

# TOBACCO CONTROL

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## Editorials

### Taking aim at the bull's-eye: the nicotine in tobacco products

The epidemic of tobacco-caused illness and death may be seen as the rings of a target. Each concentric ring represents a different advocacy strategy for mitigating its harm. Although reasonable minds may differ over the exact order of the rings, the target might look something like this: the outermost ring promotes tobacco cessation programmes. The first interior ring supports effective enforcement of strong restrictions on access by young people. The next ring advocates the end of tobacco advertising, whereas the ring inside that champions well-funded counter-advertising and education. Further in is a ring backing restrictions on smoking in public places and worksites. The last ring supports price increases, including excise tax hikes.

Finally, there is the bull's-eye, the most challenging but also the most rewarding point on the target. It represents control of the product itself.

The new focus on the bull's-eye is what the tobacco industry fears most, and why it continues to resist unrestricted regulation over tobacco products by the United States Food and Drug Administration (FDA). The headline of a *New York Times* editorial—after a federal court in North Carolina upheld FDA jurisdiction over tobacco products as drug delivery devices—spotlighted the industry's worst nightmare. It read simply: "NEW POWER TO REDESIGN CIGARETTES".<sup>1</sup> This year, landmark tobacco control legislation was killed by the industry's friends in Washington, DC, at least in part because "Congress [was] considering measures to let the Food and Drug Administration regulate the nicotine out of cigarettes."<sup>2</sup>

The legal challenge to the FDA's assertion of jurisdiction over tobacco products is expected to eventually make its way to the United States Supreme Court. On 14 August 1998, a panel of three judges of the United States Court of Appeals for the Fourth Circuit, located in Richmond, Virginia, reversed the 1997 lower court ruling.<sup>3</sup> President Clinton immediately announced that the government would appeal the decision. He also called on Congress to enact legislation "to confirm the FDA's authority and take this matter out of the courtroom",<sup>4</sup> thus underscoring that the agency's jurisdiction may ultimately be ratified either by the judiciary or by the enactment of federal legislation.<sup>5</sup>

Although these early battles over product regulation have been predictably bruising, they have set the stage for progressive action by crystallising the issues involved and by placing squarely in the mainstream the notion that the tobacco industry should be forced to change its products for the benefit of the public's health.

It is timely, therefore, that this issue of *Tobacco Control* features the remarkable new report from the American

Medical Association's (AMA's) Council on Scientific Affairs.<sup>6</sup> Although most proposals for mitigating the damage caused by tobacco historically have taken aim at the concentric rings on the tobacco-control target, the AMA report recommends setting our sights directly on the bull's-eye. Specifically, it proposes "that the AMA encourage the FDA to assert its authority over the manufacture of tobacco products to reduce their addictive potential at the earliest practical time, with a goal for implementation within 5–10 years." The report's recommendations may seem dramatic, but they constitute a logical and sensible response to the unprecedented breakthroughs that have taken place, particularly in the United States, since evidence of the tobacco industry's manipulation of nicotine first gained widespread public notice in February of 1994.

#### Revelations of nicotine manipulation launch a revolution

It was in that pivotal month that the FDA and ABC News announced that American cigarette manufacturers were deliberately controlling nicotine levels in their products to dose consumers with fine-tuned deliveries of the drug.<sup>7–15</sup> The revelations launched a revolution. Perhaps most importantly, they spurred the FDA to embark on a two-and-a-half-year probe into the industry's knowledge of nicotine's drug effects and its exploitation of sophisticated technology to foist nicotine dependency on millions of tobacco consumers.<sup>10 16–19</sup>

The FDA's investigation was augmented by 10 months of historic congressional hearings before the Subcommittee on Health and the Environment, Committee on Energy and Commerce, House of Representatives, in 1994.<sup>18–23</sup> Representative Henry Waxman (Democrat from California) later supplemented his subcommittee's findings by reading hundreds of previously secret documents on nicotine research from Philip Morris into the *Congressional Record* on the floor of the House of Representatives in July 1995, not long after a front-page exposé in the *New York Times* first disclosed their existence.<sup>24–30</sup> The crucial timing of those events, moreover, helped persuade President Bill Clinton to support the FDA's initiative to assert jurisdiction over tobacco products as drug-delivery devices.<sup>31 32</sup>

Providing additional synergy with the FDA and congressional investigations were reams of internal tobacco company documents obtained in lawsuits filed by state attorneys general, classes of addicted and injured smokers, and individual plaintiffs. The flood of documents further exposed tobacco companies' awareness of nicotine's addictiveness and their control of the drug. Some of the most damaging provided fodder for headline-grabbing news exposés.<sup>33–45</sup>

