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Title: **THE EMERGING MARKET FOR LONG-TERM NICOTINE MAINTENANCE**

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Word count (text): 5117

ABSTRACT

In increasing numbers, Americans will seek to satisfy nicotine addictions through the use of novel nicotine-delivery products devoid of the tar and carbon monoxide that make cigarettes so deadly. In the vanguard are tobacco industry devices that heat rather than burn tobacco and pharmaceutical industry nicotine-replacement products, with nicotine "gum" and the patch now available over the counter. Ostensibly, these two industries have diametrically opposed objectives, the tobacco industry striving to sustain nicotine addictions, the pharmaceutical industry to end them. However, a series of technological, economic, political, regulatory, and social developments augurs a strange-bedfellows competition in which these industries will vie for shares of a new multibillion dollar long-term nicotine maintenance market. Regulatory options range from encouraging competition to banning all nicotine-delivery devices. A more realistic approach discourages use of the most dangerous products, while making relatively nonhazardous products readily available to adults.

Accounting for a fifth of all deaths in America,[1] the toll of tobacco is all too familiar. So, too, is the ultimate source of tobacco's toxicity: the extraordinary grip that nicotine places on its users.[2]

As with other addictions,[3,4] becoming abstinent from nicotine is definitely possible; half of currently alive Americans who have ever smoked have quit, usually without clinical assistance. However, for many of the millions who remain smokers, most of whom say that they want to stop, efforts to quit have failed, often despite frequent attempts.[5]

Recognition of the tenacity of their smoking and its eventual deleterious consequences has led some health professionals to question continued, complete reliance on the traditional treatment paradigm, which has regarded abstinence as the only therapeutic goal. Instead, they are cautiously considering a harm reduction strategy that envisions a role for long-term nicotine maintenance using products that deliver nicotine without the other toxic substances in tobacco products.[6-10]

At the heart of the nicotine maintenance concept lies the belief that, although it is not risk-free,[11-14] nicotine *per se* does not directly cause most of the enormous burden of tobacco-related disease. Rather, it is the tobacco products themselves (and their combustion products), the vehicles that deliver nicotine, that are "dirty" and dangerous.

The avoidance of tobacco use is thus considered far more important than kicking an addiction to nicotine. For those who cannot or will not stop using nicotine, might it not be prudent to offer an alternative to tobacco products, one that satisfies their addiction while dramatically reducing their risk of disease?

This question is actually quite complicated, requiring resolution of a myriad of issues.

Can consumer-acceptable products be developed that will satisfy nicotine needs without subjecting consumers to substantial health risks? (What constitutes "substantial"?) Would such products induce children who do not now use tobacco products to initiate nicotine addictions? Would they cause former smokers to relapse? To what effect? (What is the abuse potential of such products?) Would users of such products also use conventional tobacco products? Would the availability of alternative nicotine delivery devices substantially reduce the numbers of people who successfully become abstinent in the future? Again, to what effect? (Again, what is "substantial"?) How would the nation's drug regulatory apparatus respond? Under what circumstances would the sale of such products be permitted?

These are not merely abstract questions. A series of technological, economic, political, regulatory, and social developments has brought us to the brink of a new market for long-term nicotine maintenance. Whether or not the health community finds this desirable, these developments mean that tobacco users -- and possibly nonusers -- are likely to have growing numbers of nicotine-maintenance options available to them soon. Some will involve no tobacco; others will use tobacco in ways not previously imagined. There are scores of patents for such devices, including an electrically-fired pseudo-cigarette.[15]

The options that will eventually be brought to market and the conditions of their availability remain to be defined. It is here that the health community can work with the larger society and its formal policy-making apparatus to shape the future of long-term nicotine maintenance. To broaden the debate, we describe developments that are forcing the issue and consider alternative approaches to defining and regulating a future market for nicotine-maintenance products, including those that use tobacco derivatives as the vehicle for

delivering nicotine and those that do not. We derive salient lessons for the emerging environment of nicotine delivery from the history of innovation in the cigarette industry.

RECENT AND ANTICIPATED DEVELOPMENTS

New technology for delivering nicotine is evolving rapidly and dramatically. Some of the technology already commercially available is very familiar, such as two nicotine replacement therapy (NRT) products: "gum" (nicotine polacrilex) and the patch.[16,17] Some new technology has been introduced but is less familiar, including two cigarette-like devices from the R. J. Reynolds Tobacco Company, Premier and Eclipse.[18-20] Finally, some of the new nicotine-delivery technology is quite unfamiliar. For example, nicotine nasal spray became available as a prescription drug in 1996 and Food and Drug Administration approval of a nicotine inhaler has recently been recommended by a federal scientific advisory panel.[21,22]

All such products emerge in response to market conditions and the social, regulatory, and political considerations that define them. As discussed below, the cigarette manufacturers' introduction of products like Eclipse represents a marketing response to a social environment increasingly hostile towards environmental tobacco smoke and to a marketplace of health-concerned tobacco consumers. Unlike NRT products, which also represent a response to consumer health concerns, Eclipse is not intended as a bridge to abstinence. Also unlike NRT products, the manufacturer has not submitted Eclipse to the FDA for evaluation of safety and determination of marketing conditions.

In terms of their purposes, new products from the cigarette companies and nicotine

replacement pharmaceuticals appear to be worlds apart, the former dedicated to the perpetuation of nicotine dependence, the latter to its curtailment. However, plausible developments in both product categories and in the conditions of their availability could well make the cigarette and pharmaceutical companies the strangest of bedfellows, competing vigorously for a large market of long-term nicotine maintainers. The logic underlying this statement will emerge following consideration of each industry's innovations.

New-generation cigarette-like devices, and old-generation effects on health

Eclipse might appear to represent a radical and even revolutionary change in both industry product and approach. As we discuss below, however, Eclipse follows a tradition of industry response to threats to sales posed by consumer concerns about the conventional product.

Structurally, Eclipse is dramatically different from the conventional cigarette, especially since it burns very little tobacco-like material. A carbon fuel element, insulated with a fiberglass jacket, heats a glycerin-laden charge of reconstituted tobacco. This vaporizes material that cools to condense into an aerosol largely made up of water and glycerin droplets that, in turn, carry nicotine and other volatiles. The consumer inhales an aerosol consisting largely of water, glycerin, nicotine, and the oxides of carbon. Nicotine is delivered at about the same rate and amount as a cigarette having an FTC rated yield of 0.9 mg. Carbon monoxide is moderately higher than that delivered by such a cigarette.[19,20,23,24]

Eclipse is being test-marketed in Chattanooga, Germany (under the name HI-Q), Sweden (Inside), and Japan (AIRS). The only similar device was its immediate predecessor,

Premier, a more radical innovation that produced an aerosol from glycerin and a tobacco extract adsorbed onto alumina beads just proximal to the carbon fuel element. Introduced in 1988, Premier failed market tests and was taken off the market amid mounting pressure on the FDA to regulate it under the Food, Drug and Cosmetic Act.[25]

Both Premier and Eclipse seem designed to address two industry problems: smokers' concerns about the health effects of smoking, specifically its carcinogenic potential (aerosols from both products contain low levels of carcinogens compared to conventional cigarettes), and nonsmokers' concerns about environmental tobacco smoke (ETS) (neither product produces much visible smoke). The latter has implications for the social acceptability of such products and quite possibility their legal acceptability. Would workplace policies and public regulations be modified to permit consumers to use such reduced-smoke devices in places where smoking is banned?

Both of these industry problems have been addressed, largely without success, by earlier generations of product innovation. The ETS issue is of more recent vintage, and relevant innovations are fewer in number. Two were cigarettes with a built-in perfume and low-smoke cigarettes, designed with special papers resulting in less visible sidestream particulate matter.[26,27]

Health concerns drove the two major previous paradigm shifts in cigarette architecture: filter-tipped cigarettes in the 1950s and low tar and nicotine cigarettes at the end of the following decade, both presented to the public as radical design changes, much like the emerging generation of devices.

