What should be the elements of any settlement with the tobacco industry?

Introduction
The epidemic of disease caused by tobacco use has largely been a twentieth century phenomenon. As this century draws to a close, reaction by both the public and private sectors has focused on the role of the major tobacco manufacturers in creating and maintaining demand for an addictive product marketed to children that kills a large fraction of those who use it as the manufacturers recommend.

The causal relationship between smoking and disease, and the addictive nature of cigarettes, are widely recognised by the general public. The impact of tobacco advertising and marketing practices on smoking initiation by children is also a principal concern of the public health community. Local, state, and federal actions have increased the cost of, and decreased adolescent access to, cigarettes; but adolescent tobacco use has recently increased, reversing a decline over the last two decades. The United States Food and Drug Administration (FDA) has asserted jurisdiction over nicotine as a drug, and over cigarettes and smokeless tobacco products as drug delivery devices, and they have promulgated regulations to reduce tobacco advertising and marketing targeted at children.

A large number of state attorneys general have sued tobacco companies to obtain reimbursement for state expenditures for smoking-attributable disease and to prohibit tobacco marketing to children. Several class action lawsuits have been filed on behalf of those addicted to cigarettes, and on those exposed to environmental tobacco smoke.

As a result of these multiple pressures, and most particularly the litigation pressure, the tobacco industry may be willing to moderate its 40-year history of denial and obstruction. Tobacco manufacturers may be willing to accept a negotiated settlement to address the problems created by their behaviour and their products. Representatives of several tobacco manufacturers have suggested that they might be willing to pay a substantial price, and change a number of their practices, in exchange for limitation of their liability.

Rumours continue to circulate about the possibility of a settlement with the tobacco industry, mediated by or through Congress. These rumours force the questions of whether the public health community should support the concept of a settlement; and if so, what should be the core principles that the public health community define as essential to any agreement?

There are several reasons to be "wary" of a legislative settlement, including: (a) the public health community does not have a seat at the negotiating table; (b) the other parties involved have specific interests that are completely contrary to ours (the tobacco industry) or at least not perfectly congruent (the state attorneys general); (c) ongoing litigation poses a major financial threat to the industry, and provides a steady stream of incriminating evidence against the industry and media coverage about tobacco and health; and (d) in the past, congressional legislative compromises to secure industry buy-in have diminished or subverted the original policy objective. Moreover, other questions have been raised about the implications of a settlement.

However, if settlement negotiations or legislation begin to move forward meaningfully and the public health community adopts the position that no solution is acceptable, then it is likely that public health concerns will be peripheral rather than central to the resulting legislation or agreement. Because this may be a once-in-a-generation situation, the public health community must fight for a comprehensive package of truly effective tobacco policies.

What are the minimum elements that the public health community feels are essential to any legislation or settlement? The relief sought by the tobacco companies is comprehensive and would limit liability for the damages or injuries caused by their products or actions to date. Therefore, the appropriate exchange should include both acceptance of responsibility by the tobacco companies for the problems they have created, and actions on their part to reduce the death and disability caused by smoking as rapidly as possible.

The minimal corporate responsibility expected of a company manufacturing a product that injures those who use it is for that company to admit that the risk of injury is real, to redress existing damage, and to mitigate future damage. Any proposed limitation of liability for tobacco manufacturers must fulfill these criteria. It is useful to define in some detail what these obligations might generate as terms of an actual agreement.

Acceptance of responsibility
Limiting the industry’s liability must be accompanied by an acceptance, publicly and for purposes of formation of public policy, that tobacco use is a major cause of death and disability and that nicotine is an addictive agent. Simple logic mandates that the tobacco companies should only be freed of liability for those damages or injuries that they acknowledge to be real. To absolve tobacco manufacturers of liability for damages, while allowing them to continue to deny that their products cause any damages, would be both hypocritical and an extremely poor precedent for public policy.

Acceptance of the risks caused by tobacco smoke exposure must include those risks produced by exposure to environmental tobacco smoke. One demonstration of this acceptance would be a withdrawal of opposition to clean indoor air laws and support for final promulgation and
expeditious implementation of the Occupational Safety and Health Administration's proposed regulations on smoking in the work environment.\textsuperscript{7}

Redress the damage that has been created

The simplest form of redress, and the most common provided through the court system, is monetary compensation for the damages caused. However, monetary compensation cannot be the sole basis of any agreement for release of liability from tobacco, because the damages created exceed the resources of tobacco industry. Tobacco is a $45 billion industry,\textsuperscript{6} and estimates of just the direct, smoking-attributable healthcare costs for 1993 in the United States are $50 billion\textsuperscript{6} with another $50 billion in indirect costs. Clearly any monetary redress would have to be provided at a discount. The sums currently being suggested\textsuperscript{6} as a basis of settlement ($6–12 billion per year)\textsuperscript{6} for a payment of $15–25 000 per death. A yardstick for the monetary damages the industry could pay is the $32 billion that might be generated through monopoly profit-maximising pricing of cigarettes.\textsuperscript{11}

Absolving the tobacco industry of its liability for 400 000 deaths each year, while allowing them to continue to market freely an addictive product that causes those deaths, is morally repugnant, as well as contrary to our traditions of justice and protection of public health. As a result, any agreement to limit the liability of the tobacco industry for the damages caused by its products must include modifications to tobacco products that reduce their capacity to continue to cause damage.