Based on these disclosures, we now understand that senior tobacco industry officials knew what they were talking about when they secretly made the following observations, as well as countless others like them. “Without nicotine . . . there would be no smoking. . . . No one has ever become a cigarette smoker by smoking cigarettes without nicotine. . . . Think of the cigarette pack as a storage container for a day’s supply of nicotine. . . . Think of the cigarette as a dispenser for a dose unit of nicotine. . . . Think of a puff of smoke as the vehicle of nicotine. . . . Smoke is beyond question the most optimized vehicle of nicotine and the cigarette the most optimized dispenser of smoke.”<sup>46</sup> “Moreover, nicotine is addictive. We are, then, in the business of selling nicotine, an addictive drug effective in the release of stress mechanisms.”<sup>47</sup> “Our industry is then based upon design, manufacture and sale of attractive dosage forms of nicotine which have more overall value, tangible or intangible, to the consumer than those of our competitors.”<sup>48</sup> “In a sense, the tobacco industry may be thought of as being a specialized, highly ritualized, and stylized segment of the pharmaceutical industry.”<sup>48</sup>

Now we know, in a way that even the ground-breaking surgeon general’s report of 1988<sup>49</sup> could not convey, that tobacco manufacturers have long perceived themselves as drug merchants, and that nicotine is their lifeblood.

### Industry arsenal revealed

We also have learned that, to capitalise on their knowledge of the drug effects of nicotine, cigarette makers developed an arsenal of methods to manipulate its delivery with extreme precision.<sup>16 17 19 50</sup> Indeed, these techniques, combined with the industry’s fraudulent denial that nicotine is addictive, are now the focus of a broad criminal investigation being conducted by the United States Department of Justice.<sup>51–58</sup> The techniques, some of which are also used by smokeless tobacco manufacturers, include the following.

- Adjustment of tobacco blends by using high-nicotine tobaccos and higher nicotine parts of tobacco leaves to raise the nicotine concentration in lower “tar” cigarettes<sup>59 60</sup>
- Addition of extraneous nicotine to fortify tobacco stems, scraps, and other waste materials, which are processed into “reconstituted tobacco”, a product not found in nature that is used in significant quantities in most major cigarette brands<sup>11 56 59 61–69</sup>.
- Addition of ammonia compounds, which speed the delivery of free nicotine to smokers by raising the pH, or alkalinity, of tobacco smoke, causing the smoker to “freebase” the drug into his or her bloodstream, much as crack users freebase cocaine<sup>70–72</sup>.
- Use of filter and ventilation systems that remove a higher percentage of tar than nicotine<sup>59</sup>.
- Genetic engineering of tobacco plants to substantially boost nicotine content, as Brown & Williamson has done by producing and using in mass-marketed cigarettes the super-charged “Y-1” tobacco, conduct which earlier this year led to a federal criminal conviction<sup>51 73–76–92</sup>.
- Use of nearly invisible ventilation holes that dilute the smoke and thus reduce nicotine delivery in machine tests—leading to lower advertised nicotine levels—but which are often covered by the fingers and lips of human smokers, who consequently inhale much higher levels of the drug, as well as the cancer-causing tar<sup>59 77</sup>.
- Addition of chemicals, such as acetaldehyde and pyridine, that act synergistically to strengthen nicotine’s impact on the brain and central nervous system.<sup>21 78 79</sup> (WA Farone, 7 and 11 April 1996, unpublished papers).

Dr William A Farone, a former Director of Applied Research at Philip Morris, where he supervised a directorate of more than 150 research scientists, has pointed out that cigarette makers also use ingredients such as chocolate, cocoa, and menthol, which they claim are nothing more than innocuous food additives (WA Farone, 7 April 1996, unpublished papers; American Tobacco Company *et al*, 12 April 1994, unpublished document disseminated to the media). As Dr Farone notes, however, chocolate and cocoa, when burned, produce theobromine, a bronchodilator that helps open up the air passageways and facilitate easier inhalation. Menthol, in turn, numbs the throat, also facilitating inhalation. These observations highlight why it is critical for the FDA to have, and exercise, unrestricted regulatory oversight so that full attention can be given to controlling not only nicotine but also the tobacco industry’s use of other additives that affect the brain and body of the user.

### “Safer” cigarettes are not a panacea

Although the AMA report does not explicitly address the broader issue of the tobacco industry’s use of additives, it musters sound arguments in support of its proposal to combat nicotine addiction, which currently afflicts an estimated 77–92% of all cigarette smokers in the United States.<sup>49 80 81</sup> It effectively counters the concerns raised by some that even a gradual phaseout of nicotine from conventional tobacco products, coupled with greatly improved access to low-cost, attractively marketed replacement products, would spawn such a wave of compensatory smoking and such a horrendous black market in nicotine-loaded cigarettes that it would nullify the benefits of the huge saving of lives that the Council predicts.