Filters were the industry's response to the then newly emerging public concern about

smoking's relation to lung cancer.[28] The cigarette companies marketed filters as trapping the dangerous components of cigarette smoke but letting the "flavor" through, although filters never received independent reviews confirming the claims.[26] Affording smokers an apparent alternative to quitting smoking, filters quickly became the dominant product on the market. Their introduction and effective marketing reversed a two-year decline in per capita cigarette consumption in 1953 and 1954 that had resulted from new evidence linking lung cancer to smoking, which then meant unfiltered cigarettes.[25] Ironically, the most successful early filter, touted quite explicitly for its health protection properties, the Kent Micronite filter, used crocidolite asbestos as the filtering agent.[29,30] That filters were introduced primarily as a public relations gambit, rather than as a truly less dangerous product, is suggested by the fact that some early filtered cigarettes used harsher tobaccos, so that the filtered smoke would taste like the unfiltered smoke of old.[28]

The 1964 Surgeon General's report[31] began a process that led to the industry's next technological "fix": low tar and nicotine (t/n) cigarettes, marketed, often explicitly, with the theme that health-conscious smokers had the choice of either quitting smoking or switching to low t/n brands.[32] By 1981, low t/n cigarettes had captured a majority of the market. Medical textbooks frequently recommended their use by patients unable or unwilling to stop smoking.[33,34]

Since then, scientists have learned that smokers who switch from regular cigarettes to low t/n brands engage in "nicotine regulation," compensatory behaviorial changes that greatly narrow the supposed gap between high and low yielding cigarettes. Low t/n smokers may consume more cigarettes, take larger and more frequent puffs, inhale more deeply, smoke to

a shorter butt length, and subvert the technologies that lower machine-measured t/n yields (by blocking ventilation holes in filters that, unoccluded, dilute smoke by mixing it with air).[2,35,36]

The net effect is that, consistent with smoking being a drug dependence process, the variance in smokers' blood cotinine levels is significantly smaller than the variance of nicotine deliveries indicated in cigarette ads.[37] The public is unaware that t/n ratings are derived from standardized machine smoking of cigarettes, in which cigarettes are puffed at a constant volume (35 ml) and at a constant interval (60 seconds). As the data on nicotine regulation demonstrate, people do not usually smoke like the machines.[38]

Low t/n cigarettes would likely reduce health risks if smokers did not engage in nicotine regulation to a significant degree and if they would have continued to smoke even if low t/n cigarettes were not on the market. However, most smokers who "switch down" to low t/n cigarettes do engage in nicotine regulation.[35,36,39] Further, logic, available survey and marketing data, and internal tobacco company documents suggest that the availability of low t/n cigarettes substantially impeded smoking cessation.[25,40-43] On balance, therefore, low t/n cigarettes may well have *increased* the aggregate societal burden of smoking, primarily by reducing the number of people who would have quit in the absence of their availability, and secondarily by switchers smoking more cigarettes.[25]

A similar phenomenon undoubtedly characterized the success of filtered cigarettes in reversing the decline in cigarette consumption in 1953-54. In both instances, a major technological innovation, marketed as promising reduced harm from smoking, may well have had the opposite effect in the population as a whole. Cigarette use likely would be much

lower today if the only products for sale were 70 mm unfiltered smokes. The introduction and diffusion of these new types of cigarettes thus clearly benefitted the industry by maintaining or increasing sales. Industry documents show that industry scientists regarded low-tar cigarettes as "health-image" products, public relations gimmicks, rather than truly "health-oriented" products.[41]

The introduction of Eclipse thus follows a decades-old tradition of industry product innovation in response to public concern, with the industry's intent being to reduce concern and thereby maintain or expand sales. More similarly motivated new-generation products will likely soon appear, especially if Eclipse is successfully introduced.[15,19] Whether past history is relevant to the new generation products remains to be seen. The promise of reduced risk for confirmed smokers may be genuine this time, especially with regard to cancer. If history repeats itself, however, this ostensibly less-hazardous product might sustain high levels of nicotine addiction and, on balance, increase the aggregate disease toll.

One great risk specific to low-smoke devices is that they may be deemed acceptable for use in settings in which smoking is prohibited, such as workplaces. A plausible consequence would be regular cigarette smokers' consuming these devices during work hours, when at present they do not smoke, and then continuing to smoke their regular brands outside of work. The net effect would be increased exposure to nicotine and carbon monoxide, since workplace smoking bans decrease daily cigarette consumption.[44] For people who would have quit smoking in the absence of the day-time nicotine alternative, all of the risks associated with smoking would be greatly increased.

Nicotine-containing pharmaceuticals

The advent of NRT pharmaceuticals revolutionized the treatment of nicotine dependence, in part by medicalizing it. Prior to their availability, the clinical armamentarium was limited primarily to behavioral counseling, which, for a variety of reasons, held little appeal for either physicians or patients.[45] Although a few smoking-cessation products were available in the commercial market, none had demonstrated efficacy in controlled trials.[25,46] Tests of both nicotine polacrilex ("gum") and patches as adjuncts to behavioral counseling demonstrated efficacy, on average doubling quit rates.[16] NRT products thus afforded physicians the opportunity to prescribe something potentially efficacious for patients who wanted to quit smoking, thereby making the physician-patient interaction more conventional and comfortable for both parties.

Nicotine gum introduced the era of NRT pharmaceuticals in the United States in 1984, followed by patches in 1991 and nicotine nasal spray last year, with the nicotine inhaler on the horizon. A nicotine-containing lozenge on a stick (like a lollypop)is also being developed.[47] Each of these newer products has its own set of attractive features and limitations, the latter including abuse potential and other adverse side effects. Each product holds the promise of helping an as-yet undefined subset of smokers. Researchers are investigating combination therapies as well, attempting to exploit the specific virtues of the different products.[48]

As important as the development of NRT products may be a major change in product distribution: over-the-counter (OTC) sale, of gum and patch thus far. Although the quit rate will be lower than that associated with using NRT under the guidance of experienced

clinicians, greater NRT accessibility could more than compensate, leading to more quitting in the aggregate.[49]

OTC availability will also likely increase the use of nicotine-bearing products as partial or complete *ongoing* substitutes for cigarette smoking (and other tobacco-product use). It will likely routinize the use of NRT products by smokers not trying to quit, to supply nicotine when they are not smoking, either because they want to reduce their cigarette consumption or because law or custom precludes their smoking in certain locations (e.g., workplaces or airplanes).[10,50] For this use, NRT products should logically be called nicotine *maintenance* products.

Strange bedfellows

Through product innovation by tobacco companies, pharmaceutical companies, and other consumer products companies, and through OTC distribution of NRT products, the lines distinguishing different types of new-generation nicotine delivery devices could eventually become blurred. More or less intentionally, each company could find itself maintaining nicotine dependence among consumers whose choices would otherwise be limited to conventional tobacco products or abstinence. Ironically, tobacco companies and pharmaceutical companies, which approach nicotine addiction from diametrically opposite positions, could find themselves in direct competition for sales of nicotine maintenance products among the same group of consumers.

In this regard, the history of tobacco company innovation, described above, is not encouraging: previous generations of ostensibly "less hazardous" products may well have

increased the harm caused by cigarettes, by encouraging the maintenance of smoking rather than quitting. Still, some future tobacco industry product may overcome enough of smoking's dangers that the cost of substitution of this product for cigarettes -- continued dependence on nicotine -- will fall short of the benefit of reduced aggregate exposure to the other poisons in cigarette smoke.

There is insufficient history of pharmaceutical industry activity in this arena to draw direct historical lessons. However, with a potential market in the tens of millions of consumers in the U.S. alone, the pharmaceutical industry would have to seriously consider aggressive involvement in a reconceptualized nicotine maintenance market. Drug companies are competing with advertising campaigns for OTC gum and patch exceeding $100 million, which would certainly pay off more handsomely if consumers used these products over a long period of time.[51,52] The relative ease of the transition from focusing exclusively on nicotine replacement to contemplating a much larger market for nicotine maintenance has been hinted at in ads promoting a non-nicotine smoking cessation aid, CigArrest, "for those times when you want to stop smoking, *for a moment* or forever" (emphasis added).

ALTERNATIVE SCENARIOS FOR THE FUTURE AVAILABILITY OF NICOTINE

For many health professionals, contemplating competition between the tobacco and pharmaceutical industries for long-term nicotine users will generate a sense of moral repugnance. Like it or not, however, this competition is developing and will continue to develop, barring extraordinary regulatory measures (e.g., the FDA's returning gum and patch to a prescription-only distribution and prohibiting the marketing of any new tobacco

industry products not demonstrated to be safe).

An optimal set of market and regulatory circumstances could conceivably create incentives that encourage the development of truly much less hazardous methods of consuming nicotine. Note that we have had a market for long-term nicotine maintenance for decades: the tobacco market. Through strict regulation of nicotine in nontobacco products, and virtually no regulation of tobacco products, we have, essentially, granted the tobacco industry a monopoly in the nicotine maintenance market. This market has been accompanied by an unprecedented burden of disease and death. Reconceptualizing that market, opening it to innovative, less hazardous products introduced through competition between the tobacco and pharmaceutical industries, could conceivably satisfy the public's desire for nicotine without exacting the current enormous cost in ruined lives.

The creation and marketing of novel nicotine delivery devices raise a myriad of possible scenarios concerning the future availability and use of both tobacco and non-tobacco nicotine-bearing products. Here we summarize scenarios defined by the regulatory approach adopted. Product availability and use will also be defined by consumer demand. Without discussing this explicitly hereafter, we assume that many consumers will want to use nicotine devices characterized by convenience, reasonable price, social acceptability, and provision of a high degree of nicotine satisfaction.

