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REGULATION was first published in July 1977 "because the extension of regulation is piecemeal, the sources and targets diverse, the language complex and often opaque, and the volume overwhelming." REGULATION is devoted to analyzing the implications of government regulatory policy and its effects on our public and private endeavors.

Pursuing Less Risky Smokes—At Last

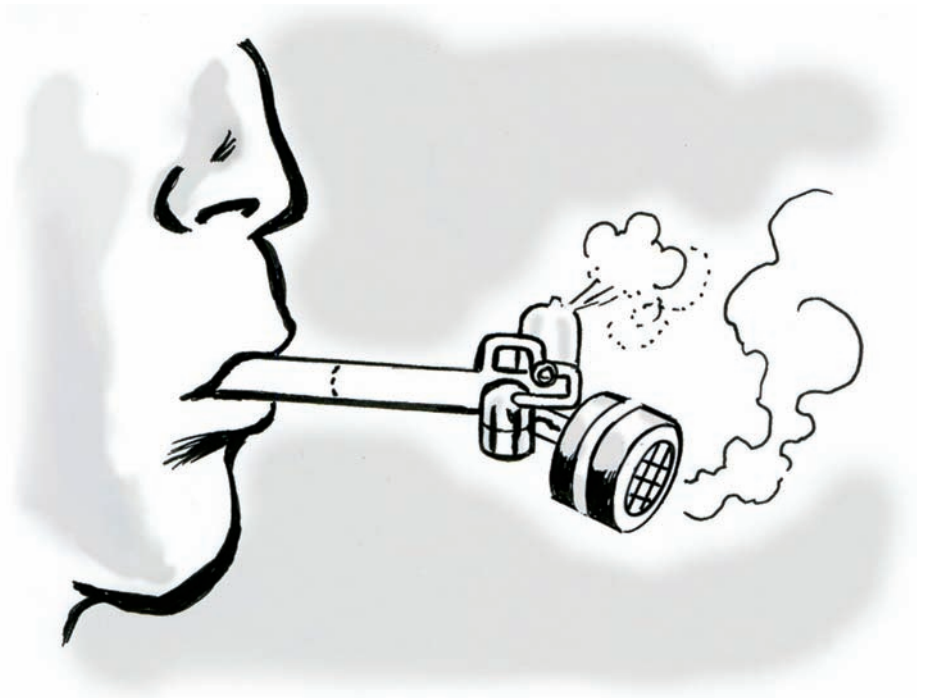
By Gio Batta Gori
Health Policy Center

Late last spring, President Obama signed the Family Smoking Prevention and Tobacco Control Act, placing tobacco products under the regulatory control of the Food and Drug Administration. The law is the world's first effort to regulate cigarettes based on relative risks to health. This innovative, consequential, and morally compelling feature recognizes that less hazardous cigarettes are feasible and should be advertised according to risk reduction claims certified by the FDA. In so doing, the act spurns nearly 40 years of disappointing prohibitionist policies, in favor of a more tolerant, humane, and successful public health approach.

Unfortunately, as the bill moved through Congress, several contravening measures were slipped into its final version to satisfy various special interests, including prohibitionists. What ultimately becomes of these measures will determine if the act truly benefits the nation's health and serves as a positive template for legislation around the world.

CHANGING COURSE Efforts to give the FDA authority over tobacco have been floundering on Capitol Hill for at least 15 years. Tobacco prohibition was the objective of earlier attempts, but it soon became clear that such a goal is many decades distant. The official count of U.S. smokers has leveled off at around 50 million, and it is probably more, thanks to a thriving black market. Globally, the World Bank has projected as many as 1.5 billion smokers by the end of this decade, thus making effective prohibition unlikely, no matter how stringently enforced.

An alternative policy approach emerged following the 2001 release of *Clearing the Smoke: Assessing the Science Base for Tobacco Harm Reduction*, a report of the Institute of Medicine (IOM) of the National Academy of Sciences. The report concluded that nicotine is safe at the levels experienced by smokers, and that less hazardous cigarettes could be produced by maintaining nicotine levels and reducing other toxic components of smoke. That conclusion dealt a capital blow to prohibitionist policies, a blow that redoubled because it had been known since the 1970s that less hazardous cigarettes are both technically and economically feasible. Antismoking crusaders, intent to force a "smoke-free America by the year 2000," suppressed that knowledge for 30 years. Could those crusaders be responsible for hundreds of millions of deaths that would have been prevented worldwide by an earlier introduction of less hazardous smokes?



KEVIN TUMA

QUESTIONABLE CONSTRAINTS
Although smoking entails varied inputs, the 2001 IOM report concluded that nicotine is essential because cigarettes without nicotine do not sell. The report also distanced nicotine from hard-drug addictions, observing that nicotine does not cause derangement or anti-self or anti-social violence, but rather favors good socialization, good behavior, and enhanced personal performance. Most importantly, the report found that nicotine is safe at the doses experienced by smokers. That echoed prior conclusions of the FDA and regulators worldwide, which have long permitted over-the-counter sales of nicotine patches and gums at doses that can exceed what smokers obtain from cigarettes.

