behaviors change but not others, then the QALYs that accrue to the population will be greater. This is evident from the fact that all estimates in Tables 3a and 3b are larger than those in Table 1. Further, decreases in cessation combined with

increases in relapse are likely to have a larger impact on QALYs than increases in initiation. Assuming that cigarettes were safer such that smokers experienced a 10 percent reduction in excess mortality, a 50 percent decrease in cessation combined with a 50 percent increase in relapse would result in a loss of 41 million QALYs (Table 3a) while the same percent increase in initiation would result in a loss of 14 million QALYs (Table 3b). Finally, the QALY implications of behavior change appear synergistic. For example, as shown in Table 1, a 10 percent reduction in mortality combined with a 50 percent change in all three behaviors (50 percent increase in initiation and relapse combined with a 50 percent decrease in cessation) would result in a loss of 90 million in QALYs. This exceeds the 55 million loss (41 million from Table 3a + 14 million from Table 3b) that might be expected if effects were additive.

Increases or decreases in QALYs reflect a combination of changes in quality and quantity of life. To better understand which component plays the more important role in the QALY estimates in this research, we performed a sensitivity analysis in which we estimated years of life gained without quality of life considerations. Results (not shown) indicated that the magnitude (absolute value) of the change in QALYs exceeds the change in life-years in most instances. For example, assuming a 50 percent change in mortality and behavior, a gain of 59 million QALYs might be expected of which 43 million represents a gain in life-years. Thus, improvements in survival account for approximately 80 percent of the gain in QALYs and improvements in quality of life approximately 20 percent. Although the magnitude of estimated population health gains differed depending on whether quality of life was, or was not, included, the threshold between gains and losses remained almost identical.

DISCUSSION

The wisdom of mandating safer cigarettes has been hotly debated. Advocates of harm reduction (e.g., Farone, 2002) point out that safer cigarettes may mean improved survival for those who choose to smoke. Detractors (e.g., Moore et al., 1994) fear that recent history with "safer image" cigarettes will repeat itself and that tobacco use will continue or even increase as a result. The value of computer simulation is that it offers a way to combine both concerns and the best available data into a single model to estimate the likely cumulative impact on population health over the long term. Prior work includes that of Sumner (2003) who modeled the impact of replacing cigarettes with nicotine inhalers and Kozlowski et al. (2001) who discussed the risk-use equilibrium. Our work expands on prior research in three ways. First, we quantify the gain in population health that might be expected for a given level of tobacco risk and use. Second, since the prevalence of tobacco use is just the more observable result of the more fundamental inflow and outflow rates of initiation, cessation, and relapse, we model the latter. Third, we use a state-transition computer simulation model that is calibrated for accuracy.

Our simulation results reveal that whether such a policy change would represent a net gain or loss in the collective health of U.S. citizens would depend critically on two factors. The first is the degree to which cigarettes can, in fact, be made less hazardous. The second is the increase in smoking that might occur due to the enhanced attractiveness of this now-safer product. On the first point, it is unclear whether cigarettes can be made less hazardous, and if so, to what degree. If improved safety does prove feasible, then the degree of safety is largely a matter of the stringency of the law or regulation. Policymakers can set the maximum level of toxins allowed and control the intensity of enforcement. The reaction of citizens to the availability

of safer cigarettes can also be influenced by policy changes, but perhaps to a lesser degree. For example, in addition to mandating less hazardous cigarettes, policymakers can increase public education, raise excise taxes on tobacco, pass public smoking restrictions, or use other means to influence tobacco use. The extent of behavior change that might ensue, however, is uncertain.

It is noteworthy that if excess mortality in smokers can be reduced by 70 percent, then our results reveal that net gain in population health is likely. This holds true even if the annual probabilities of initiation, cessation, and relapse change by 100 percent so that the prevalence of current smokers in the population increases from 23.2 percent to 54.1 percent, or 30.9 percentage points, after 50 years.