Either consistently or idiosyncratically, each of the product categories -- current tobacco products, new tobacco industry nicotine delivery systems, and nicotine devices produced by the pharmaceutical or other industries -- could be regulated according to the following options: (1) no regulation; (2) legal availability on a nonprescription basis; (3)

availability by prescription only; (4) not legally available. In addition, regulation could include limits on advertising, disclosure of information to consumers, and so on.

Conventional tobacco products are currently subject to no health and safety regulation. In contrast, all pharmaceutical company innovations have been submitted to and regulated by the FDA, with efficacious nicotine replacement products first permitted for prescription sale and then OTC, if their abuse liability is deemed low. The FDA has also asserted its authority over other nicotine delivery devices not submitted to the agency for approval. Favor, a precursor to the new inhaler, was prohibited as an untested drug delivery system. Similarly, the FDA determined that Masterpiece Tobacs, a chewing gum containing shredded tobacco leaf intended for use "Anytime, when you can't smoke," was a food product adulterated with an unapproved additive, tobacco.[25]

The regulatory status quo is thus well defined, with one critical exception: innovative tobacco industry products. To date, no tobacco company has submitted an innovation for FDA approval, and the agency has not asserted its regulatory authority when confronted with a product from a major producer. However, the FDA has been petitioned to regulate Eclipse.[53] The agency was considering claiming regulatory jurisdiction over Premier before R. J. Reynolds removed it from the market.[25]

A future regulatory structure for nicotine delivery devices could continue current policy, with new tobacco industry products either treated like conventional tobacco products or like conventional pharmaceutical products. Alternatively, it could treat all nicotine-yielding products identically, regulating them as either prescription or nonprescription drug delivery devices. In theory, a decision could be reached to keep government out of the

nicotine market altogether, allowing a free enterprise shoot-out between the tobacco and pharmaceutical giants. As unlikely as that seems, another possibility -- banning all nicotine-yielding products -- is even less conceivable.

A more rational regulatory approach might be to advantage less toxic products, instead of honoring accidents of history, as at present. All currently available nicotine delivery devices would continue to be sold, but the least toxic would be the most easily available and attractively presented, as discussed below. Such an approach could also provide incentives, or requirements, for incremental improvements in conventional products, for instance by requiring that cigarettes be fire safe.[25]

A more radical differential regulatory strategy would require reduction of the nicotine content of conventional tobacco products over se/veral years to levels unlikely to cause or sustain addiction.[54] This would afford current users ample opportunity to wean themselves off of tobacco products, while simultaneously reducing the ability of tobacco products to addict future generations of children.

All other nicotine-yielding products, regardless of industry of origin, would be evaluated as drug delivery devices by the FDA, permitting on the market only those that met a relative harm standard. The harm theshold might (for example) tolerate nicotine addiction, at levels deemed unlikely to be harmful to human health, but prohibit any other substances known or believed dangerous to health.

Under this policy, de-nicotined tobacco products could be freely sold, despite their delivery of toxic compounds (possibly subject to age restrictions, as at present). If people really smoke for "flavor" or "taste" -- the predominant tobacco industry claim -- sales of

tobacco products should not be impacted. If, in fact, people smoke primarily to satisfy nicotine addictions, few if any consumers likely would choose to use de-nicotined products on a regular or even frequent basis. This appears to have been the experience with Next, a de-nicotined brand introduced by Philip Morris in the late 1980s that failed its market tests.[55]

In addition to determining legal availability, regulatory agencies frequently regulate circumstances of manufacture, marketing, time and location of sale, and age of purchase. FDA regulation of cigarettes and smokeless tobacco, to protect children, focuses exclusively on just such conditions of marketing and sale.[56]

Future nicotine delivery device regulation could rely heavily on differential marketing and sale conditions to reduce the attractiveness of the most hazardous products and increase that of the less hazardous. For example, firms might be permitted to advertise, without restrictions, products that FDA found minimally dangerous. In contrast, if permitted at all, cigarette ads might be limited to black-and-white block-letter factual text. Similar distinctions could be made with regard to packaging, with plain packaging required for the most dangerous products, such as cigarettes, with warning labels consuming a third to a half of the front panel of the package.[57,58] Differential rates of excise taxation might be employed to encourage consumer use of the less hazardous products.

Developing a comprehensive, rational, politically feasible nicotine policy is a challenge of the first order. It ought to begin with a few basic principles. First, conventional tobacco products should be grandfathered in the early-going. For political and social reasons, a phase-in period of years should be established for mandated major changes in conventional products, such as lowering nicotine to nonaddicting levels,[54] with the

assurance that reasonable alternative nicotine delivery devices will be available. There is no reason, however, to delay marketing, packaging, and sales restrictions to reduce the glamorous imagery associated with tobacco use, or incremental product design changes helpful to the public's health (e.g., fire safety).

The second principle should be consistency, to the extent pragmatically possible. If any new nicotine delivery device is subject to FDA approval, all should be treated likewise. Thus, since the new nicotine inhaler requires FDA approval, so should Eclipse. If the FDA deems that the risks associated with the inhaler warrant prescription-only distribution, a similar conclusion about Eclipse should lead to a similar requirement.

The call for consistency reflects the ironic reality that new pharmaceutical products currently face a long and expensive marketing approval process, while the most dangerous nicotine delivery device ever invented, the cigarette, is introduced and sold without regulatory impediments. In essence, the deck of competition has been stacked heavily in favor of conventional tobacco products. An entrepreneur with a tobacco- (but not nicotine-) free product that is unarguably less dangerous than cigarettes, as was Favor, cannot simply take that product to market in an attempt to compete with cigarettes.[25]

The final principle is that the primary goal of a new nicotine policy should remain to help everyone who wishes to be free from nicotine and tobacco to achieve abstinence. For those unable or unwilling to be nicotine-free, the policy should offer alternative means of achieving homeostasis that minimize abuse potential and risks to health.

TOWARD DEVELOPMENT OF A NICOTINE POLICY

The intent of a rational nicotine policy must be to deal realistically and constructively with the public health disaster wrought by the widespread use of tobacco products. An underlying premise, supported by a wealth of evidence, is that, because of addiction, tobacco products exact their toll predominantly involuntarily on the part of consumers. With rare exceptions, nicotine addiction begins during childhood and adolescence; despite sincere desires to quit, many simply find the chore too taxing.

With tens of millions of Americans currently addicted, continued dependence on nicotine for large numbers is a virtual certainty for the foreseeable future. "Large numbers" does not imply that all or even most of today's addicted population will always remain addicted; even a relatively small proportion represents a substantial number of people. Furthermore, a variety of social forces leading new generations of children to become nicotine-dependent will persist during much of that future.

People who are nicotine-dependent are victims of addiction and not social miscreants. They deserve a policy that recognizes their individual dignity, the difficulty many would have in being forced to forgo nicotine, and the opportunity to continue consuming nicotine should they so desire. At the same time, children deserve the opportunity to grow up free of inducements to become addicted to nicotine. As such, the option of having minimally harmful nicotine products available to adults, in a social and policy environment that deglamorizes nicotine consumption, seems worthy of open-minded consideration. To achieve such an environment requires serious restriction of children's access to nicotine products and of the marketing of such products. Assuring adults continued availability of nicotine products acknowledges that significant numbers of Americans will be unable or unwilling to

stop using nicotine.

The notion of nicotine maintenance in less harmful forms, rather than complete abstinence, is not new. Following the introduction of filtered and then low t/n cigarettes, numerous health professionals supported switching from the conventional product to the innovation.[41,59] More recently, an oral pathologist has advocated the use of smokeless tobacco products as a less-dangerous alternative for addicted cigarette smokers.[60]

With hindsight, support of filtered and then low t/n cigarettes appears to have been misguided, quite possibly the cause of more rather than less tobacco-produced disease. Similarly, encouraging addicted smokers to switch to smokeless tobacco products appears short-sighted,[61] especially given the availability of the new NRT devices, the spray and the inhaler. These are far "cleaner" than smokeless tobacco and may satisfy nicotine needs at least as effectively.

The approach considered here, nicotine maintenance for some addicted consumers through the provision of less toxic nicotine delivery devices, has been advocated for quite a while by a handful of prominent scientists.[6,62,63] Nevertheless, nicotine maintenance is certain to be unpopular with many seasoned veterans of the tobacco wars. Acknowledgment of the possibility of a world in which nicotine addiction might be tolerated, and even encouraged, would be a bitter pill to swallow for many health professionals.

Stopping short of supporting a ban on cigarettes, universally recognized as implausible (and we believe undesirable), a prevalent "zero tolerance" philosophy derives in part from the accurate perception that, to date, ostensibly risk-reducing product innovations have typically had quite the opposite effect. For at least some members of the tobacco-

control community, it also likely derives in part from a puritanical streak and a cynicism fed by decades of consistently dishonest and dangerous tobacco industry behavior.[28,41,64] Such people may find completely unacceptable the tobacco industry's continuing to profit from the sale of any kind of product, especially one that perpetuates nicotine dependence.

