Prying open the door to the tobacco industry's secrets about nicotine: The M... Richard D Hurt; Channing R Robertson JAMA; Oct 7, 1998; 280, 13; Health Module pg. 1173

# Health Law and Ethics

# Prying Open the Door to the Tobacco Industry's Secrets About Nicotine

# The Minnesota Tobacco Trial

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In 1994 the state of Minnesota filed suit against the tobacco industry. This trial is now history, but its legacy will carry on into the 21st century because of the revelations contained in the millions of pages of previously secret internal tobacco industry documents made public in the trial. In this article, we review representative documents relating to nicotine addiction, low-tar, low-nicotine cigarettes, and cigarette design and nicotine manipulation in cigarette manufacture. These documents reveal that for decades, the industry knew and internally acknowledged that nicotine is an addictive drug and cigarettes are the ultimate nicotine delivery device; that nicotine addiction can be perpetuated and even enhanced through cigarette design alterations and manipulations; and that "health-conscious" smokers could be captured by low-tar, low-nicotine products, all the while ensuring the marketplace viability of their products. Appreciation of tobacco industry strategies over the past decades is essential to formulate an appropriate legislative and public policy response. We propose key elements for such legislation and urge no legal or financial immunity for the tobacco industry.

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# THE STAGE: THE MINNESOTA TOBACCO TRIAL

The medical community was allowed a glimpse inside the tobacco industry with the 1995 publication of the Brown and Williamson (B&W) tobacco papers.<sup>1-6</sup> Shortly before, in August 1994, the state of Minnesota filed suit against the tobacco industry, ultimately leading to the relinquishment of millions of pages of internal tobacco industry documents. The recent release of previously protected attorney-client-privileged documents, ordered to be produced on the basis of crime or fraud, shed even more light on the industry's secrets.

During preparation for testifying as expert witnesses for the state of Minnesota, we reviewed thousands of pages of documents dealing with addiction, low-tar, low-nicotine cigarettes, and cigarette design and nicotine manipulation. We focus on these areas in this article. The documents cited here were en-

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tered as exhibits in the trial, and each one is representative of hundreds of similar documents. That the documents come from all major cigarette companies (hereafter referred to as the industry) validates and extends the findings reported in the B&W papers.<sup>1-6</sup> Although documents relating to cigarette marketing to children<sup>7-10</sup> and describing involvement of tobacco company legal counsel in controlling certain aspects of company research<sup>11-14</sup> were entered as evidence in the Minnesota trial, our analysis focuses specifically on those documents addressing nicotine addiction, delivery, and manipulation. (The names, positions, and company affiliations of the individuals named in this article are available from Dr Hurt.)

The documents we reviewed reveal little positive about the tobacco industry or its supporters in advertising and public relations. They draw a dark cloud over the conduct of the attorneys who have defended the industry over the years. It is critical for the medical community to be aware of the evidence introduced in this trial about the actions and behavior of the tobacco industry so that it may help shape national policy toward the industry aimed at protecting the public health. Full disclosure and full accountability without consideration of immunity has been called for by organized medicine and public health leaders,15 and the evidence from this trial unequivocally supports that position.

# THE BEGINNING: CLOSING THE DOOR TO THE TOBACCO INDUSTRY SECRETS

The story began on December 15, 1953, when tobacco executives and representatives of the public relations firm Hill and Knowlton met secretly to develop an industry response to recently published data linking cigarettes to lung cancer.<sup>16-19</sup> From this meeting emerged a strategy of creating doubt and controversy over the scientific evidence, which was to be the centerpiece of the industry's defense for decades to come. The industry position was made public on January 4, 1954, with the publication of "A Frank Statement to Cigarette Smokers."20,21 Working drafts of the statement reveal that just before publication, substantial changes were made, including the elimination of the sentence, "We will never produce and market a product shown to be the cause of any serious human ailment."16

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Importantly, the final version of the statement made the following pledge: "We accept an interest in people's health as a basic responsibility, paramount to every other consideration in our business,"<sup>20</sup> a pledge the industry failed to keep.

Efforts to gain the public trust amidst in-house acknowledgment of the deceit were widely evident in these early years. Documents detailing planning that occurred in the early months of 1954 contained the following statements:

There is only one problem—confidence, and how to establish it; public assurance, and how to create it—in a perhaps long interim when scientific doubts must remain. And, most important, how to free millions of Americans from the guilty fear that is going to arise deep in their biological depths . . . every time they light a cigarette. . . . The very first problem is to establish some public confidence in the industry's leaders themselves, so that the public will believe their assertions of their own interest in the public health; . . . to reassure the public and still instinctive fears . . . if any cancer-causing agent is ever really found in tobacco, the manufacturers will quickly find a way to eliminate it.<sup>16</sup>

Review of internal company documents from the 1950s revealed industry acknowledgment of the scientific evidence of nicotine's addictive properties and linking illness with cigarette smoking. Research directors interviewed in early 1954 commented, "It's fortunate for us that cigarettes are a habit they can't break," and "Boy, wouldn't it be wonderful if our company was the first to produce a cancer-free cigarette. What we could do to the competition!"16 Interviews conducted in 1958 by British American Tobacco (BAT) scientists at 18 institutions and research laboratories in North America, including 3 tobacco companies, the Scientific Advisory Board of the Tobacco Industry Research Committee, the National Cancer Institute, and several academic institutions, found only 1 dissenting voice to the question of whether a causal relationship between cigarette smoking and lung cancer had been established.22

