

## The Institute of Medicine Report on Smoking: A Blueprint for a Renewed Public Health Policy

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This past September, the Institute of Medicine (IOM) published the report *Clearing the Smoke: Assessing the Science Base for Tobacco Harm Reduction*.<sup>1</sup> The report's leading conclusion is that tobacco products of reduced risk, and especially less hazardous cigarettes, are within technical reach and should be officially endorsed

and regulated. The report speaks of unparalleled public health opportunities in tobacco harm reduction and in the abatement of the awesome morbidity and premature mortality of more than 1 billion smokers worldwide.<sup>1(p23)</sup>

Since a preview draft was released in early 2001, the report has hardly been noticed by the public health community, because it implies a policy shift that many would find uncomfortable. Indeed, especially the endorsement of less hazardous cigarettes would be at odds with long-standing policies aimed exclusively at the elimination of tobacco use, policies whose effectiveness the proposed shift also may appear to question.

In reality, the IOM report continues to insist on reinforcing traditional tobacco control efforts to discourage users and would-be users while asserting that “[f]or many diseases attributable to tobacco use, reducing risk of disease by reducing exposure to tobacco toxicants is feasible.”<sup>1(p5)</sup> The report covers the entire spectrum, from snuff to cigars, with potentially less hazardous cigarettes receiving prominent attention. The authors of the report find the technology of such cigarettes to be within short-term reach, given resolute official prodding of an industry that has to date resisted them on a variety of pretexts.

In a crucial departure from current tenets, the report affirms that there is “misinformation regarding the safety of nicotine,”<sup>1(p110)</sup> which it finds relatively safe: “Many studies of nicotine suggest that nicotine is unlikely to be a cancer-causing agent in humans,”<sup>1(p167)</sup> “high doses of nicotine do not seem to cause acute adverse events even among smokers who have experienced cardiovascular disease,”<sup>1(p115)</sup> and long-term nicotine replacement therapy has been “without an apparent cardiovascular hazard, not only in the general population . . . but also in patients with established cardiovascular disease.”<sup>1(p252)</sup> The report also notes how the Food and Drug Administration has affirmed the safety of nicotine for more than 15 years, by approving over-the-counter sales of patches and gums that contain more nicotine than a pack of cigarettes.

The massive epidemiological evidence that risk relates to dose is found by the report to allow estimates of “a dose–response relationship between exposure to whole tobacco smoke and major diseases.”<sup>1(p9)</sup> Building on

these findings, the report considers a general strategy for cigarette harm reduction as “[r]etaining nicotine at pleasurable or addictive levels while reducing the more toxic components of tobacco.”<sup>1(p29)</sup>

It continues by recommending that “Congress enact legislation enabling a suitable agency to regulate tobacco-related products that purport to reduce one or more tobacco toxicants or to reduce the risk of disease”<sup>1(p205)</sup> so that “[p]romotion, advertising and labeling of these products are firmly regulated to prevent false or misleading claims” and “[m]anufacturers have the necessary incentive to develop and market products that reduce exposure to tobacco toxicants and that have a reasonable prospect of reducing the risk of tobacco-related disease.”<sup>1(p7)</sup> The report backs up such deeply heterodox but testable conclusions and prescriptions with an impressive review of the scientific evidence.

Coming full circle, the IOM’s message reconnects with virtually the same science and public health recommendations advanced more than 20 years ago by the Smoking and Health Program of the National Cancer Institute and the National Heart, Lung, and Blood Institute<sup>2</sup>—recommendations that were suppressed with the adoption of “smoke-free America” policies from the late 1970s and onward. Although the IOM report does not broach the issue, the report is apt to raise disturbing regrets in the minds of those who for more than 20 years have contributed to delaying the life-saving benefits of less hazardous cigarettes. Such regrets, and the opposition they might engender, could be a significant hindrance to progress but should yield to determined action, because the evidence revisited by the report brings forth an unavoidable moral obligation to learn and act now.

Time is of the essence, because people are dying or at risk as we read these words, and the IOM report shows that there can be a remedy while also implying that, ethically speaking, the plight of smokers is no less deserving than that of people with other afflictions. Despite all warnings, close to a billion people will continue to smoke for decades to come, making a compelling case for a radically fresh approach in the prevention of tobacco-related diseases. The report makes it clear that action cannot be expected from a

tobacco industry mired in controversy and of nonexistent credibility and aims its message directly toward Congress and the government, academic, and private institutions and charities that embody the public health community.

Aside from generally upbeat conclusions about the feasibility of less hazardous cigarettes, the IOM report leaves the operational detail largely unanswered and bristles with caveats and questions that need teasing out. Technical approaches to reduction of dose and risk ought to be sifted; methods and markers for toxicological evaluation need to be discussed and standardized; risk models and regulatory measures should be sensibly reconciled to avoid disabling complexities; ways for monitoring and surveillance should be devised; legislative issues have to be worked on. These and other questions must be aired and resolved in a broader dialogue that should begin immediately, in the pages of this venerable journal that strives to be the voice of our conscience. ■

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This brief was accepted January 10, 2002.

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2. *A Safe Cigarette?* Gori GB, Bock FG, eds. Cold Spring Harbor, NY: Cold Spring Harbor Laboratory Press; 1980. Bambury report 3.