Adoption of a nicotine maintenance policy is fraught with dangers, as well as opportunities; the two may occur together. For example, to compete successfully with cigarettes and other tobacco products, nicotine-only pharmaceuticals may need to be made more attractive to consumers. The current unappealing flavor of nicotine gum may have to be improved. Similarly, more efficient (rapid) means of getting nicotine into the brain may be required (e.g., the new spray or inhaler). Therein lies the promise of consumer-driven shifts away from tobacco products; but the very process of making nicotine products competitive with tobacco products, from a consumer's perspective, will increase the abuse potential associated with the new products. This amplifies the need to ensure that any involved regulatory authority develops explicit objectives and criteria with both foresight and flexibility. Flexibility may prove essential to deal with failures in the domain of foresight: any regulatory system will need to make adjustments in light of actual experience.

The presence of alternatives to conventional tobacco products will influence the degree to which people seek abstinence, and there may be shifting back and forth among delivery devices. The risks faced by novices, the young, under various scenarios will have to be carefully considered as well. What may be good policy for dealing with the current generation of tobacco users may not be so good for future generations. It would be prudent for a national nicotine policy to be subject to periodic review and revision.

A nicotine maintenance market will emerge from the present ferment in device innovation. However, its precise characteristics remain to be established. We urge the health community, and the broader public as well, to engage in thoughtful research and discussion on the nature of this market and on the characteristics it ought to have. In so doing we should draw on the experiences of numerous countries around the world, in which governments are developing a variety of approaches to manage this market. The stakes are extraordinarily high.

ACKNOWLEDGMENTS

Preparation of this article was assisted by grants #026421 and #028627 from the Robert Wood Johnson Foundation, Princeton NJ. We are grateful for constructive comments from Neal Benowitz, MD, Ronald Davis, MD, Karl Olov Fagerstrom, PhD, and Jack Henningfield, PhD.

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HAS SMOKING CESSATION CEASED? EXPECTED TRENDS IN THE PREVALENCE OF SMOKING IN THE UNITED STATES

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Running head: Expected Trends in the Prevalence of Smoking.

Abstract word count: 209

Text word count: 3,891

HAS SMOKING CESSATION CEASED? EXPECTED TRENDS IN THE PREVALENCE OF SMOKING IN THE UNITED STATES

ABSTRACT

From 1965 to 1990 the prevalence of cigarette smoking among U.S. adults fell steadily and substantially. Data for the 1990s suggest that the smoking initiation rate is increasing, and that the decline in smoking prevalence may have stalled, raising the fear that it will not continue its historic 25-year decline. In this paper, using a newly developed dynamic forecasting model, the authors show that although it is possible that the decline in smoking prevalence will slow down, the demographics of smoking imply that prevalence will inexorably continue to decline over the next several decades, even absent any intensified efforts at tobacco control. The authors estimated and validated the model using historical data on adult smoking prevalence. Their results indicate that the current rise in the smoking initiation rate partially explains the flattening of smoking prevalence, but even under the most grim assumptions about future initiation rates, adult smoking prevalence will continue to decline for several more decades. The authors predict that if current initiation and quitting behaviors persist, adult smoking prevalence will fall automatically from its current level of 25 percent to a value between 15 and 16 percent by the second quarter of the next century. Even so, smoking would remain the nation's leading cause of premature mortality.

Keywords: Forecasting; Prevalence; Smoking; Smoking cessation

HAS SMOKING CESSATION CEASED? EXPECTED TRENDS IN THE PREVALENCE OF SMOKING IN THE UNITED STATES

The prevalence of smoking among U.S. adults fell steadily and substantially for a quarter of a century following publication of the first Surgeon General's report on smoking and health in 1964 (1). In 1965, prevalence was 42 percent; by 1990 it had fallen to 25 percent (2). The decline was particularly notable among men, from 52 percent to 28 percent. Recent data suggest that the decline may have stalled, however. Government surveys through 1994 show adult prevalence holding steady at about 25 percent (3). Data on 30-day smoking prevalence among high school and junior high school students, the harbinger of future smoking patterns, show annual increases since the beginning of the decade (4). Health officials have expressed alarm at the apparent leveling off of smoking prevalence among adults and the potential for its future increase suggested by increasing smoking by teens.

We think the alarm is misplaced. Although it is certainly possible that the decline in smoking prevalence will slow down, the demographics of smoking imply that prevalence will inexorably continue to decline over the next several decades, even absent any intensified efforts at tobacco control. Indeed, assuming that nothing changes in terms of contemporary patterns of smoking initiation and quitting, we demonstrate in this paper that adult prevalence will automatically fall to about 16 percent by the end of the first quarter of the next century. This will be the inevitable result of the aging of the population and anticipated birth and mortality patterns, combined with cohort-specific rates of peak smoking prevalence, contemporary prevalence, and quitting rates. In this paper we describe the model used to derive this

conclusion and consider how robust our findings are with respect to plausible changes in smoking behavior on the part of young people and quitting behavior in older cohorts.

MATERIALS AND METHODS

Model

In this section, we describe a dynamic model to forecast future smoking prevalence among U.S. adults ($\geq$ 18 years). The model computes prevalence over time by keeping track of the inflow of new smokers as well as the outflow caused by death or smoking cessation. (See Figure 1.)

***** Insert Figure 1 about here *****

The mathematical specification of the model is as follows:

$$P_{a,t} = P_{a-1,t-1} \times \left(1 - \delta_{a-1,t-1}\right) \qquad a = 1,\ldots,110 \tag{1}$$

$$P_{0,t} = \alpha_t \tag{2}$$

$$C_{a,t} = C_{a-1,t-1} \times \left(1 - \mu_{a-1,t-1}\right) \times \left(1 - \beta_{a-1,t-1}\right) \qquad a = 19,\ldots,110 \tag{3}$$

$$C_{18,t} = \gamma_t \times P_{18,t} \tag{4}$$

$$R_{(a_i:a_f),t} = \frac{\sum_{a=a_i}^{a_f} C_{a,t}}{\sum_{a=a_i}^{a_f} P_{a,t}} \tag{5}$$

$\mu_{a,t}$ = (6)

Year (t) \ Age (a)	18-30	31-50	>50
1970-1980	ν_1	ν_2	ν_3
1981-	ν_4	ν_5	ν_6

where:

$P_{a,t}$ = Size of cohort age a in year t

$C_{a,t}$ = Current smokers of age a in year t

$R_{(a_i:a_f),t}$ = Smoking prevalence between ages a_i and a_f in year t

$\delta_{a,t}$ = Death rate in year t for individuals of age a in the general population

$\beta_{a,t}$ = Death rate in year t for smokers of age a

$\mu_{a,t}$ = Smoking cessation rate in year t for smokers of age a

γ_t = Smoking prevalence for 18 year - olds in year t

α_t = Size of the birth cohort in year t

The number of people of age a in year t is computed by multiplying the number of people of age a-1 in year t-1 by the appropriate survival rate (1 - death rate). Birth cohort sizes are supplied exogenously to the model. The model ignores the effect of migration on future population size and smoking prevalence. The smoking patterns of future immigrants cannot be predicted. Given the small size of the immigration pool with respect to the domestic population, this omission is not likely to bias our results substantially.

Death rates are differentiated by year, age and smoking status. Current smokers in any given year are estimated as the number of current smokers in the previous year who survived to the current year and did not quit smoking. Smoking prevalence at age 18, supplied exogenously to the model for each cohort under study, is used to calculate the size of each year's cohort of new adult smokers. Smoking prevalence for any specific age group in a

specific year is computed by taking the ratio of current smokers to the total number of people within the group that year.

The model assumes that there is no more smoking initiation after age 18, when prevalence attains its peak value for the cohort. After age 18, smoking cessation drives the dynamics of the model. This is consistent with data that shows that by the 1980s almost all regular smoking began before the age of 20 years, and by 1991, the mean age of becoming a daily smoker was 17.7 years (5).

Smoking cessation rates are the parameters in the model to be estimated from historical data on smoking prevalence. The model recognizes that quit rates have changed historically with age and cohort. Existing data show that among cohorts born before 1935, cessation rates appear to be influenced primarily by calendar year, while the more recent cohorts appear to have cessation rates that are determined by age, with cessation rates generally higher at older ages (6). A preliminary analysis of the available data led to the age-group breakdown shown in expression 6 above. Additionally, it is particularly important to allow for different values of the cessation rate before and after 1980. Given that our observations consist of smoking prevalences, we are only able to estimate net rates of change in prevalence; that is, initiation and quitting rates are necessarily confounded in our estimates. Prior to 1980, a non-inconsequential proportion of individuals became regular smokers after age 20, particularly among women. As such, rates estimated for that period will not truly correspond to cessation rates, particularly those of the younger age-group. This is not the case for the period post-1980, when initiation has rarely occurred after age 20.

Parameter estimation

To use the model for forecasting, we first needed to estimate the smoking cessation rates used by the model to compute future smoking prevalence. The estimation procedure can also be used to test the validity of the model against past data. The procedure is described below.