# NICOTINE AND ADDICTION Industry Understanding

Nicotine's addictive properties were acknowledged internally by 1963,<sup>2</sup> but a reason for continued public denial was made clear in a 1980 Tobacco Institute document from Mr P. C. Knopick to Mr W. Kloepfer, senior vice president for public relations:

Shook, Hardy [Shook, Hardy, and Bacon, LLP, is a Kansas City, Mo, law firm that has directed legal strategy for the tobacco industry<sup>1,3,4</sup>] reminds us, I'm told, that the entire matter of addiction is the most potent weapon a prosecuting attorney can have in a lung cancer/ cigarette case. We can't defend continued smoking as "free choice" if the person was "addicted."<sup>23</sup>

Other documents revealed a long-standing recognition of the pharmacological effects of smoking and nicotine, including both addiction and tolerance. Sir Charles Ellis, a scientific adviser to BAT, in a 1962 document stated, "What we need to know above all things is what constitutes the hold of smoking, that is, to understand addiction."<sup>24</sup> He went on to say:

As a result of these various researches, we now possess a knowledge of the effects of nicotine far more extensive than exists in published scientific literature.... We believe that we have found possible reasons for addiction in two other phenomena that accompany steady ab sorption of nicotine. Experiments have so far only been carried out with rats, but with these it is found that certain rats become tolerant to repeated doses and after a while show the usual nicotine reactions but only on a very diminished scale.... Supposing the tranquilizing action of nicotine can be tracked down in this way, then these reactions will be compared in the case of rats who have never had nicotine, or alternatively have become addicted to it. Subsequent similar measurements will be made on human nonsmokers and on addicted smokers.<sup>24</sup>

The addictive potential of a drug is enhanced by delivery systems that cause it to reach the brain more quickly,<sup>25</sup> a concept fully appreciated by industry scientists. A 1964 document from H. D. Anderson, vice president of research and development (R&D), to R. P. Dobson, president of BAT, discussed adding potassium carbonate to tobacco: "There seems no doubt that the 'kick' of a cigarette is due to the concentration of nicotine in the bloodstream which it achieves, and this is a product of the quantity of nicotine in the smoke and the speed of transfer of that nicotine from the smoke to the bloodstream."<sup>26</sup>

### Sustaining the Health Conscious Market

As public concern about the health effects of smoking increased, the industry developed strategies to confront that concern. In a 1972 Tobacco Institute document, Fred Panzer, vice president, in a report to Horace R. Kornegay, president, reviewed the industry's strategy to "defend itself on three major fronts-litigation, politics, and public opinion."27 That strategy included "creating doubt about the health charge without actually denying it." He went on to say, "In the cigarette controversy, the public--especially those who are present and potential supporters (e.g. tobacco state congressmen and heavy smokers)-must perceive, understand, and believe in evidence to sustain their opinions that smoking may not be the causal factor."27 A possible new strategy was proposed: "Thus there are millions of people who would be receptive to a new message, stating: Cigarette smoking may not be the health hazard that the anti-smoking people say it is because other alternatives are at least as probable."27 In this way, the industry sought to create doubt about the health consequences of smoking, allowing smokers to rationalize their continued use.

The industry also understood that reassuring the smoker that low-tar and low-nicotine delivery cigarettes were safe supported continued smoking. A December 1976 Lorillard document stated:

Health concerns are the usual reasons for switching to a low T&N [tar and nicotine] brand. Such cigarettes are "better for you"—milder and less irritating (now) as well as less likely to cause serious problems (later)... To many SHF [super-high-filtration] smokers, a low T&N cigarette represents a compromise smoke between a more satisfying smoke and not smoking at all... Most "health oriented" smokers exhibit an openness to changing their cigarette brand on safety as well as other grounds. To deal with this ambivalence, they rationalize (e.g., "I may be better off smoking"), they compromise (turning to "milder" or lower tar and nicotine cigarettes; trying to smoke less), and they temporize ("I'll quit when things quiet down around here").<sup>28</sup>

The report concluded by saying, "This research indicates a number of directions for approaching the 'health-oriented' cigarette market with viable new, improved and optimized product/marketing concepts" and outlines a way of "Targeting to Health-Oriented Market Segments."<sup>28</sup>

## **Characteristics of Addiction**

Denial, rationalization, and reinforcement are key elements in the addictive process, concepts that the industry understood very well. The importance of nicotine in the addictive process was expressed in a variety of ways. In a 1969 Philip Morris memo, W. L. Dunn (known within the industry as "The

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Nicotine Kid") discussed reinforcement: "Perhaps this is the key phrase: the reinforcing mechanism of cigarette smoking. If we understand it, we are potentially more able to upgrade our product."<sup>29</sup> In a 1978 Philip Morris memo from senior scientist T. S. Osdene summarizing a Council for Tobacco Research meeting, he stated, "Dr. Seligman [Philip Morris research director] brought up the grant by Dr. Abood in which one of the stated aims was to make a clinically acceptable antagonist to nicotine. This goal would have the potential of putting the tobacco manufacturers out of business."<sup>30</sup> In a 1978 B&W memo from H. D. Steele to M. J. McCue, Steele stated, "Very few consumers are aware of the effects of nicotine, i.e., its addictive nature and that nicotine is a poison."<sup>31</sup> Others were more blunt, such as a 1983 B&W memo that stated, "Nicotine is the addicting agent in cigarettes."<sup>32</sup>

Further understanding of the addictive process is shown in a 1979 BAT document summarizing a survey of 2018 smokers.<sup>33</sup> It stated:

Rationalization through modifying smoking behavior is a feasible means of conflict reduction... One way of reducing the conflict within the smoker is to deny, devalue or otherwise rationalize the health argument. The four modes of potential conflict reduction discussed so far rely on either a fatalistic disposition to health or a faith in "safer" smoking, or a denial of anti-smoking information.<sup>33</sup>

This health reassurance strategy was pervasive among the companies. In a 1973 speech, Dr A. W. Spears, then a researcher and now the chief executive officer at Lorillard, said:

Before concluding my remarks on product acceptance, I want to return to the element of psychologic acceptance and discuss another component of this element which I will call "Health Psychology." Clearly the consumer is concerned about smoking and health and is convinced in varying degrees that smoking is a possible deterrent to his health. Presently, this factor is of active interest to R&D since it has been used to an advantage in marketing both the Kent and True brands.<sup>34</sup>

#### Nicotine the Addicting Drug and the Threshold Dose of Nicotine

For cigarettes, as with all drug delivery devices, it is critical to ensure that the drug (ie, nicotine for cigarettes) is delivered to the recipient within a dose range window, the upper bound dictated by toxic effects and the lower bound defined by the minimal dose required to achieve the desired pharmacological effect. Recent proposals from the scientific community have called for consideration of reducing the absolute level of nicotine in cigarettes to a point where adolescents would not be able to become dependent.<sup>35</sup> The industry also focused on this "threshold dose" but from the opposite and much darker perspective, ie, not to avert addiction but to maintain it. A 1980 Lorillard document summarized the goals of an internal task force, one of which was to "[d]etermine the minimum level of nicotine that will allow continued smoking. We hypothesize that below some very low nicotine level, diminished physiological satisfaction cannot be compensated for by psychological satisfaction. At this point, smokers will quit or return to higher T&N brands."36 Another example of this thinking is a 1971 R. J. Reynolds (RJR) document that listed as an item for future research "Habituating level of nicotine (how low can we go?)."<sup>37</sup> A 1982 BAT memo noted:

If delivery levels are reduced too quickly or eventually to a level which is so low that the nicotine is below the threshold of pharmacological activity then it is possible that the smoking habit would be rejected by a large number of smokers.... The simple answer would seem to be to offer the smoker a product with comparatively high nicotine deliveries so that with a minimum of effort he could take the dose of nicotine suitable to his immediate needs.  $^{\rm 38}$ 

Similar sentiments had been expressed in 1978 by Creighton at BAT who added, "It is not known where this threshold between just acceptable and rejection lies."39 In 1976 S. J. Green, a scientist and research director at BAT, stated, "Nicotine is an important aspect of 'satisfaction', and if the nicotine delivery is reduced below a threshold 'satisfaction' level, then surely smokers will question more readily why they are indulging in an expensive habit."40 Similar research was under way at RJR in 1977, where researchers were conducting an extended-use consumer study to provide a more definitive idea of "optimum and minimum nicotine levels."41 A 1980 Philip Morris memo from W. L. Dunn to R. B. Seligman, vice president for R&D, about cigarettes with high ratios of nicotine to tar stated, "If even only some smokers smoke for the nicotine effect (I personally believe most regular smokers do), then in today's climate we would do well to have a low TPM [total particulate matter] and CO [carbon monoxide] delivering cigarette that can supply adequate nicotine."42

For decades, industry scientists, executives, and lawyers have known full well that nicotine is addicting and that they are in the business of developing, manufacturing, and selling a drug delivery device—the cigarette. Clearly, the industry was concerned with identifying the minimum dose threshold for nicotine that the device could deliver. This is further exemplified by brands designed to explore the lower reaches of nicotine delivery levels, ie, Merit-DeNic, Benson and Hedges DeNic, and Next, the failure of which was prophesied by W. L. Dunn in 1972: "No one has ever become a cigarette smoker by smoking cigarettes without nicotine."<sup>43</sup>

## CIGARETTES: THE HOLY GRAIL OF DRUG DELIVERY DEVICES Tobacco or Drug Industry?

The cigarette is a sophisticated nicotine delivery device allowing nicotine to be manipulated both physically in terms of amount and chemically in terms of form to ensure a pharmacologically active dose can be obtained by the smoker. That the smoker can control the nicotine dose by altering smoking behavior makes the cigarette one of the most technologically sophisticated drug delivery devices available.

That nicotine is a drug, that the cigarette is a delivery device, and that tobacco companies are in the drug business have not escaped the industry. Claude E. Teague, Jr, assistant director of research at RJR, could have been speaking for the entire industry in a 1972 memorandum:

In a sense, the tobacco industry may be thought of as being a specialized, highly ritualized and stylized segment of the pharmaceutical industry. Tobacco products, uniquely, contain and deliver nicotine, a potent drug with a variety of physiological effects.... Thus a tobacco product is, in essence, a vehicle for delivery of nicotine, designed to deliver the nicotine in a generally acceptable and attractive form. Our  $In dustry \, is then \, based \, upon \, design, manufacture \, and \, sale \, of \, attractive$ dosage forms of nicotine, and our Company's position in our Industry is determined by our ability to produce dosage forms of nicotine which have more overall value, tangible or intangible, to the consumer than those of our competitors.... If nicotine is the sine qua non of tobacco products and tobacco products are recognized as being attractive dosage forms of nicotine, then it is logical to design our products-and where possible, our advertising-around nicotine delivery rather than "tar" delivery or flavor. . . . If, as proposed above, nicotine is the sine qua non of smoking, and if we meekly accept the allegations of our

