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Editorial: Dealing with Tobacco—The Implications of a Legislative Settlement with the Tobacco Industry

The battle for the hearts (and lungs) of tobacco consumers has reached near-mythic proportions. The tobacco industry is under assault at every level. The Food and Drug Administration (FDA) has introduced strong, unprecedented policy on youth-oriented tobacco marketing.[1] Tobacco control emerged as a significant issue in the national presidential campaign. Voters have raised state tobacco taxes and allocated revenues to antismoking media campaigns.[2,3] Forty states and cities are suing the tobacco industry to recover tobacco-related health care expenditures. Cities are banning smoking in public places, including restaurants and workplaces. Agreeing to a negotiated settlement and acknowledging that its products addict and kill their users, the Liggett tobacco company violated the longstanding industry policy of stonewalling.[4] Industry whistle-blowers serve up increasingly damning evidence about what the industry knew and when.[5,6] The grandson of R.J. Reynolds lobbies against tobacco.[7]

Tobacco control has its dark side, however. Adult cigarette consumption has leveled off after two decades of uninterrupted annual declines.[8] Smoking by children has risen annually since the early 1990s.[9] Cigars have achieved a new cachet among twenty-somethings. Tobacco companies continue to report fantasy-level profits. The tobacco industry has a strategy for responding to every assault.[10,11]

The David-and-Goliath struggle has pitted public health against the industry in legislative battles, in the media, in court, and at the ballot box. With ballot initiatives likely to remain an active battleground, tobacco-control activists should study the successful campaign to increase the tobacco tax in Massachusetts, described by Heiser and Begay in this issue of the Journal[2] and, elsewhere, by Koh.[3]

For the immediate future, however, the attention of veteran tobacco watchers is focused on Congress and the courts.[12] As of this writing (May 1997), while preparing for their historic lawsuits, attorneys for the states suing the industry are simultaneously attempting to hammer out a deal with lawyers representing the industry, to be embodied in congressional legislation that would confirm FDA regulatory authority over tobacco products, establish marketing restrictions, and impose financial penalties on the industry in exchange for limitations on the industry's legal exposure.[13,14]

It would be difficult to exaggerate the potential importance of this develop-

Editor's Note. See related article by Heiser and Begay (p 968) in this issue.

ment. It could conceivably present an opportunity to finally achieve something substantial in federal tobacco control policy. However, it also risks the virtual extinction of the threats to the industry's vitality that are themselves unprecedented and that have brought the industry to its current readiness to bargain.

There is ample reason for the public health community to be wary of a legislative settlement.[15–17] Despite assurances that our voice will be heard, we have only two seats at the negotiating table. The principal parties involved have very specific interests that are either completely contrary to those of public health (the tobacco industry) or at least not perfectly congruent (the states' attorneys).

In addition to constituting a major direct financial threat, the barrage of individual, class action, and state lawsuits against the tobacco companies reveals a flood of incriminating evidence concerning the industry's denial of what it well knew, and it keeps the issue of smoking and health part of America's daily news diet. This further discredits the industry and marginalizes smoking as a socially acceptable behavior. A legislative settlement could cut off the flow of new evidence and remove tobacco from the daily news.

Yet another critically important reason to be wary of a negotiated legislated solution is that in the past, congressional legislative compromises to secure industry buy-ins have consistently diminished, and sometimes entirely subverted, the original policy objective. The industry has invariably emerged the beneficiary of policies ostensibly intended to diminish its market.[7,10,16]

Thus, the essential question: is it possible to strike a deal that will genuinely serve the public's health, or will the industry, with its powerful allies in Congress, void any agreement with genuine teeth?

The public health community is likely to balk at any deal with the tobacco industry, and with good reason.[15–17] As the saying goes, when you wrestle with a pig, you both get dirty and the pig loves it. The question confronting us, however, is whether we can afford to stay clean. Although attainment of a workable compromise faces truly imposing barriers,[13] if legislation is drawn up without our active input, it could benefit the finances of the states and the industry without focusing primarily on the health of the public.

Because this may well be a once-in-a-generation situation, we must make certain that a truly open process guarantees that the health community's concerns are heard and indeed made the centerpiece of any legislation. Then, we must fight hard for a comprehensive package of truly effective tobacco control policies.

If legislation does emerge, what public health provisions should it contain? I believe that legislation ought to strive to achieve four fundamental principles of tobacco control:

(1) Children should have a right to an environment devoid of inducements to use tobacco products, and replete with encouragement not to use them.

(2) Addicted adults should have assistance with quitting, including an environment that does not intentionally reinforce cravings for nicotine.

(3) Everyone should have a right to breathe air not fouled by tobacco smoke.

(4) Adults truly well informed about the dangers of tobacco should have the right to consume tobacco products, so long as they are not infringing on the rights of others to clean air.

