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Forum

In the Balance

Nonsmoked Nicotine Products Can Cost People Their Health, Money

By Norm Kjono

Should pharmaceutical companies widely distribute nonsmoked nicotine products that are highly addictive and inherently harmful to consumers? Would it be appropriate to statutorily exempt these manufacturers from liability? What would the probable effect of such actions be on the value of the \$18 billion in tobacco-settlement bonds that the states have issued to investors?

A research paper written by a doctor at Washington University in Saint Louis forcefully presents these issues. See Walton Sumner II, M.D., "Estimating the Health Consequences of Replacing Cigarettes with Nicotine Inhalers," 12 Tobacco Control Journal 124-132 (2003). Sumner has published previous works on tobacco issues. Tobacco Control Journal is a leading tobacco-policy publication, often featuring future applications of current policy to new subject areas, as in Sumner's strategy.

Sumner's paper outlines a broad strategy that would give pharmaceutical nicotine-delivery devices clear competitive advantages over tobacco, while exempting tobacco and nontobacco nicotine products from product liability for harm to consumers.

Sumner acknowledges that all nicotine products are inherently harmful, yet says that "[l]egislation could shield the nicotine and tobacco industries from liability for the health effects of nicotine use." He describes how "[t]axation and product liability costs

are already raising the price of cigarettes, and could create a significant price difference between cigarettes and less hazardous nicotine delivery systems."

But how "less hazardous" than tobacco are pharmaceutical nicotine products? The evidence shows that not only do such products present many of the health risks of tobacco, but they can impose risks unique to nonsmoked nicotine.

In September 2002, the Journal of the American Medical Association reported on

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three studies of nicotine-replacement therapy that included 21,000 California smokers.

"Since becoming available over-the-counter, [nicotine-replacement therapy] appears to be no longer effective in increasing long-term successful smoking cessation in California smokers," the study said. On Jan. 2, 2003, CBS News aired a report on National Cancer Institute research, quoting the institute's Dr. Philip "The take-home point is that nicotine is clearly not harmless," Dennis said. He explained that nicotine stops the body's process of eliminating damaged cells, thereby increasing the risk of cancer.

On June 30, 2001, the Associated Press published an article on the work of Dr. John

Cooke at Stanford University School of Medicine. Cooke concluded that nonsmoked nicotine stimulates the growth of blood vessels, which can increase the growth of tumors. This phenomenon is the opposite of what occurs with smoked nicotine, which reduces blood flow.

Despite the acknowledged medical risks and highly addictive nature of pharmaceutical nicotine products, Sumner advocates a strategy by which pharmaceutical companies would distribute these products widely, with little or no legal accountability for the harm that they cause. "As a special form of counter-advertising, legislation should permit promotion of clean nicotine delivery systems as an alternative to cigarettes, perhaps with fewer constraints than we apply to

tobacco products," Sumner says. Sumner states that "[p]olicies to encourage substitution of nicotine inhalers for cigarettes would reflect established principles of tobacco control policy, such as raising tobacco product prices, informing customers of risks, counter-advertising, restricting youth access and marketing, and limiting opportunities to smoke."

Smoking bans are a well-established way to limit smoking by reducing the opportunities for consumers to use nicotine products.

Under Sumner's strategy, products that are acknowledged to be highly addictive and inherently harmful could be promoted aggressively, with fewer constraints than tobacco. Expanded smoking bans

artificially would constrain consumer opportunities to use tobacco products; distribution of pharmaceutical nicotine products would increase dramatically, and manufacturers of such products would be statutorily exempt from liability for any harm to consumers.

Even if this nicotine-inhaler strategy were effective in reducing risks to smokers, it would be highly objectionable because of its restraint of trade, its influencing of tobacco prices and its coercion of consumer choices. But the strategy's presumed benefits also are open to question. Sumner says, "Although some observers might welcome a competitive market to supply chronic nicotine users, others have discouraged chronic nicotine use because of health risks."

This statement becomes particularly important in light of Sumner's view that "[i]f people believe that these products are safer than cigarettes, then nicotine use may increase. Some smokers would switch nicotine sources rather than quit. Some ex-smokers and never-smokers might become regular users, exposing those groups to the hazards of nicotine."

This strategy would have an additional consequence, an outcome that is beyond the scope of personal-injury law and within the realm of securities fraud. If successfully employed, it could decimate the market value of \$18 billion in tobacco-settlement bonds that the states already have sold to public investors.

Why? Because were cigarettes to be replaced successfully with nicotine inhalers, this would eliminate settlement payments to states by tobacco companies, which are the source of funds for interest and principal payments on most of those bonds.

The state of Washington's Oct. 25, 2002, prospectus for its offering of \$517 million in 2002 tobacco-settlement bonds states: "The settlement represents the resolution of large potential financial liability of the [participating manufacturers] for smoking-

related injuries, the costs of which have been borne and will likely continue to be borne by cigarette consumers."