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critics and move toward reduction or elimination of nicotine from our products, then we shall eventually liquidate our business. If we intend to remain in business and our business is the manufacture and sale of dosage forms of nicotine, then at some point we must make a stand.<sup>44</sup>

Summarizing future courses of action for the industry, Teague made 8 key points about nicotine, including the need to "more precisely define the minimum amount of nicotine required for 'satisfaction' in terms of dose levels, dose frequency, dosage form and the like" to be investigated through biological and other experiments; and the need to "[s]tudy means for enhancing nicotine satisfaction via synergists, alteration of pH, or other means to minimize dose level and maximize desired effects."<sup>44</sup>

Publicly admitting that nicotine is a drug had potential regulatory implications. In a 1969 Philip Morris document, Dunn wrote to H. Wakeham, director of R&D, "I would be more cautious in using the pharmic-medical model-do we really want to tout cigarette smoke as a drug? It is, of course, but there are dangerous FDA implications to having such conceptualization go beyond these walls."29 Dunn expressed similar concerns in a 1980 letter to R. B. Seligman concerning nicotine receptor programs: "Any action on our part, such as research on the psychopharmacology of nicotine, which implicitly or explicitly treats nicotine as a drug, could well be viewed as a tacit acknowledgment that nicotine is a drug. Such acknowledgment, contend our attorneys, would be untimely."<sup>12</sup> He went on to say, "Our attorneys, however, will likely continue to insist upon a clandestine effort in order to keep nicotine the drug in low profile."12 A. D. McCormick at BAT in 1974 was also concerned about the FDA: "If tobacco were to be placed under a Food and Drug law, classification of tobacco under the food section would be acceptable, but classification of tobacco as a drug should be avoided at all costs."45 In a 1972 RJR memo, Claude Teague (senior researcher at RJR) wrote: "What we should really make and sell would be the proper dosage form of nicotine with as many other built-in attractions and gratifications as possible-that is, an efficient nicotine delivery system with satisfactory flavor, mildness, convenience, cost, etc."44 In a 1980 memo to R. B. Seligman and directors of Philip Morris, Osdene outlined the priorities for "Evaluation of Major R&D Programs,"46 a memo that also shows the level of communication by the scientists to top management. About the nicotine program, he stated, "This program includes both behavioral effects as well as chemical investigation. My reason for this high priority is that I believe the thing we sell most is nicotine."46 And, in a 1983 brainstorming session at RJR, D. L. Roberts wrote: "A short definition is that a cigarette supplies nicotine to the consumer in a palatable and convenient form."47

The concept of the cigarette as a drug delivery device is deeply rooted in the industry. W. L. Dunn, in a 1972 Philip Morris document, summarized the discussion at a conference attended by 25 scientists from England, Canada, and the United States:

The majority of conferees would accept the proposition that nicotine is the active constituent of cigarette smoke.... The cigarette should be conceived not as a product but as a package. The product is 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>43</sup>

B. Reuter, from the marketing division of Philip Morris, and R. R. Johnson, a brand manager and senior scientist at B&W,

voiced similar opinions. Reuter said, "Different people smoke for different reasons. But, the primary reason is to deliver nicotine into their bodies."<sup>48</sup> Johnson's opinion was that "we are in a nicotine rather than a tobacco industry."<sup>49</sup> With a comparable mindset, researchers at BAT wrote, "BAT should learn to look at itself as a drug company rather than as a tobacco company."<sup>50</sup>

Indeed, each of the major cigarette companies has designed, manufactured, and in some cases test-marketed nicotine delivery devices that have the look and feel of cigarettes but are engineered for the sole purpose of delivering nicotine in controlled dosage forms: "Philip Morris has chosen to pursue a nicotine delivery device that, like RJR's Premier [previously marketed as a smokeless 'cigarette'], continues the cigarette tradition of sucking on a cylindrical mouthpiece to inhale flavorings and nicotine from a tobacco based product."<sup>48</sup> Importantly, what sets cigarettes apart from other drug delivery devices is that any "therapeutic" effect is outweighed by the adverse consequences of the delivery system.

#### Manipulating Nicotine Delivery

The industry pursued multiple avenues to manipulate nicotine to achieve desired delivery concentrations. In a 1963 memo from R. B. Griffith of B&W to J. Kirwan at BAT, Griffith wrote:

Nicotine is by far the most characteristic single constituent in tobacco, and the known physiological effects are positively correlated with smoker response.... I think that we can say even now that we can regulate, fairly precisely, the nicotine and sugar levels to almost any desired level management might require. Of this I am confident.<sup>51</sup>

A 1984 BAT R&D memo stated:

Irrespective of the ethics involved, we should develop alternative designs (that do not invite obvious criticism) which will allow the smoker to obtain significant enhanced deliveries should he so wish... Another area of importance is the exploitation of physical and chemical means to increase nicotine transfer, i.e. to increase the effective utilization of nicotine.<sup>52</sup>

Apparent changes in crop processing in the early 1980s caused the industry some concerns. H. E. Guess<sup>53</sup> of RJR wrote that trends in lower levels of nicotine in flue-cured crops would produce "less satisfying" cigarettes, and he suggested a "nicotine control system with upper and lower limits" to address this problem. Summaries from a 1984 BAT conference on smoking behavior noted the need to "improve our ability to 'control' the level of nicotine in smoke,"<sup>54</sup> and a 1982 report from Lorillard documents a significant long-term effort to investigate adding nicotine to cigarettes from exogenous sources.<sup>55</sup>