The disease burden created by tobacco results from two characteristics of tobacco use. Tobacco, and tobacco smoke, contain a variety of toxic and carcinogenic compounds that cause disease when ingested over a prolonged period of time. Also, the nicotine in tobacco causes addiction, and it is addiction which maintains the repetitive ingestion of these toxic and carcinogenic substances. Addiction robs many individuals of a free choice about whether to continue to be exposed to the risks of smoking.

The FDA has asserted jurisdiction over nicotine as an addictive agent, and there is no question that maintaining an addictive agent in a formulation as hazardous as the cigarette is contrary to both the public health and the mandate of the FDA. However, there has been concern that, if nicotine levels were reduced in cigarettes, smokers might compensate by smoking more cigarettes per day, puffing more frequently, or inhaling more deeply; and such compensatory behaviour might actually increase their risks. Removal of nicotine from cigarettes is possible, but sudden elimination of nicotine might precipitate withdrawal in many smokers, most of whom are addicted, also an unacceptable alternative. Nicotine replacement therapy is available over the counter as a cessation aid, and these formulations provide substantial relief of the withdrawal syndrome.

Experimental formulations of nicotine more closely mimicking the pattern of nicotine delivery available from cigarettes are being examined,\textsuperscript{13} including nasal sprays and inhalers as well as other formulations.\textsuperscript{13–18} These formulations rapidly deliver nicotine to the circulation in a pattern similar to that provided by a cigarette, raising the expectation that they, or other formulations, may be much more acceptable to addicted smokers; and they may also be much better substitutes for cigarettes in avoiding withdrawal and breaking addiction. In addition, these and other newer formulations offer the promise of acceptable long-term pharmacological substitutes for addicted smokers as part of a harm reduction strategy.\textsuperscript{13–15}

It is likely that the immediate future will provide products with cigarette-like satisfaction of the nicotine needs of addicted smokers through formulations of pure nicotine that do not contain the other toxic and carcinogenic constituents present in cigarette smoke. These formulations could allow the FDA to mandate removal of nicotine from all cigarettes, removing their addictive potential, without creating a black-market demand for nicotine-containing cigarettes. Those who are addicted to nicotine could satisfy their addiction through ingestion of formulations of pure nicotine, without exposure to other toxic and carcinogenic compounds. Smokers of nicotine-free cigarettes would have a free, non-addicted choice about continuing their exposure to the risks of smoking, and most would likely quit.

A minimum requirement for providing limitation of liability is the acceptance by tobacco manufacturers of FDA jurisdiction over the nicotine content of tobacco products, with a mandate for the FDA to require removal of nicotine from these products as soon as it is feasible. Research funding, provided by the agreement, should be dedicated to the discovery of the most effective nicotine replacement strategies and the development of ways that would help addicted smokers change to these nicotine delivery approaches. As soon as reasonable alternatives for converting nicotine-addicted smokers are available, the FDA should mandate the removal of nicotine from all tobacco products provided in the American market.

As part of FDA jurisdiction, tobacco manufacturers should be required to publicly disclose the additives in their tobacco products and any research performed to evaluate the safety of these additives. The manufacturing, labelling, and marketing of tobacco products, including use of additives, should be subject to FDA jurisdiction, as are all other forms of nicotine delivery currently on the market.

Mitigation of future damage

Perhaps the most objectionable current behaviour of tobacco manufacturers is continued advertising and promotion of tobacco products, particularly to children. There is substantial public concern and outrage over use of cartoon characters in tobacco advertising, and even the tobacco manufacturers claim to agree that marketing approaches targeting children are unacceptable.

Once the enormous magnitude of disease risks is acknowledged, it is unclear what legitimate justification exists for encouraging anyone of any age to start smoking, or for discouraging anyone of any age from stopping. Even marketing practices directed at brand loyalty and brand switching lose their legitimacy, as it is hardly ethical to attempt to increase the burden of the death and disability for which an individual company is responsible.

A core element of the mitigation of future damage is avoidance of any influence that might encourage non-smokers to begin smoking or smokers to continue. One way these influences can be avoided with certainty is to eliminate all tobacco advertising and promotional activity, other than FDA-approved activities for pure nicotine replacement. This could be done by limiting liability for most promotional activity, while explicitly defining liability for any future promotional activity judged to encourage initiation, discourage cessation, or promote use. Elimination of advertising and promotional activity has the additional benefit of allowing transfer of the approximately $5–6 billion per year spent by the tobacco industry on these activities\textsuperscript{16,17} to an account used to repair the damages done by their products.
Monetary compensation

Financial reparation by the tobacco companies could be structured in two parts: a fixed sum and a per-pack charge. An annual sum of $5–6 billion would be available if all advertising and promotional expenditures were abandoned. This sum equals the 1993/1994 advertising and promotional expenditures by the tobacco manufacturers, and could be paid without increasing the net expenditures by each company. It should be adjusted annually for inflation and paid proportionate to each company’s current market share. Using the 1993 expenditure of $6 billion, $5 billion of this sum could be paid to the states to compensate them for their smoking-attributable Medicaid expenditures, and $1 billion could be allocated to tobacco control programmes and research. Eighty per cent of the tobacco control funds could be allocated directly to the states with 20% retained for allocation by the federal government.