Data. To estimate cessation rates, we collected data on past smoking prevalence. Specifically, we used smoking prevalence for the age-groups 18-24, 25-44, 45-64, and 65 and over, for the years 1970, 1974, 1978-1980, 1983, 1985, 1987-1988, 1990-1993. These prevalences were estimated by the Centers for Disease Control and Prevention (CDC) from the National Health Interview Surveys (NHIS) (2). The data are shown in Table 1.

*** Insert Table 1 about here ***

The National Health Interview Survey (NHIS) is a principal source of information on the health of the civilian noninstitutionalized population. The annual survey consists of a basic set of questions on health, socioeconomic and demographic items. To determine the prevalence of smoking among adults, the NHIS collects self-reported smoking information on cigarette smoking from adults, defined as individuals 18 years of age and older. Prior to 1992, the NHIS classified as current smokers those who answered "yes" to the following two questions: "Have you smoked at least 100 cigarettes in your entire life?" and "Do you smoke

cigarettes now?" Since 1992, the second question has been replaced by the following: "Do you smoke cigarettes every day, some days or not at all?" Current smokers are defined as those who have smoked 100 cigarettes and now smoke either every day or some days. According to the CDC, explicitly including some-day smoking in the definition of current smoking increases the overall smoking prevalence estimate by approximately 1 percentage point compared to the old definition (7). To make the reported CDC prevalence estimates comparable in our analysis, we subtracted one percentage point from the prevalence data reported in 1992 and 1993.

Data on age-specific death rates for the general population were obtained from the Statistical Abstracts of the U.S. for the years 1970 to 1990 (8). We assumed 1990 deaths rates for years after 1990. Death rates for current smokers were obtained from the 1986 NHIS National Mortality Followback Study (9), which estimated age-and gender-specific death rates for current smokers. To combine male and female death rates into a composite figure for the general population, we weighted the gender-specific death rates by the proportion of male to female current smokers at each age. We used these composite death rates to calculate the age-specific relative risk of death between current smokers and the general population in 1986. To calculate current smokers' death rates for years other than 1986, we multiplied each year's death rates for the general population by the age-specific relative risk between current smokers and the general population observed in 1986. We acknowledge that this just an approximate procedure. As smoking prevalence changes, the death rates for the general population (which includes smokers) will change, and hence so will the relative risk between current smokers and the general population. However, this effect is not large enough to influence our results. We

performed a sensitivity analysis on this assumption by repeating the analysis conducted in this paper employing just the 1970 death rates for the general population (as opposed to the ones for the 1970-90 period) and obtained almost identical results.

Estimation procedure. The dynamic model specified in the previous section was implemented in an EXCEL spreadsheet. The unknown parameters of the model (the six cessation rates) were estimated by selecting the set of values that made the model conform as closely as possible to the past observations on smoking prevalence. Weighted Least Squares was chosen as a distance measure between model response and data. Weights were included in the estimation procedure because the observed smoking prevalences for the distinct age-groups have different variances, and therefore convey different amounts of information in the determination of the parameter values. Observed prevalences are the ratio of the number of smokers in the age group to total number of people within the age group. Because the age groups have different populations, and the sample sizes were not adjusted to reflect this, the observed prevalences are more "noisy" the smaller the population size (and hence the sample size) of the age group. The appropriate set of weights is one proportional to the inverse of the variance of the observations (10). Fortunately, along with the observed prevalence for the specific age groups, the data source included the maximum length for the 95 percent confidence intervals corresponding to those prevalences (See Table 1). Assuming that for a given sample size the prevalences are distributed normally, we used the lengths of the confidence intervals to obtain an estimate of the variance of the observed prevalence. The

calculated variances of the observations were used to weight the prevalence observations in the estimation process. (See Appendix for details.)

The Weighted Least Squares estimation was carried out by feeding the response of the dynamic model and the observed data to a minimization routine that controlled the changes in parameter values until the optimization criterion was satisfied. This combination of dynamic model and optimization routine for parameter estimation has been used previously. (See for example (11).) The optimization routine employed to estimate the parameters of our model was the Generalized Reduced Gradient (GRG) algorithm, an optimization technique for nonlinear problems. A current version of the algorithm, GRG2, is embedded in the "Solver" component of the Microsoft EXCEL spreadsheet software. Details on the GRG algorithm are provided by Lasdon et al. (12)

RESULTS

Estimation results

The estimated values and confidence intervals for the six cessation rates specified in the model are given in Table 2.

*** Insert Table 2 about here ***

The results show that the smoking cessation rate rises sharply with age and has increased from the 1970s to the 1980s, consistent with prior expectations. Coefficients for the rates corresponding to the two older age groups are significantly different from zero in the post 1980 time period. For the period 1970-80, just the coefficient for the older age group was

statistically significant. Again, it is important to note that particularly in the earlier time period, the estimates of the cessation rate are confounded by initiation rates. This confounding has the effect of downwardly biasing the estimates, and might partially account for the lack of significance in some of the coefficients.

The significance test was conducted by linearizing the model around the estimated values for the parameters and computing their asymptotic covariance matrix. Once the variances of the estimates have been calculated, a Z test can be readily performed to test the significance of the coefficients. (This procedure is discussed in detail in the Appendix.)

The model produced an extremely good fit for the data. The overall adjusted R^2 was 0.98. Figure 2 shows the fit of the model to data on overall adult prevalence (all four age groups combined).

*** Insert Figure 2 about here ***

Given that the observations for each specific age group constitute a time series of 18 elements, autocorrelation in the series could bias our estimates of the standard errors of the model parameters. To test for autocorrelation we assumed first that if it existed, it was defined by an autoregression process of order one (10). Furthermore, we assumed that the same autocorrelation structure held up among the four different age groups. Thus, we merely need to estimate the statistical significance of one correlation coefficient to determine the existence of autocorrelation in the data. Not all the data could be used for the determination of autocorrelation, because of gaps in the series. After the estimation was done, without

considering any autocorrelation structure, we computed one-year differences in the residuals and tested for first order autocorrelation according to the procedure described in (13). The null hypothesis that such autocorrelation did not exist could not be rejected at the 5 percent significance level. Details of the computations are presented in the Appendix.

The likelihood ratio test was used to test alternative model specifications. In particular, we tested the hypothesis that there was no statistically significant difference among the cessation rates post 1980 corresponding to the three age groups. We focus on the cessation rates post 1980 because they will be used to forecast future prevalence. Explicitly, the hypotheses tested were:

$$H_0^{(1)}: \ \nu_4 = \nu_5 \tag{7}$$

and $$H_0^{(2)}: \ \nu_5 = \nu_6 \tag{8}$$

against the alternative specification:

$$H_a: \ \nu_4 \neq \nu_5 \neq \nu_6 \tag{9}$$

The two hypotheses were rejected at the 5 percent significance level. Thus, we concluded that the three estimated cessation rates post-1980 were significantly different from each other.

Given the apparent stalling of smoking prevalence in recent years, it was particularly important to test the hypothesis that the quitting rates in the 1990s were not significantly different from the ones in the 1980s. To test this hypothesis we re-estimated the model, allowing for the cessation rates from 1990 and subsequent years to be different from the corresponding quitting rates in the 1980s. Employing the likelihood ratio test we did not

find a statistically significant difference between 1980s and 1990s quitting rates at the 5 percent significant level. We then concluded that there is no basis to assume that quitting rates in the 1990s are lower than the ones in the 1980s. (See Appendix for details.)

Forecasting Results

Using the estimated cessation rates for the post-1980 period, we forecasted future smoking prevalence in the U.S. to the year 2100, to give the model the opportunity to achieve a steady-state solution. The size of all future birth cohorts was held constant at the size of the average birth cohort for the period 1981-1990 (3,643,582). Sensitivity analysis was conducted on the future smoking prevalence of 18 year-olds. The smoking prevalence for the age group 18-24 year-olds in 1993 was 25.8 percent. This age group's smoking prevalence has been declining steadily for more than two decades now. Smoking prevalence for 18-24 year-olds has not reached 30 percent since 1985, nor 35 percent since about 1975. To forecast future prevalence, we examine the behavior of the model assuming that the smoking prevalence for 18 year-olds will remain constant at one of the following rates: 20, 25, 30, and 35 percent. At 27 percent, current prevalence for 18 year-olds lies between the two middle figures. The other two prevalences were selected as extreme cases for purposes of sensitivity analysis. In particular, 35 percent represents a worst-case scenario. Use of a 20 percent prevalence among youths indicates the potential impact on eventual adult smoking prevalence of modestly successful policies directed towards the reduction of smoking among youths.

Figure 3 shows the forecasted smoking prevalence for the adult population of the U.S., given the four different selected values for smoking prevalence at age 18. If cessation rates do

not decrease from the values they exhibited during the 1980s, overall adult smoking prevalence in the U.S. will continue to fall, even under an unlikely extreme value of 35 percent for the smoking prevalence for 18 year-olds. The results show that if current quitting conditions persist, with a prevalence of 25 percent at age 18 adult smoking prevalence will decline from its current level of 25 percent to a steady state value of between 15 and 16 percent by the second quarter of the next century. Prevalence rates of 20, 30 and 35 percent will produce steady state adult smoking prevalence rates of 12.2 percent, 18.4 percent and 21.5 percent, respectively.