The following policies would constitute important components of a legislative package consistent with these principles:

Implementation of the FDA's restrictions on sale and marketing to youth. The FDA policy measures[1] should be implemented immediately and without exception. Additional marketing restrictions should be considered as well, such as the elimination of all outdoor advertising and the adoption of plain packaging.[18] As specified by the FDA, if youth tobacco use has not fallen by half within a 7-year period, the measures should be revisited and strengthened.

Muscle should be put behind the FDA's call for stricter enforcement of minimum-age-of-purchase laws. Minors can readily purchase cigarettes in most jurisdictions throughout the country,[19] despite federal legislation tying states' receipt of federal monies to enforcement of minimum-age laws.[20]

Assurance of complete FDA authority to regulate all nicotine-delivery devices. The FDA currently regulates all nicotine-delivery products introduced by the pharmaceutical and other industries. Formulation of a sound national policy on nicotine requires that the same should apply to all existing tobacco products and all new nicotine-bearing products manufactured or sold by the tobacco industry.[21]

A guarantee that cigarettes will remain legal for adults is consistent with the fourth principle enunciated above and essential to consummation of a congressional deal. However, this should not preclude FDA's independent consideration of other health and safety regulations pertaining, for example, to fire safety, additives, and levels of allowable tar and nicotine.[21,22] In particular, the FDA should have the authority to require the eventual removal of nicotine from tobacco products.[22]

Compensatory industry payments of $30 billion per year to a tobacco disease prevention and compensation fund, in perpetuity and indexed to inflation. Compensation of the states for smoking-related Medicaid expenditures and of individual smokers lies at the heart of proposals made to date. Such compensation can also serve to discourage future smoking, especially among children, by forcing the manufacturers to increase cigarette prices. The larger the annual levy, the greater the deterrent effect on smoking by the next generation.[19,23]

Often-cited figures project annual industry payments of $6 billion to $12 billion for up to 25 years.[12,13] The industry could cover this amount and remain highly profitable by increasing the price of cigarettes by 50 cents to $1 per pack and temporarily losing 10% to 15% of its market until the term of the payments ended. Furthermore, restriction of the threat of liability in lawsuits, the tobacco industry's quid pro quo, could jack up the companies' stock values enough to compensate for the legislated financial penalty.[24]

According to estimates by health economist Jeffrey Harris, the industry could absorb a penalty of $30 billion or more per year and still remain financially viable.[25] An annual assessment of $30 billion would raise cigarette prices by $2 or more per pack; smoking would decline by roughly a quarter, with smoking initiation by children falling dramatically.

As an alternative to an annual industry assessment, a $2-per-pack increase in the federal cigarette excise tax would achieve the same health outcomes. Such an increase would merely bring the price of American cigarettes in line with the prices prevailing in many other industrialized nations.[26]

Use of industry payments to fund a large, sustained, professionally designed and marketed antitobacco broadcast media campaign. Media campaigns have worked to sell cigarettes for years[27,28]; a

variety of evidence indicates that they can unsell them as well.[29–31] A national media campaign should be on the order of $1 billion per year, adjusted for inflation. In 1994, the industry spent $5 billion marketing cigarettes.[32]

Prompt adoption of strong restrictions on workplace smoking, as proposed by the Occupational Safety and Health Administration (OSHA). All workers deserve a workplace free of the hazards posed by environmental tobacco smoke, a Class A carcinogen.[33] OSHA's policy,[34] held up by bureaucratic and legal wrangling, would ensure this basic protection.

Explicit admission by the tobacco companies that they have consistently lied about their knowledge of the disease and addiction consequences of their products. A wealth of evidence demonstrates that the tobacco companies have known for decades that smoking kills and that nicotine is addictive.[5,6] As has Liggett,[4] the other companies should, without reservation, confess to their intentional campaign of deception and distortion of the facts. The then chief executive officers who testified before Congress that they did not believe that nicotine is addictive[5] should publicly acknowledge that they were lying to protect company coffers.

As its quid pro quo for accepting the above measures, the industry might receive specifically defined limitations on criminal prosecution and some modest limits on its liability in civil lawsuits related to its products and actions to date. Such limits should not preclude tobacco's victims from receiving compensation for damages. Further, the industry should not be immunized against the consequences of any future wrong doings or deceptions.

Political scientist John Kingdon has observed that windows of policy opportunity open rarely, affording interested parties a chance to realize their policy objectives only if they are prepared to embrace the opportunities whenever and however they arise.[35] Today may be such a moment in the history of tobacco control. The danger, however, is that congressional legislation may represent an opportunity primarily for the tobacco industry. Much of the public health community undoubtedly would prefer to see the current scenario, devoid of federal legislation, played out to its logical conclusion: FDA policy fully implemented, legal liability fought out in court battles that will be bloody and protracted, but potentially devastating to the industry.