The fixed payment described above would not necessarily increase the cost of cigarettes because it is a transfer of advertising and promotional expenditures. However, it is appropriate that the cost of cigarettes be increased both to decrease consumption and to compensate society for the disease burden and social costs caused by tobacco companies and their products. The monopoly profit-maximising price of cigarettes ($4.08 per pack, compared with the current price of $1.88) would yield more than $32 billion annually for liability payments or pre-tax profits. Therefore, an additional payment per pack of cigarettes could be required. Payment of an additional $1 per pack initially, increasing to $2 per pack once the FDA mandates removal of nicotine from tobacco products, would provide partial compensation for the societal burdens resulting from smoking. A fraction of these payments would cover cessation assistance for addicted smokers, transitional aid for tobacco farmers, and whatever compensation is judged appropriate for individual smokers. Additionally, a substantial, professionally designed and implemented, national anti-tobacco broadcast media campaign should be funded to help correct the results of decades of tobacco advertising. The remainder of the funding could be used for national priorities such as funding the Medicare programme and solving the indigent healthcare problem.

Transitional aid for tobacco farmers

One of the groups most likely to be affected by the proposed changes is tobacco farmers. Declining American cigarette consumption would place financial pressures on tobacco farmers. It can be argued that these changes are inevitable and that tobacco farmers deserve no special consideration, but both political and humanitarian motivations support providing assistance to tobacco farmers as they change to other crops. Several states in the southeast are disproportionately dependent on tobacco as a crop, and much of the investment in equipment and infrastructure for growing tobacco cannot easily be transferred to other crops. Economic dislocation from changes in tobacco may be considerable in some counties of these states, and assistance could minimise the impact.

Effects on stockholders of tobacco manufacturers

It is apparent that the changes proposed above would lead to a much more rapid decline in tobacco use than would occur otherwise. Indeed, no solution to this problem that does not lead to a more rapid decline in tobacco consumption will be acceptable to the public health community. A superficial examination of this conflict suggests that shareholders of tobacco companies would be better served by a continuation of the “scorched earth” slow retreat that has been the tobacco industry’s practice for the past 40 years.

Ultimately they would arrive at bankruptcy, but they would preserve profits in the short run. However, much has changed in the structure of the major cigarette companies during the past four decades, including diversification into food and other businesses and growth of the international segments of these companies. Stock values for these diversified companies, based on a price/earnings ratio, are depressed by threats of tobacco regulation and litigation, and it is likely that these threats will inflict real damage on the industry in the next months to years, further depressing stock values. Currently the stock values of several of these companies are depressed by litigation risks by as much as 50%.

The depression in stock values is large enough that the domestic tobacco earnings could be eliminated with the residual company having a price/earnings ratio comparable to that of the stocks of other American companies. This suggests that the net value of domestic tobacco earnings to the stock price is roughly counterbalanced by the decline in stock value produced by the threat of litigation. Therefore, domestic tobacco earnings could be traded for limitation of liability without a sharp decline in stock values. If one or more of the current actions by the state attorney general are successful, then tobacco stocks are likely to fall sharply; and even a resolution of tobacco liability that sacrificed all of the domestic tobacco earnings could result in stable stock values.

Summary

Litigation and regulatory assaults on the tobacco companies may create a willingness among tobacco manufacturers to bargain resources and acceptance of public policy changes for limitations of liability, as has been seen by the recent settlement with the Liggett Group. Two elements absolutely critical to any plan are the elimination of tobacco advertising and promotion and the removal of addiction as a reason for tobacco use.

Minimal components of any settlement should include:
(a) acceptance by the tobacco manufacturers of the causal relationship between tobacco use and disease, and the addictive nature of nicotine;
(b) a total ban on tobacco advertising and promotion;
(c) FDA jurisdiction over tobacco products and their nicotine content, with the intent of removing nicotine as soon as acceptable nicotine substitution products are available;
(d) reimbursement to the states for Medicaid and other state expenditures attributable to smoking, to the maximum extent feasible;
(e) funding for local, state, and federal programmes and research in tobacco control;
(f) acceptance of legislation and regulations protecting the right of non-smokers to breathe air free of tobacco smoke;
(g) funding for a large, national, media-led, anti-tobacco campaign; and
(h) cessation assistance for addicted smokers.

If negotiations toward a settlement proceed, it is essential that the public health community participate in defining the elements of any agreement to ensure that whatever agreement develops is focused on reducing tobacco-related disease rather than continuing the profitability of American tobacco companies. That participation requires articulation of the core elements essential to an acceptable agreement. If resolution of the public health issues surrounding continued sale of tobacco products can be reached in the United States, it may provide a model for similar resolution in other countries.
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