As expected, the cigarette industry was and is highly skilled in the physical and chemical means to manipulate nicotine. These range from tobacco blend modifications, alterations in cigarette dimension, filtration, ventilation, paper porosity, additives, and the ratio of tobacco shred size to tobacco weight per cigarette. "Puffing" (a process of expanding reconstituted tobacco to increase its volume) of tobacco for cigarettes was once accomplished by adding Freon to the reconstituted tobacco.<sup>56</sup> (Burning Freon produces the toxic gas phosgene.) In an effort to make blend adjustments, RJR entered into a joint research agreement with a biotechnology company to genetically engineer tobacco plants to manipulate nicotine levels.<sup>57</sup> With similar goals, B&W developed and has used a genetically engineered tobacco called Y1, which has "increased nicotine

content versus traditional tobaccos" while containing the same tar level.  $^{58}$ 

# THE SCAM: LOW-TAR, LOW-NICOTINE CIGARETTES Feeding the Smoker's Addiction

In further exploitation of smokers' rationalization and denial defenses, the industry developed and promoted low-tar, low-nicotine cigarettes with an implied reduction in health consequences. Benowitz et al<sup>50</sup> published the first widely recognized article in a medical journal about smoker compensation when smoking low-tar, low-nicotine cigarettes. Commenting on this article in an internal memo, J. H. Robinson, an RJR researcher, wrote:

The paper itself expresses what we in Biobehavioral have "felt" for quite some time. That is, smokers smoke differently than the FTC [Federal Trade Commission] machine and may very well smoke to obtain a certain level of nicotine in their bloodstream. If a given level of nicotine in the blood is the final goal of a smoker, one would predict that he would smoke an FFT [full flavor tar] and ULT [ultra low tar] cigarette differently.... This all falls under the area of smoker compensation which we have been interested in studying for some time now.<sup>90</sup>

Citing an earlier investigation of smoking compensation comparing the German Camel cigarette and Marlboro, Robinson wrote, "The smokers apparently obtained almost exactly the same amount of nicotine no matter which of the four cigarettes they smoked. This was one of the first indications that smokers may in fact smoke to obtain a certain level of nicotine in the bloodstream."<sup>60</sup> Despite his apparent recognition of smoking behavior with the goal of obtaining a given level of nicotine in the bloodstream, consistent with behaviors associated with other drugs of addiction, Robinson<sup>61</sup> has been a vociferous opponent to classifying nicotine as an addicting drug.

#### Making and Marketing Health Reassurance Cigarettes

In response to health concerns surrounding cigarettes, the industry began to produce products that were meant to reassure the health-conscious consumer. A Philip Morris review of the 1964 surgeon general's report stated:

The onus of proof has been moved by the report from its usual position with the industry's accusers to the tobacco industry itself.... An unfortunate impression at the committee's press conference that "filters do no good" was at least substantially rectified by Senator [John Sherman] Cooper [of Kentucky].<sup>62</sup>

One of the recommendations for company research policy was to "provide a substantive basis for vigorous health advertising by publication of suitable articles in the technical literature."<sup>62</sup> In a section entitled "Industry Posture Vis-a-Vis Public," the review stated, "The health value of filters is undersold in the report and is the industry's best extant answer to its problem. The Tobacco Institute obviously should foster the communication of the filter message by all effective means."<sup>62</sup> Further on the review stated that "the industry must come forward with evidence to show that its products, present and prospective, are not harmful."<sup>62</sup> Unfortunately for the consumer, the issue of harm was never addressed, and instead, the industry promoted their products as providing a modicum of "health reassurance" but not reductions in harm. R. Short, a marketing manager for BAT, wrote:

It was abundantly clear, for example, as a result of our recent visit to the U.S.A. that manufacturers are concentrating on the low TPM [to-

tal particulate matter] and nicotine segment in order to create brands with distinctive product features which aim, in one way or another, to reassure the consumer that these brands are relatively more "healthy" than orthodox blended cigarettes like VICEROY, MARL-BORO and WINSTON.<sup>68</sup>

A December 1976 Lorillard document outlined the impression most people had (and still have) about low-tar, lownicotine cigarettes:

People believe that cigarettes low in tar and nicotine have different "tobacco" ingredients and different kinds of filters than other cigarettes—the tobacco is milder or a special mild blend, perhaps treated to remove tar and nicotine, perhaps mixed with additives or fillers, perhaps cured differently—or maybe just more loosely packed.... Those who smoke low tar and nicotine cigarettes generally do so because they believe such cigarettes are "better for you."<sup>28</sup>

#### **Smoker Compensation**

Industry scientists were well aware that smokers compensated when smoking low-tar, low-nicotine products. A 1978 BAT document by D. E. Creighton went into great detail about compensation: "No smoker has yet been observed who smokes with the same pattern as a smoking machine."<sup>39</sup> He defined compensation to mean "subconscious changes made to the smoking pattern by a smoker in an attempt, which may or may not be successful, to equalize the deliveries of products which have different deliveries when smoked by machine under standard conditions."<sup>39</sup> Creighton stated that many experiments have been carried out in Hamburg, Germany, Montreal, Quebec, and Southampton, England, within the company as well as other experiments by research workers in independent organizations to confirm that compensation occurred. He went on to say:

[T]here is now sufficient evidence to challenge the advice to change to a lower delivery brand, at least in the short-term. In general, a majority of habitual smokers compensate for changed delivery, if they change to a lower delivery brand than their usual brand. If they choose a lower delivery brand which has a higher tar to nicotine ratio than their usual brand (which is often the case with lower delivery products), the smokers will in fact increase the amounts of tar and gas phase that they take in, in order to take the same amount of nicotine. More realistic advice to smokers would be to choose a brand with a lower tar to nicotine ratio which gives them the satisfaction that they require in the lowest amount of smoke taken in.<sup>39</sup>

An early 1970s paper by Colin Greig, in R&D for BAT, addressed compensation with some personal observations of his mother-in-law, whom he surreptitiously provided with lowtar cigarettes.<sup>64</sup> He watched her smoke them more intensely, apparently to compensate for lower delivery. He wrote:

I suggest that there is a parallel with cigarettes—we may smoke a low delivery cigarette—but in times of tension or altered mood we want a stronger one. What happens? Either we smoke one more intensely (remember, there is no single dose for a cigarette)—or we smoke two in rapid succession. A dilemma appears—do we design a compensatable cigarette—and sell one—or the non (or minimally) compensatable cigarette—to sell two? Given the unit cost, it is very probable that the second option is not viable—so we have, perhaps, to do the first.<sup>64</sup>

A 1975 Philip Morris memo about compensation stated:

The smoker profile data reported earlier indicated that Marlboro Lights cigarettes were not smoked like regular Marlboros. There were differences in the size and frequency of the puffs, with larger volumes taken on Marlboro Lights by both regular Marlboro smokers and Marlboro Lights smokers. In effect, the Marlboro 85 smokers in this study did not achieve any reduction in the smoke intake by smoking a cigarette (Marlboro Lights) normally considered lower in delivery.<sup>65</sup>

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The mechanics of compensation, ie, smoking with greater intensity, deeper inhalation, and larger puff volumes, was the topic of many documents.<sup>32,36,66,67</sup>

In a 1981 BAT document by M. Oldman, major points that were discussed included:

The nature of possible compensation phenomena in relation to highly ventilated cigarettes was discussed at length. It was noted that we have very little data on the long-term consequences of smoking behavior patterns following switching to low tar products... It was agreed that efforts should not be spent on designing a cigarette which, through its construction, denied the smoker the opportunity to compensate or oversmoke to any significant degree.<sup>68</sup>

Surveys conducted as recently as 1996 indicate that more than two thirds of American smokers are unaware that there are ventilation holes in cigarettes.<sup>69-71</sup> Even regular, full-flavor cigarettes such as Winston "Reds" have had ventilation holes in the filters since the early 1980s.<sup>72</sup> Industry scientists knew the full implications of this technology as evidenced in a 1987 BAT document that reported the effects of blocking ventilation holes on tar and nicotine delivery; the more holes that are blocked, the higher the delivery becomes.<sup>73</sup>

#### **Honesty or Cheating?**

That creating doubt about the health risks of smoking was a primary goal of the industry is evidenced in a BAT Senior Marketing Conference summary report from 1977.<sup>67</sup> The outcome of the conference summarized the new approach to marketing: "All work in this area should be directed towards providing <u>consumer reassurance</u> about cigarettes and the smoking habit. This can be provided in different ways, e.g. by claimed low deliveries, by the perception of low deliveries and by the perception of 'mildness.' "<sup>68</sup>

Later that year, at a meeting of the BAT Chairman's Advisory Committee III, several questions were raised regarding low-tar, low-nicotine delivery cigarettes:

Should we market cigarettes intended to reassure the smoker that they are safer without assuring ourselves that indeed they are so or are not less safe? For example, should we "cheat" smokers by "cheating" League Tables? [League tables are the British equivalent of the FTC ratings of cigarette delivery of tar and nicotine.] If we are prepared to accept that government has created league tables to encourage low delivery cigarette smoking and further if we make league tables claims as implied health claims—or allow health claims to be so implied—should we use our superior knowledge of our products to design them so that they give low league table positions but higher deliveries on human smoking? Are smokers entitled to expect that cigarettes shown as lower delivery in league tables will in fact deliver less to their lungs than cigarettes shown higher?<sup>74</sup>

The response of the industry to these and similar questions is clear; the industry chose to continue to deceive their customers.

# OPTIMIZING THE EFFECT: FREEBASING NICOTINE Industry Knowledge of pH Effect

Perhaps the most surprising finding in the document review was the evidence of industry-wide efforts spanning 3 decades to alter the chemical form of nicotine to increase the percentage of freebase nicotine delivered to smokers. Outside the industry, little was known about this; the 1988 surgeon general's report has only a 2-page discussion of pH, with most of the discussion focused on buccal absorption of noncigarette tobacco products.<sup>75</sup> Briefly, the chemistry of nicotine is as follows: depending on pH, nicotine exists as a diprotonated salt, a monoprotonated salt, or an uncharged or neutral species.<sup>76</sup> The salt forms are sometimes known as the "bound" forms, and the neutral species are often referred to as the "freebase" or "unbound" form. As a naturally occurring base, nicotine favors the salt form at low values of pH and the freebase form at higher values of pH ( $pK_1$ =3.02 and  $pK_2$ =8.02). Uncharged nicotine transits biological membranes with considerably less resistance than do the charged counterparts and affects its physiologic response.