More conventional than the recommendation to lower nicotine content have been proposals to make cigarettes “safer”, for example, by forced reductions in tar levels.<sup>82</sup> Supporting the production of truly less hazardous cigarettes makes sense, but doing so while permitting manufacturers to cavalierly maintain addictive levels of nicotine does not. To do so would leave in the hands of the tobacco industry the extraordinary discretion to control and manipulate their most lethal weapon. As long ago as 1981, the United States surgeon general cautioned against promoting the use of cigarettes with a lower tar-to-nicotine ratio by reducing tar while maintaining a typical nicotine yield.<sup>83</sup> “Attempting to minimize smoker compensation by selectively reducing ‘tar’ and other smoke compounds while maintaining nicotine yield may carry serious disadvantages. First, maintaining nicotine delivery may reinforce physiologic habituation, and interfere with smoking cessation attempts. Second, nicotine gives rise to the tobacco-specific carcinogenic N-nitrosamines. . . . Finally, nicotine is suspected to be a major smoke constituent correlated with the increased risk of cardiovascular disease among cigarette smokers.”

The surgeon general further emphasised that there is no safe cigarette, and that any risk reduction associated with lower yield cigarettes would be small compared with the benefits of quitting smoking.

Each year, the AMA report observes, only 2–3% of American cigarette smokers successfully quit without relapsing within a year. A third of those who manage to abstain for a full year relapse the following year. In short, the presence of addictive levels of nicotine in mass-marketed tobacco products devastates efforts to combat the epidemic. Worse, it ensures that, particularly in the absence of other effective measures such as much higher prices and far more effective enforcement of restrictions on access by young people, as many as a half of all

children who experiment with tobacco products will continue to become dependent on nicotine.<sup>81</sup>

The report makes clear that such a dire situation demands dramatic new steps.

### Support for nicotine phase-out grows

As the FDA and others consider the AMA's recommendations, they may be reassured by the fact that the AMA is not the first to propose removing nicotine from tobacco products. The AMA's Minnesota Delegation deserves credit for offering a resolution in 1996 that led to preparation of the new report. Separately, an eminent group of experts recommended, in response to the settlement negotiations between the industry, state attorneys general, and others in 1997, that any agreement include FDA authority to phase nicotine out of tobacco products.<sup>84</sup> Similarly, Dr Nigel Gray, chairman of the International Union Against Cancer (UICC), proposed gradually eliminating nicotine from tobacco products worldwide,<sup>85</sup> citing the massive toll wrought by tobacco and predictions that it will grow far worse during the next 30 years.<sup>86</sup> "The status quo", he said, "is too dangerous." Drs Neal Benowitz and Jack Henningfield proposed similar action in their well-received article in a July 1994 issue of the *New England Journal of Medicine*.<sup>87</sup>

A comparable proposal was introduced in the political arena, where Representatives Martin T Meehan (Democrat from Massachusetts) and James V Hansen (Republican from Utah) offered federal legislation to enact the "Freedom from Nicotine Addiction Act of 1995",<sup>88</sup> a measure that received the AMA's endorsement.<sup>89</sup> HR 1853, which would have lowered nicotine to non-addictive levels over a period of six years, was modelled on a draft bill that I prepared in 1991 after I received a secret early education about the tobacco industry's manipulation of nicotine from an RJ Reynolds whistleblower code-named "Deep Cough". Deep Cough, who to this day remains an anonymous and unsung hero, later served as a source for the February 1994 ABC News exposé and as the industry informant who jump-started the FDA's historic tobacco investigation.<sup>9 10 15 90</sup>

Underlying all such proposals is the basic truth that nicotine addiction, fuelled by the malfaisance of the tobacco industry, is the root cause of the 20th century epidemic of lung cancer, emphysema, and cardiovascular disease. As such, it is responsible for most tobacco-related deaths.<sup>91</sup> That is because, as stated time and again in internal tobacco company documents, without nicotine there would be no smoking.<sup>45 47 48</sup>

The tobacco industry is, as some have noted, the vector of tobacco-related disease. But the vector would pose little threat to public health if denied its chief pathogen.

Thus, the AMA's Council on Scientific Affairs gets it right. If based on thorough study and understanding, the phasing out of nicotine ultimately should enable the millions of tobacco users who want to quit to do so far more easily; or, in lieu of overcoming their addictions altogether, a nicotine phase-out will at least provide powerful incentive for them to switch to far-safer replacement products. In the case of new smokers—most of whom are children and adolescents—it will prevent addiction from the outset.

When it was discovered that the Ford Pinto car had a design defect that caused the gas (petrol) tank to explode upon impact in low-speed crashes, the Ford Motor Company wasn't told, "You must curtail your marketing efforts for the Pinto", or "You must raise the price of the car to discourage people from buying it". Instead, the manufacturer had to change the product. It wasn't adver-

tising or the low price that was doing the maiming and killing. It was the product itself.

Ultimately, tobacco products should be treated no differently. It is time to train our sights on the bull's-eye.

CLIFFORD E DOUGLAS

*Tobacco Control Law and Policy Consulting,*  
3189 Rumsey Drive,  
Ann Arbor, Michigan 48105-3437, USA.  
tclpc@aol.com

See the Associated Press article on pages 315–319, which was released on 12 September 1998—ED

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