Endorsing a large body of science, the report noted "it is the cigarette constituents and pyrolysis products other than nicotine that are primarily responsible for the morbidity and mortality associated with smoking." Because the

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epidemiologic record clearly shows that risks are proportional to the doses of smoke inhaled, the report concluded that cigarettes can be made less hazardous by "retaining nicotine at pleasurable or addictive levels while reducing the more toxic components of tobacco."

Besides nicotine, cigarette smoke also provides taste and aroma, and the all-important function of buffering the harsh and unpleasant characteristics of nicotine. Thus, maintaining nicotine and reducing other smoke components is bound to compromise the traditional tastes and aromas of smoke, and to expose the harshness of nicotine. Notoriously fastidious, smokers will find challenges in less hazardous smokes.

Acceptability deficits can be overcome with safe additives, and the IOM report recognizes that reduced-risk cigarettes will "involve substantial changes in types of tobacco, in additives, or in curing, blending, or processing of the tobacco." The new tobacco control law foresees the need for additives, yet it also mandates that "a cigarette or any of its component parts (including the tobacco, filter, or paper) shall not contain, as a constituent (including a smoke constituent) or additive, an artificial or natural flavor (other than tobacco or menthol) or an herb or spice, including strawberry, grape, orange, clove, cinnamon, pineapple, vanilla, coconut, licorice, cocoa, chocolate, cherry, or coffee, that is a characterizing flavor of the tobacco product or tobacco smoke."

The exclusion is odd because the flavors listed are legally recognized as safe and have long been used in cigarettes. Contrary to the main thrust of the law, the exclusion was introduced at the behest of antismoking interests, worried that flavors and aromas would make cigarettes more pleasant. Yet, being acceptable is a necessary attribute of less hazardous smokes, suggesting that the exclusion somehow will have to be reconsidered. As well, it should not be a useful precedent for similar legislation in other countries.

From the available evidence, a cigarette containing only nicotine and buffers barely sufficient to quench its harshness would achieve the ultimate risk reduction. Such a configuration would present relatively modest technical challenges, but initially it would have questionable appeal to most smokers who would require smokes as pleasing as traditional ones. Acceptable reduced-risk cigarettes of traditional configuration are more technically challenging and would entail a gradual reduction of combustible mass, a supplement of nicotine, and the addition of acid buffers to attenuate the nicotine's harshness. Alone, such modifications could not match the composite buffers of traditional cigarettes and their flavors and aromas, but safe additives could restore acceptability.

Unfortunately, the law's prohibition on such additives stands in the way. As an option, desirable traits could be genetically engineered in new tobacco varieties, possibly overcoming strict definitions and the exclusion of desirable attributes.

REGULATORY CLIMATE The IOM report "strongly recommends that new legislation be enacted to ensure that the labeling, advertising, and promotion of all tobacco-related products are carefully regulated so that exposure reduction and risk reduction claims are supported by adequate scientific evidence and are not false or misleading." But the report also admonishes:

> [T]he regulatory process should not discourage or impede scientifically grounded claims of reduced exposure, as long as steps are taken to ensure that consumers are not misled into believing (in the absence of sound evidence) that smoking the modified product is (or is likely to be) less hazardous than smoking the conventional product. How the complex of claims and caveats associated with [reduced risk products] can best be articulated in labeling is one of the major challenges facing the regulatory agency. On the one hand, the public health is not well served by the continued use of poorly defined terms such as "light," "low tar," or other phrases that imply a benefit when none has been proven to exist. On the other hand, neither is the public health served if smokers are discouraged by unduly cautionary language from using a new product with the potential for real risk reduction.

Therefore, "acceptable restrictions on potential exposure or harm reduction products might be stringent, although not severe enough to put the industry out of business." As things develop, however, it is inevitable that costly and intensive tests and documentations and large service fees mandated by the law will weed out small producers and will promote consolidation of the industry.

CONCLUSION Promising as it is, the success and viability of the new law is not guaranteed. The IOM warns of a "continuing ambivalence among some health officials about the wisdom of embracing harm reduction as a public health policy." It plainly cautions that the management of the regulatory program should not be entrusted to antismoking crusaders, who have a record of poor judgment and insincere tactics in their overbearing and fatal hostility to less hazardous smokes.

The recent nomination of Lawrence Deyton to head the FDA's new Center for Tobacco Products is an auspicious move, provided he could persuade Margaret Hamburg, his boss and FDA commissioner, that turning regulation into an instrument of prohibition would be contrary to the law and the IOM's vision. Clearly, the new center should seek stronger means to persuade smokers to quit and youngsters not to smoke, but experience tells that progress in this effort will drag out slowly over many decades to come. Smokers, on the other hand, are with us now and for the foreseeable future, making it just as important and more pressing to provide them with the reduced risk products the IOM and the law contemplate. Any less policy would be to restate a callous death sentence, quite at odds with the "first do no harm" imperative of a public health agency. R

Readings

- *Clearing the Smoke: Assessing the Science Base for Tobacco Harm Reduction*, prepared by the Institute of Medicine, National Academy of Sciences. National Academy Press, 2001.
- "Less Hazardous Cigarettes?" by Gio Batta Gori. *Regulation*, Vol. 25, No. 4 (Winter 2002–2003).
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