Several caveats will aid the reader in interpreting our results. First, the present research considers only population health changes, and does not include other societal impacts. Policymakers will want to perform a kind of implicit or explicit cost-benefit analysis when considering a federal mandate. For example, they will want to weigh such factors as the cost of enforcing a mandate and any medical care costs or savings that might be realized. If net societal costs are expected to increase, they will want to consider whether the benefits in the form of health gains are worth the cost to society. If, on the other hand, net costs are negative, then monetary savings combined with a gain in population health would seem to indicate that a mandate is wise. This assumes, of course, that the mandate is sufficiently stringent so that QALYs are expected to be gained rather than lost.

Second, we compare a hypothetical federal mandate with a status quo scenario, where no change in tobacco use is expected to occur. We considered the alternative of simulating a modest decline in smoking prevalence under the status quo. However, because the same forces causing a modest decline under the status quo are likely to also be present following any safer cigarettes mandate, smoking prevalence would also decline at higher rates with the intervention. Thus, the incremental value of adding safer cigarettes is likely to remain largely unchanged if we had modeled declines under both scenarios, and doing so would have made the model unnecessarily complex. Further, note that the change in smoking prevalence between 2001 and 2002 was only 0.3, or less than half of 1 percent. More recent data is not available, but if this slowing in the rate of decline continues, we would not be surprised to see a 0.2 or 0.1 annual change in more recent years, changes that are not markedly different from zero. Finally, note that it is impossible to say what smoking rates will be in 30, 40, or 50 years, absent a federal mandate. The surge in cigar use that occurred during the 1990s was certainly not anticipated a few decades ago; who can say what will happen to cigarette use? Thus, in the absence of good information about what the future will hold for smoking prevalence, whether use will decrease or increase, we assumed no change. For the reasons outlined above, this is unlikely to have an important effect on the results.

A third caveat is that the excess mortality and morbidity experienced by smokers is not due solely to the fact that smokers smoke. Relative to those who do not use tobacco, smokers are inclined to drink more (Jensen et al., 2003), exercise less (Blair, Jacobs, and Powell, 1985; Campaign for Tobacco-Free Kids, 2003), and engage in other unhealthful behaviors (Blair, Jacobs, and Powell, 1985; Busen, Modeland, and Kouzekanani, 2001). Thus, the mortality differential between current and never smokers is not entirely attributable to smoking. This means that reducing the hazards of smoking by even 100 percent will not entirely eliminate the mortality differential between current and never smokers. Estimates of the smoking-attributable fraction, however, vary by data source, age, and gender. Further, it may be that if cigarettes are made safer and smoking becomes more attractive,

changes in other health-related behaviors may follow. Thus, statistical models that effectively control for or hold constant other behaviors, while estimating the fraction of mortality attributable to smoking, are misestimating mortality if those behaviors do not remain constant. The only way to consider changes in other behaviors is to simulate them, something that is beyond the scope of the Tobacco Policy Model, which simulates only cigarette use. Fortunately, we simulated a range of reductions in this excess mortality, from 0 to 100 percent, effectively allowing the reader to independently consider attributability. For example, if 50 percent of the mortality differential between smokers and non-smokers is due to smoking, and mandating safer cigarettes reduced that differential by 20 percent, and if other health behaviors remain unchanged even if smoking increases, then the effective reduction in mortality is 10 percent (0.5*0.2 = 0.1). By examining the rows marked 10 percent in our results tables, the interested reader wishing to consider attributability can obtain the likely gains in population health for that level of federally mandated cigarette safety.

Our research also gives insight into the future research directions that are needed. Most importantly, it will be essential to understand the relationship between any reduction in particular toxins and the reduction in disease and mortality that might occur (Stratton et al., 2001)—that is, whether cigarettes can be made less harmful in any meaningful way. Also important to assess are the synergistic effects of the components of tobacco smoke. Finally, it would be helpful to better understand the increase in tobacco use that might occur if cigarettes are marketed as safer.

In this paper we considered the following hypothetical question: *"If* cigarettes could be made safer, and *if* policymakers were to mandate their safety, then what might be the public health implications?" We found that whether there is a public health gain or loss depends critically on degree of safety and the extent to which tobacco use increases as a result. We hope that the thresholds presented in this paper will prove useful as scientists move forward in examining the technical feasibility of producing a safer cigarette and legislators contemplate the wisdom of federal mandates.

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