*** Insert Figure 3 about here ***

The nearly steady prevalence of smoking among adults observed in the U.S. during the 1990s (see Fig. 2) has led many to believe that, short of dramatic new smoking control policies, prevalence will no longer decline. We examined the necessary rise in initiation rate (peak prevalence at 18) to keep the smoking prevalence constant at the current level of 25 percent. We performed this experiment under two sets of cessation rates: the ones estimated for the post-1980 period and the lower limits of their corresponding 95 percent CI. Note that the second set of cessation rates corresponds to a very unlikely worst case scenario. We found that the 18 year-old prevalence necessary to maintain the current level of adult smoking prevalence (25 percent) is 41 percent, for the first set of cessation rates, and 35 percent for the second. Current levels of smoking initiation rates are about 27 percent; this implies that, unless initiation rates rise well above 35 percent, overall adult smoking prevalence will continue to decline, regardless of the adoption of significant new tobacco-control initiatives.

DISCUSSION

Observed smoking prevalence data in the 1990s suggest that adult prevalence has stalled, raising the fear that it will not renew its historic 30-year decline. Our results suggest otherwise. If age-specific smoking cessation rates remain stable at the levels exhibited during the 1980s, overall prevalence is likely to continue falling during the remainder of this decade and through the next. In fact, we predict that overall prevalence will continue to fall even if the initiation rate rises to 35 percent, a level not reached since 1975. Under current initiation rates, the decrease in cessation rates necessary to maintain current smoking prevalence is extremely unlikely.

It is important to emphasize that we are not implying that smoking prevalence will decline naturally down to zero. On the contrary, we predict that, if current conditions persist, smoking prevalence will eventually stabilize at a level between 12 percent and 22 percent. Today's higher smoking prevalence reflects the smoking (and quitting) histories of many cohorts of smokers who joined the pool at different (and, over time, decreasing) initiation rates. For example, the cohort of current (1997) 50 year-olds had a smoking prevalence of 46 percent when those individuals were 18. Such a high prevalence for people aged 18 to 24 has not been observed since then (i.e., since 1965.) Even the most grim assumptions for future initiation rates are far below 46 percent. Even though initiation rates may be rising at present, and may continue to rise in the near future, we are still likely to observe a decline in overall smoking prevalence because older smokers who joined the pool at extremely high prevalence rates continue to boost the aggregate rate of smoking. These smokers are rapidly disappearing

from the pool due to death and smoking cessation, and their disappearance will continue to reduce overall prevalence.

Several reasons may account for the current apparent stalling of adult smoking prevalence. First, even though prevalence is still decreasing, as indicated in Figure 2 our model suggests that the rate of decrease is slowing down. Given this flattening of the adult smoking prevalence, it is more difficult to estimate the slope of the series than, for instance, 10 years ago, given the same number of data points.

Second, the 1990s have been sampled for smoking prevalence far more frequently than any earlier period. An inference of trend based on observations that are clustered so closely together might be clouded by noise in the series.

Third, as discussed previously, the NHIS changed its definition of current smokers in 1992 to explicitly include some-day smokers, many of whom likely escaped categorization as smokers in prior years' surveys. CDC estimates that this has increased their measure of prevalence by about 1 percentage point compared to the old definition. This artificial increase in prevalence creates the impression that the trend has flattened when smoking prevalence values pre - and post - 1992 are compared. We have adjusted CDC's prevalence estimates for 1992 and 1993 downward by 1 percentage point. As seen in Figure 2, the adjustment suggests a continuing decline in prevalence.

Fourth, and finally, initiation rates among teens have been on the rise in the 1990s. As discussed before, these high initiation rates are not enough to stall the reduction in overall smoking prevalence, but they will definitely slow its decrease and they provide some explanation for the apparent flattening of the smoking trend. This surge in smoking among

teens may reflect a response to significant declines in the price of cigarettes. For several years now, lower-priced "generic" and discounted brand cigarettes have gained in popularity, to the point that they now account for over 40 percent of the entire cigarette market. In response to the growing popularity of discounted brands, the major cigarette producers dropped the price of their premium brands by 40 percent in April, 1992. The net effect is that the average retail price paid for cigarettes, adjusted for inflation, is lower today than it was in 1991. A wealth of evidence demonstrates that price significantly affects smoking rates (14).

Our analysis indicates that cessation rates have been reasonably stable for at least a decade and a half. This implies that if the observed flattening of the smoking prevalence is really due to changes in the population's smoking behavior, this modified behavior is more likely to correspond to initiation, rather than quitting rates. Although we anticipate that adult smoking prevalence will continue to decline even if initiation rates rise to 35 percent, the eventual decline will be modest, to a rate of about 21.5 percent. If, in contrast, youth initiation rates can be brought down to 20 percent from their current level of about 27 percent, adult prevalence will decline to a steady-state rate of just over 12 percent. The difference is substantial in terms of the burden that smoking will place on the health of Americans well into the next century.

Our intent has been to forecast the "natural history" of smoking prevalence into the next century, assuming that current trends in initiation and quitting persist. Just as there is nothing natural about inhaling 4,000 chemicals from burning plant material, however, there is no need for us to consider this "natural history" inevitable. Through aggressive educational and policy efforts, the toll of tobacco can be brought well below the course it is on at present. We

note, however, that even if our most optimistic assumption about smoking initiation is realized, nearly an eighth of Americans will be smokers in the middle of the next century. The health toll of smoking will remain extraordinarily high. The health of our children and their children will depend on our not resting on tobacco-control achievements realized today.

Acknowledgements:

Preparation of this paper was assisted by a grant from the Robert Wood Johnson Foundation, Princeton, NJ, on which Dr. Warner is Principal Investigator.

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Table 1. Proportion of Current Smokers by Age Group

Year	Age Group				
	18-24	25-44	45-64	65 & over	Overall
1970	0.380	0.446	0.386	0.161	0.374
1974	0.378	0.445	0.377	0.173	0.371
1978	0.344	0.393	0.367	0.163	0.341
1979	0.344	0.389	0.348	0.164	0.335
1980	0.333	0.378	0.356	0.172	0.332
1983	0.342	0.363	0.333	0.167	0.321
1985	0.293	0.348	0.316	0.160	0.301
1987	0.271	0.332	0.309	0.152	0.288
1988	0.259	0.329	0.294	0.149	0.281
1990	0.245	0.297	0.270	0.128	0.255
1991	0.229	0.304	0.269	0.133	0.257
1992	0.264	0.308	0.273	0.140	0.265
1993	0.258	0.292	0.260	0.118	0.250
95% CI[1]	0.024	0.018	0.018	0.025	0.012

[1] These figures represent the maximum length of the 95% CI for the age group.

Table 2. Estimated Values for Annual Smoking Cessation Rates

			95% C.I.	
Period	Age-group	Est. Value	Lo-bound	Hi-bound
1970–1980	18–30	-0.00953	-0.02221	0.00315
	31–50	0.00718	-0.00125	0.01560
	51+	0.04528	0.03531	0.05525
1981–	18–30	0.00209	-0.00689	0.01107
	31–50	0.02147	0.01588	0.02706
	51+	0.05958	0.05441	0.06475