Too often in the past, the opportunity for fundamental health-enhancing reforms has been compromised away precisely at the time the tobacco industry was most vulnerable. The same mistake should not be made again. The interests of the public's health must remain preeminent in any seriously contemplated congressional legislation. This is no time for yet another smoke-filled-room deal. □

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Editor's Note. On June 20, as this issue was going to press, negotiators for the states and the tobacco industry announced the terms of the settlement. Congressional consideration of the proposal is anticipated to begin in early fall.

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Annotation: Emergency Contraception—Parsimony and Prevention in the Medicine Cabinet

Public health practitioners have known for decades that contraception saves both lives and dollars—its health benefits far outweigh its risks,[1] and its fiscal benefits far exceed its costs.[2] These advantages have led the vast majority of sexually active US couples who do not wish a current pregnancy to use some form of contraception—over 90% in 1990.[3] Unfortunately, this high prevalence of reported contraceptive use has not prevented the occurrence of frequent unintended pregnancy.[4] In absolute numbers, approximately 3.5 million pregnancies are unintended at the time of conception. Nearly half of these occurred to couples who reported using some form of contraception.

To address this health problem, a new "contraceptive revolution" has been proposed.[5] This blueprint for contraceptive development recommends that a consortium of government, industry, private insurers, and the general public work together to bring to market new contraceptive methods. The strategy defines a "women-centered agenda" and sets highest priorities on (1) chemical or physical barriers to both conception and sexually transmitted diseases, including human immunodeficiency virus (HIV), (2) once-a-month methods to induce menstruation, targeted at different points in the menstrual cycle, and (3) contraceptives to expand the choices available to men. However, these exciting possibilities will occur only if industry and government together commit resources to the necessary basic and applied research and if manufacturers are convinced that the demand for contraceptives will justify huge investments of time and capital.

While we wait for development of new contraceptives, we can do much better with our existing methods. One in particular is most promising—emergency contraception.[6,7] As described in this issue of the Journal,[8] use of emergency contraception would reduce a woman's risk of pregnancy by at least 74%.[9] Increasing access for those who need it would also save money. Using modeling methods similar to their previous landmark article on the benefit and cost of other contraceptive approaches,[2] Trussell and colleagues demonstrate clearly that wider use of emergency contraception can reduce overall medical care expenditures by decreasing the level of unintended pregnancies, which are far more expensive than the emergency contraceptives. As with any model, their assumptions are open to challenge, yet their estimates are probably conservative. For any area involving uncertain data, the authors chose options that understated the cost savings.

Emergency contraception remains an underutilized public health gem. Unfortunately, women don't know about it, clinicians don't talk about it, regulators don't label it, policymakers don't endorse it, and pharmaceutical companies don't market it—but in each case they should! Even those organizations or clinicians that will provide emergency contraception don't advertise it—thus making a national toll-free hotline number necessary (1-888-NOT-2-LATE). The lack of immediate consumer access to emergency contraception is especially troubling. We believe we can have the greatest population-level impact on unintended pregnancy by making emergency contraception readily available to all who want it.

If we consider exposure to unintended pregnancy as a health risk, a prudent first step is to provide emergency contraception for every sexually active person's medicine cabinet. Just as home fire extinguishers are helpful to extinguish flames before they spread, having emergency contraception readily available at the time of an unprotected sexual exposure would increase the likelihood it will prevent an unintended pregnancy. As the current article points out, emergency contraceptive pills are remarkably safe. Having them handy in the home next to Betadine and Band-Aids would add little toxic risk. Moreover, providing emergency contraception prophylactically to all sexually active persons seeking any family planning method presents an educational opportunity. Awareness must be raised for all consumers about these supplemental ways to prevent pregnancy, thus helping couples take charge of their reproductive lives more effectively.[10]

Other spin-off benefits are possible. By providing backup pregnancy protection, use of emergency contraception might encourage wider use of barrier contraceptive methods, thus reducing sexually transmitted infections. Condoms (both male and female) and spermicides provide simultaneous protection against both pregnancy and sexually transmitted disease (STD).[11,12] However, because barrier methods are less effective than other contraceptives in preventing pregnancy,[13] both clients and providers alike have shied away from using them as the primary family planning method. Rather, barrier contraceptives are increasingly being recommended as a backup method for their STD/HIV prophylactic value.[4] Unfortunately, this approach has had mixed results; women who use contraceptive methods with the best record of preventing pregnancy are least likely to report consistent and concurrent use of condoms.[14]

Making emergency contraception more widely available would allow us to shift our thinking to an approach that would benefit both individual women and public health. The primary contraceptive would be mechanical and/or chemical barrier methods for their *dual-purpose* protection against pregnancy and STD. Emergency contraception would be the backup. This new approach to dual contraceptive methods—emphasizing consistent use of barrier methods, plus emergency contraception as a backup—might pay reproductive health dividends. If making emergency contraception widely available to reinforce barrier contraception led more couples to choose condoms

Editor's Note. See related article by Trussell et al. (p 932) in this issue.