The prospectus also states, and language in Section VII(d) of the Tobacco Master Settlement Agreement confirms, that the obligations of participating manufacturers (such as Philip Morris or RJ Reynolds) are not those of any affiliate. For example, neither the Altria Group, parent of Philip Morris, nor its Kraft Foods sister subsidiary, bears any financial responsibility for making settlement payments.

That places the burden for 50 percent of tobacco-settlement payments, and thus bond principal and interest payments, exclusively on Philip Morris USA and its cigarette customers. Anything that affects tobacco-consumer behavior is, therefore, reasonably within the scope of mandatory prospectus disclosure.

Sumner's article describing his broad strategy to replace cigarettes with nicotine inhalers was received at Tobacco Control on Jan. 17, 2002, nine months before the date of the Washington tobacco-bond prospectus. Under the tobacco settlement, states are repositories of tobacco-control program information. They often participate in coordinating future program focuses and are conversant with important strategies. It is, therefore, likely that most state tobacco-control coordinators were aware of Sumner's recommendations well before they were published.

Several initiatives that resulted in new smoking bans, such as one in New York, began before the date of the Washington prospectus. And many initiatives consistent with Sumner's described strategy took place well before many states issued their tobacco bonds, yet the Washington prospectus does not discuss in meaningful detail or depth such activity, providing only a perfunctory discussion.

Furthermore, the prospectus includes future tobacco-consumption forecast tables that not only are misleading as to how calculations are made but also exclude

reference to important material facts, such as Sumner's strategy.

Investors rely on tobacco-consumption forecasts because they provide the basis for demonstrating that revenues from cigarette sales will be sufficient to make settlement payments, which in turn pay bond interest and principal. As consumption falls below forecast levels, timely payment of interest and principal becomes increasingly doubtful. Under those conditions, the principal value of the bonds discounts to produce higher yields that reflect current risks.

Sale of tobacco-bond securities to public investors is a transfer of risk for receipt of tobacco-settlement revenue from the states to those investors. Perhaps it is time for tobacco lawyers to dust off their securities-fraud textbooks and take a hard look at the basic requirements of a securities-fraud claim.

Principal among the subjects that inquiring minds may wish to explore is whether some states have transferred the risk of receiving tobacco-settlement payments from themselves to public investors, with the knowledge that tobacco-control strategies already in play could reduce consumption well below the forecasts in their prospectuses. To put the question in a more transparent light, has tobacco-control advocacy begun to damage the integrity of our financial markets?

The \$18 billion of public investment in tobacco-settlement bonds now on the line says that these are important questions. These issues should be given careful judicial scrutiny. If not, the damage to public investors' tobacco-bond portfolios may become collateral damage in the war on tobacco.

Norm Kjono has served as an expert witness in securities-fraud litigation since 1979. He is a columnist for Forces.org, a consumer advocacy Web site that addresses tobacco and other issues.

RESEARCH PAPER

Estimating the health consequences of replacing cigarettes with nicotine inhalers

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Background: A fast acting, clean nicotine delivery system might substantially displace cigarettes. Public health consequences would depend on the subsequent prevalence of nicotine use, hazards of delivery systems, and intrinsic hazards of nicotine.

Methods: A spreadsheet program, DEMANDS, estimates differences in expected mortality, adjusted for nicotine delivery system features and prevalence of nicotine use, by extending the data and methods of the SAMMEC 3 software from the US Centers for Disease Control and Prevention. The user estimates disease risks attributable to nicotine, other smoke components, and risk factors that coexist with smoking. The public health consequences of a widely used clean nicotine inhaler replacing cigarettes were compared to historical observations and public health goals, using four different risk attribution scenarios and nicotine use prevalence from 0–100%.

Main outcome measures: Changes in years of potential life before age 85 (YPL85).

Results: If nicotine accounts for less than a third of smokers' excess risk of SAMMEC diseases, as it most likely does, then even with very widespread use of clean nicotine DEMANDS predicts public health gains, relative to current tobacco use. Public health benefits accruing from a widely used clean nicotine inhaler probably equal or exceed the benefits of achieving Healthy People 2010 goals.

Conclusions: Clean nicotine inhalers might improve public health as much as any feasible tobacco control effort. Although the relevant risk estimates are somewhat uncertain, partial nicotine deregulation deserves consideration as part of a broad tobacco control policy.

<http://tc.bmjournals.com/cgi/content/abstract/12/2/124?etoc/cgi/content/full/12/2/124>

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Author's Note: This commentary discusses a recent research paper published by *Tobacco Control* at *TC Online*. An abstract and the URL for that report appear above. A copy of full text for that report can be downloaded for \$8.00 from *TC Online*. I highly recommend that those who have an interest in tobacco control subjects download and carefully read Dr. Sumner's report about substituting a pharmaceutical nicotine inhaler for tobacco products.

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