Figure 1. Overview of Forecasting Model

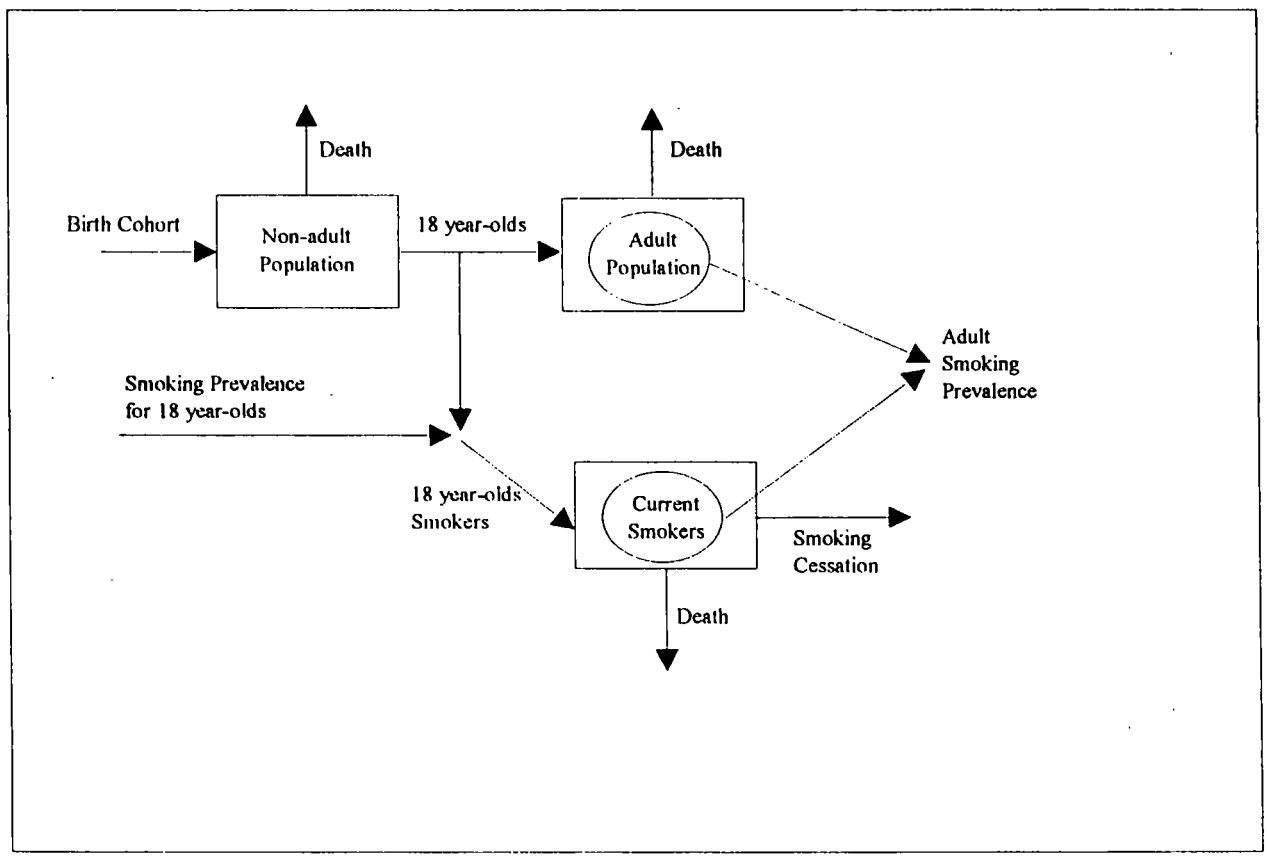
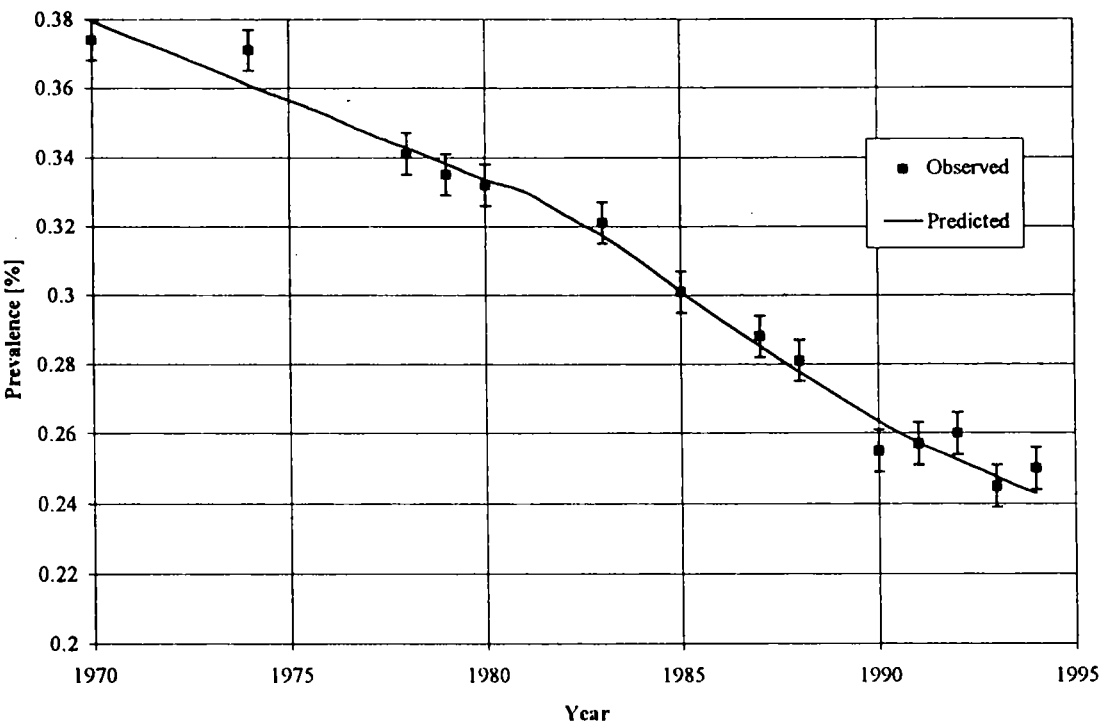
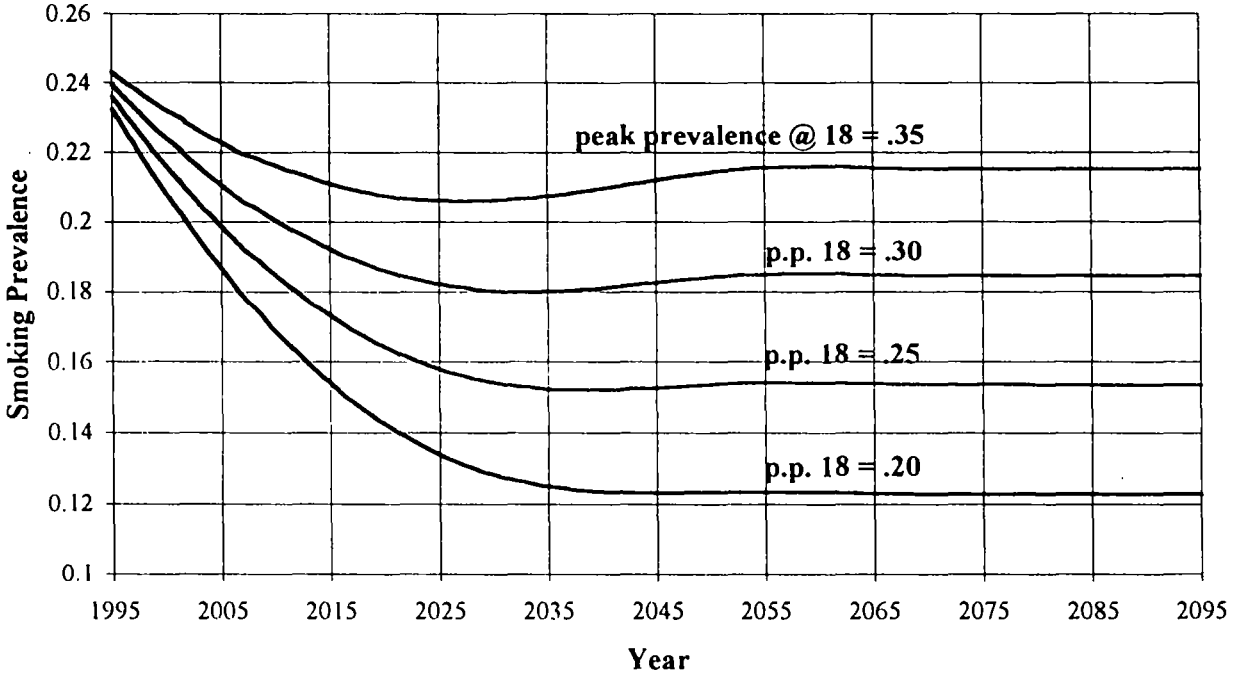


Figure 2. Observed vs. Predicted Smoking Prevalence



Observed values are shown with 95 percent confidence intervals.

Figure 3. Forecasted Overall Smoking Prevalence by Different Peak Prevalence at 18.



TECHNICAL APPENDIX TO ACCOMPANY: HAS SMOKING CESSATION CEASED? EXPECTED TRENDS IN THE PREVALENCE OF SMOKING IN THE UNITED STATES

In this appendix we present and discuss in detail the data and analysis mentioned in the Materials and Methods section of the paper.

Model

The forecasting model employed in this paper is presented on page 3 in the text.

Data

Data from the National Health Interview Surveys on adult smoking prevalence were used to estimate parameters (cessation rates) for the model. These prevalences were available for selected years and the following age groups: 18-24, 25-44, 45-64, and 65 and over. These data are shown in Table 1 in the text.

Parameter Estimation

Nonlinear weighted least squares was used to estimate the model. A weighting matrix for the data was used to account for the fact that prevalences from different age groups are likely to exhibit unequal variances due to the difference in population sizes among the age groups. The weights for the data were selected to be proportional to the inverse of the data variances, to closely follow a Generalized Least Squares (GLS) estimation procedure (1). These variances were estimated from the reported maximum

lengths for the 95 percent confidence intervals for the data. Assuming a normal distribution for the data, the length of the 95 percent confidence interval is related to the variance by the following expression:

$$Var = \left(\frac{Length\ of\ 95\%CI}{2 \times 1.96} \right)^2$$

The reported 95 percent confidence intervals and the calculated variances for data in each of the four age groups are shown in Table A1.

Table A1. Variances for Data by Age Group

	Age Group			
	18-24	25-44	45-64	65 +
95% C.I.	2.4	1.8	1.8	2.5
Variance	0.3748	0.210	0.210	0.4067

For the implementation of the weighted non-linear least squares estimation, the following matrices/vectors were identified:

$$\vec{R}_{[52,1]} = \left(R_{(18\text{-}24),1970}, R_{(25\text{-}44),1970}, \ldots\ldots, R_{(65+),1993} \right)' \quad \text{Observed prevalences}$$

$$\hat{R}_{[52,1]} = \left(\hat{R}_{(18\text{-}24),1970}, \hat{R}_{(25\text{-}44),1970}, \ldots\ldots, \hat{R}_{(65+),1993} \right)' \quad \text{Calculated prevalences}$$

$$\Omega_{a[4,4]} = \begin{bmatrix} 0.3748 & & & \\ & 0.2109 & & \\ & & 0.2109 & \\ & & & 0.4067 \end{bmatrix} \quad \text{One-year weighting matrix}$$

$$\Omega_{[52,52]} = \begin{bmatrix} \Omega_a & & & \\ & \Omega_a & & \\ & & \ddots & \\ & & & \end{bmatrix}$$ Weighting matrix

$$\hat{\mathrm{N}} = \begin{bmatrix} \hat{\nu}_1 & \hat{\nu}_2 & \hat{\nu}_3 & \hat{\nu}_4 & \hat{\nu}_5 & \hat{\nu}_6 \end{bmatrix}'$$ Estimated cessation rates

The vector of cessation rates was estimated by solving the following optimization problem:

$$\underset{\mathrm{N}}{Min}\left(\left(\vec{R} - \hat{R}(\mathrm{N})\right)' \Omega^{-1}\left(\vec{R} - \hat{R}(\mathrm{N})\right)\right)$$

This minimization problem was solved with the Generalized Reduced Gradient algorithm, available in the Solver component of the Microsoft EXCEL spreadsheet program. The estimated values for the cessation rates are presented in Table 3 in the text.

Confidence Intervals

95 percent confidence intervals were developed for the estimated cessation rates. The asymptotic covariance matrix of these estimated coefficients is (1):

$$\hat{\sigma}^2\left(\left(\frac{\partial \hat{R}(\mathrm{N})}{\partial \mathrm{N}'}\bigg|_{\hat{\mathrm{N}}}\right)' \Omega^{-1}\left(\frac{\partial \hat{R}(\mathrm{N})}{\partial \mathrm{N}'}\bigg|_{\hat{\mathrm{N}}}\right)\right)$$

where the multiplicative scalar in the expression can be computed as:

$$\hat{\sigma}^2 = \frac{\left(\left(\vec{R} - \hat{R}(\hat{N})\right)' \Omega^{-1} \left(\vec{R} - \hat{R}(\hat{N})\right)\right)}{(52-6)}$$

Partial derivatives in the above expression were computed numerically in an EXCEL spreadsheet. Matrix computations were performed using the MATLAB software. The resulting asymptotic covariance matrix for the estimated cessation rates is:

$$0.001479 \times \begin{bmatrix} 0.0283 & 0.0005 & -0.0012 & -0.0032 & -0.0060 & 0.0008 \\ 0.0005 & 0.0125 & 0.0013 & 0.0019 & -0.0040 & -0.0023 \\ -0.0012 & 0.0013 & 0.0175 & -0.0002 & 0.0009 & -0.0062 \\ -0.0032 & 0.0019 & -0.0002 & 0.0142 & -0.0016 & 0.0000 \\ -0.0060 & -0.0040 & 0.0009 & -0.0016 & 0.0055 & -0.0003 \\ 0.0008 & -0.0023 & -0.0062 & 0.0000 & -0.0003 & 0.0047 \end{bmatrix}$$

The 95 percent confidence intervals for the cessation rates were obtained assuming that these parameters are asymptotically normally distributed. For instance, the 95 percent CI for ν_1 is:

$$-0.00953 \pm 1.96 \times \sqrt{0.001479 \times 0.0283}$$

The 95 percent confidence intervals for the estimated cessation rates are shown in Table 2 in the text.

Alternative Models

Several alternative specifications for the cessation rates were formulated, to test whether the data supported a more parsimonious model. Since the post-1980 cessation rates are the ones that will be used for forecasting, the alternative specifications dealt with

imposing restrictions on such rates to simplify the model. Specifically, the following alternative models, identified by the restrictions on the ν's were proposed:

$H_0^{(1)}$: $\nu_4 = \nu_5$

$H_0^{(2)}$: $\nu_5 = \nu_6$

These two models were tested against the alternative specification:

H_a: $\nu_4 \neq \nu_5 \neq \nu_6$

which corresponds to the original (unrestricted) model estimated in the paper.

We tested the proposed restrictions on the model employing the likelihood ratio test (1). In order to describe the procedure, we introduce the following notation:

$$S(\mathrm{N}) = \left(\left(\vec{R} - \hat{R}(\mathrm{N}) \right)' \Omega^{-1} \left(\vec{R} - \hat{R}(\mathrm{N}) \right) \right)$$

$\tilde{\mathrm{N}}^{(i)}$ = Cessation rates estimated under model restriction (i)

$\hat{\mathrm{N}}$ = As before, cessation rates estimated under 'full' model.

$$\lambda_{LR}^{(i)} = 52\left[\ln\left(S\left(\tilde{\mathrm{N}}^{(i)} \right) \right) - \ln\left(S\left(\hat{\mathrm{N}} \right) \right) \right]$$

At the 5 percent significance level, the likelihood ratio test calls for the rejection of the proposed restricted model (i), in favor of the full model if $\lambda_{LR}^{(i)}$ exceeds $\chi^2(J, 0.05)$, where the number of degrees of freedom J is equal to the number of restrictions that the proposed model (i) imposes on the full model. The following table shows, for each of the proposed models, its calculated λ_{LR} .and the critical value for rejecting the restrictions.

Table A1. Test of Alternative Models

Model (i)	$\lambda_{LR}^{(i)}$	J	$\chi^2(J,0.05)$
1	4.61	1	3.84
2	21.16	1	3.84

The values in the table indicate that the two restricted models were rejected in favor of the unrestricted model.

We employed the likelihood ratio test to test the hypothesis that the cessation rates for the 1990s are not different from the ones in the 1980s. To test this hypothesis, we re-estimated the model allowing for the cessation rates from 1990 and after be different from the ones in the 1980s. By doing that, we added three new parameters to the model: ν_7, ν_8 and ν_9, which represent the 1990's cessation rates corresponding to the age-groups 18-30, 31-50 and >50 respectively. Specifically, we tested the restrictions:

H_0 : $\nu_4 = \nu_7$ and $\nu_5 = \nu_8$ and $\nu_6 = \nu_9$

versus a fully unrestricted model, where all the cessation rates are allowed to be different.

For this test, we obtained a $\lambda_{LR} = 2.60$. With 3 restrictions, at the 5 percent significance level, the critical value to reject the null hypothesis is $\chi^2(3,0.05) = 7.81$. Therefore cannot reject the restricted model and conclude that the cessation rates for the 1990s are no different from the ones in the 1980s. In fact , the p-value for this test is between 30 and 50 percent.

Autocorrelation

First order autocorrelation in the model was tested according to the procedure described in (2). Table 2 shows the residuals (e_t) of the model (observed minus predicted value) that correspond to contiguous observations.

Table A2. Model Residuals for Contiguous Observations

Year	Age Group			
	18-24	25-44	45-64	65 & Over
1978	-0.00514	-0.00266	0.00132	0.00146
1979	-0.00237	-0.00160	-0.01373	0.00859
1980	-0.00761	-0.00850	-0.00135	0.02198
1987	-0.00906	0.00243	0.00992	0.00214
1988	-0.00905	0.00667	0.00309	0.00250
1990	0.00116	-0.01214	-0.00628	-0.01028
1991	-0.00385	-0.00018	-0.00096	-0.00073
1992	0.01687	0.00458	0.00386	-0.00383
1993	0.00644	-0.00357	-0.00159	-0.02446

From (2) we have that under the null hypothesis that the first order autocorrelation in the residuals is equal to zero, the statistic $\sqrt{N} \times \frac{\sum e_t \times e_{t-1}}{\sum e_t^2}$ is asymptotically normally distributed with mean 0 and variance 1. At 5 percent significance level, we

would reject the null hypothesis if the absolute value of the statistic is greater than 1.96. Evaluating the statistic with our data, we obtain:

$$\sqrt{36} \times \frac{0.000508}{0.002556} = 1.19 < 1.96$$

Therefore we do not reject the null hypothesis that there is no first order autocorrelation in the data, and our estimates of the standard errors are appropriate.

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