The industry was well aware of these properties. A 1966 BAT report noted:

It would appear that the increased smoker response is associated with nicotine reaching the brain more quickly.... On this basis, it appears reasonable to assume that the increased response of a smoker to the smoke with a higher amount of extractable nicotine [not synonymous with but similar to free base nicotine] may be either because this nicotine reaches the brain in a different chemical form or because it reaches the brain more quickly.<sup>77</sup>

The report goes on to say that, for both tobacco and smoke, the higher the pH, the greater the percentage of extractable nicotine.

A 1971 Liggett memo stated:

Increasing the pH of a medium in which nicotine is delivered increases the physiological effect of the nicotine by increasing the ratio of free base to acid salt form, the free base form being more readily transported across physiological membranes. We are pursuing this project with the eventual goal of lowering the total nicotine present in smoke while increasing the physiological effect of the nicotine which is present, so that no physiological effect is lost on nicotine reduction.<sup>78</sup>

A 1973 Lorillard document stated, "Furthermore, the cigarette brands which are enjoying the largest sales increase generally have smoke pH's in the 6.5 to 7.0 range.... Nicotine in alkaline cigar smoke is more readily absorbed in the lungs and mouth because of the higher concentration of nicotine in the free or unprotonated form."<sup>79</sup>

#### Importance of Speed

Industry scientists were well aware of the effect of pH on the speed of absorption and the physiologic response. A 1973 RJR report stated, "Since the unbound nicotine is very much more active physiologically, and much faster acting than the bound nicotine, the smoke at a high pH seems to be strong in nicotine. Therefore, the amount of free nicotine in the smoke may be used for at least a partial measure of the physiological strength of the cigarette."80 A. Rodgman of RJR stated in 1980: "'Free' nicotine is absorbed more rapidly by the smoker than is 'bound' nicotine."81 Scientists at BAT also were aware of the pH effect. In a 1964 BAT memo, H. D. Anderson said, "Nicotine is in the smoke in two forms as free nicotine base (think of ammonia) and as a nicotine salt (think of ammonium chloride) and it is almost certain that the free nicotine base is absorbed faster into the blood-stream."26 Another BAT document stated, "When a cigarette is smoked, nicotine is released momentarily in the free-form. In this form, nicotine is more readily absorbed through the body tissue."82 A 1984 BAT report stated, "Nicotine may be presented to the smoker in at least three forms: (i) salt form in the particulate phase, (ii) free base form in the particulate phase, (iii) free base form in the vapour phase. It has long been believed that nicotine presented as in (ii)/(iii) is considerably more 'active.' "83

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By the early 1970s it was recognized widely throughout the industry that pH alterations could serve as a means to change the form of nicotine to a more physiologically active configuration. In a 1973 RJR memo, Frank Colby said, "Still, with an old style filter, any desired <u>additional</u> nicotine 'kick' could be easily obtained through pH regulation."<sup>84</sup> In another RJR memo from 1976, McKenzie said, "The pH also relates to the immediacy of the nicotine impact. As the pH increases, the nicotine changes its chemical form so that it is more rapidly absorbed by the body and more quickly gives a 'kick' to the smoker."<sup>85</sup> A 1973 RJR document stated:

Methods which may be used to increase smoke pH and/or nicotine "kick" include: (1) increasing the amount of (strong) burley in the blend, (2) reduction of casing sugar used on the burley and/or blend, (3) use of alkaline additives, usually ammonia compounds, to the blend, (4) addition of nicotine to the blend, (5) removal of acids from the blend, (6) special filter systems to remove acids from or add alkaline materials to the smoke, and (7) use of high air dilution filter systems. Methods 1-3, in combination, represent the Philip Morris approach, and are under active investigation.<sup>86</sup>

Chen at Lorillard in 1976 stated, "If the desired goal is defined to be increased nicotine yield in the delivered smoke, there appear to be only two alternatives: either increase the absolute yield of delivered nicotine, or increase the pH, which increases the 'apparent' nicotine content without changing the absolute amount."<sup>87</sup>

#### Ammonia and pH Manipulation

The predominant form of nicotine that is transported within the alveolar space to the alveolar walls is the freebase form in the gas phase. The time scales for particle deposition and subsequent nicotine transport directly from particle to alveolar membrane are much too long to play any major role in nicotine uptake. This explains why exhaled smoke particles are essentially depleted of nicotine. The nicotine leaves the aerosol droplets in its volatile or freebase form, a phenomenon known as "off gassing." This process is enhanced by increases in pH and by aerosol dilution. Aerosol dilution occurs as smoke is taken into the lungs and is increased by cigarette ventilation. By the mid-1980s all the major cigarette manufacturers were engaged in pH manipulation of cigarette smoke, and this was seen as a way to compete in the marketplace. In a 1989 B&W document, Johnson says, "AT [ammonia technology] is the key to competing in smoke quality with PM [Philip Morris] worldwide. All U.S. manufacturers except Liggett [it is known from the documents we reviewed that Liggett has used ammonia technology] use some form of AT on some cigarette products."88 Philip Morris commenced use of ammonia in their Marlboro brand in the mid-1960s, and it subsequently emerged as the leading national brand. Reverse engineering by Philip Morris's competitors eventually led each one to the conclusion that ammoniation in some form was "the secret of Marlboro."88

Perhaps the most insidious aspect of ammonia technology was the recognition in the industry that the FTC testing method for determining "tar" and nicotine in smoke could be made meaningless. Not only does the testing method fail to accurately reflect a smoker's tar and nicotine intake, the method only measures the nicotine in the particulate or aerosol phase and is incapable of assessing the "form," ie, bound or freebase, in which nicotine exists. Schori, in a 1979 B&W document, stated, "This suspected relationship between free nicotine concentration and smoke impact implies that we could create a ultra-low tar cigarette that produces much more impact than its delivery would suggest."<sup>89</sup> Further understanding of this was evident in another B&W document from 1984:

The amount of nicotine in the vapour phase can be modified by changing the acidity (pH) of the smoke. Hence it is readily feasible to have two cigarettes which deliver the same amount of nicotine (as measured on a Cambridge pad [the FTC method]) but which are easily differentiated on the sensory basis of impact since the acidity of the smoke (and hence amount of nicotine in the vapour phase) is different.<sup>90</sup>

Woods and Harllee from RJR also were aware of this concept as early as 1973: "The FTC 'tar' and nicotine has decreased for all brands studied at about the same rate. Thus, all the brands have about the same FTC 'tar' and nicotine, but the Marlboro and Kool are stronger due to a higher smoke pH."<sup>80</sup> In a 1980 B&W document, Gregory stated:

It appears that we have sufficient expertise available to "build" a lowered mg tar cigarette which will deliver as much "free nicotine" as a Marlboro, Winston or Kent without increasing the total nicotine delivery above that of a "Light" product. There are products already being marketed which deliver high percentage "free nicotine" levels in smoke, i.e. Merit, Now.<sup>91</sup>

The race to incorporate ammonia technology in cigarettes as a means to manipulate the form of nicotine into a configuration that not only "fooled" the FTC test but presented the smoker with a more potent nicotine "kick" was driven by sales and market share. Indeed, when all was said and done, the data showed that the predominant correlating variable for brand sales was free nicotine.<sup>92</sup> A 1973 RJR document explained:

All evidence indicates that the relatively high smoke pH (high alkalinity) shown by Marlboro (and other Philip Morris brands) and Kool is deliberate and controlled. This has raised questions as to: (1) the effect of higher smoke pH on nicotine impact and smoke quality, hence market performance, and (2) how the higher smoke pH might be accomplished.<sup>36</sup>

Graphs in this document plotted sales vs pH vs freebase nicotine for Winston and Marlboro; the graphs show that Marlboro sales increased as the pH and percentage of freebase nicotine increased for the years 1955 through the early 1970s.

Additional evidence of the industry's investigation into pH manipulation comes from a 1994 Philip Morris document:

To illustrate, a study was conducted on nicotine aerosols, where subjects inhaled the same amount of nicotine at pHs of 5.6, 7.5 and 11.0. It was found that higher peak concentrations of nicotine in blood were achieved at higher pHs. Since the amounts of inhaled nicotine were the same, the results indicate that the higher the pH, the more rapidly nicotine enters the bloodstream.<sup>98</sup>

Ammonia compounds are among the most abundant additives used in the manufacture of cigarettes in this country. The industry contends that ammonia compounds are added for taste, not to "freebase" the nicotine. However, neither the science nor internal industry documents support that contention. The chemistry and physics of aerosol transport and dilution and the rapid diffusion of the various forms of nicotine within the aerosol particles and within the alveolar gas spaces provide the stark reality of why pH manipulation of nicotine is so powerful.

#### CONCLUSION

The strategy of creating doubt about tobacco's health risk and attempting to deceive the public continues today. In a deposition taken for the Minnesota trial, T. S. Osdene, a retired senior scientist for Philip Morris, pleaded the Fifth Amendment more than 100 times when presented with Philip Morris internal documents. Publicly, Mr Geoffrey Bible, the current chief executive officer of Philip Morris, is quoted to have urged Osdene to tell the truth and not plead the Fifth Amendment: "First and foremost, the company wants the truth told."<sup>94</sup> Because Osdene did not testify, there are many truths we can only wonder about. For example, what is the truth about a handwritten note from Osdene regarding Philip Morris and its research in Cologne, Germany, in which he wrote, "Ship all documents to Cologne. We will monitor in person every 2-3 months. If <u>important</u> letters or <u>documents</u> have to be sent, please send to home—I will act on them and destroy."<sup>95</sup> While we can call for honesty and truth from the industry,<sup>96</sup> is it possible that after so many decades of deceit, the meaning of the word *truth* has been forgotten?

The Minnesota tobacco trial represented a pivotal point for our country as it relates to the tobacco industry. The documents cited herein are a small but representative sample of those reviewed and entered as evidence in the trial. A more complete set of documents can be accessed on the Internet (www .mnbluecrosstobacco.com) or at the Minnesota Depository (a facility now open to the public that contains all 33 million pages of previously secret tobacco industry documents that were turned over to the state in this trial). The document topics range from marketing to youth to industry lawyer involvement in directing research to the industry's insidious influence on the political process. These documents are just as disconcerting as the ones we reviewed. There must be no doubt that the industry engaged in a major effort to mislead the public and, for over 40 years, has had an elaborate public relations scheme to create doubt and controversy about the health risks of cigarettes. That the industry knew of the addictiveness of nicotine and perpetuated that addiction through manipulation of nicotine is clear from the documents we reviewed.

What would constitute effective public health policy toward the tobacco industry? We agree with others that this is the time for full disclosure and full accountability and not "settlement" according the industry limited liability and immunity.<sup>15</sup> We urge a substantial tax increase (to reduce youth initiation of smoking) of at least \$1.50 per pack; revenue from this tax should be devoted to tobacco control efforts (multimedia counteradvertising, education, and research) and treatment initiatives that would protect our children and benefit current smokers, following the lead of successful programs in California and Massachusetts. We further recommend stringent Food and Drug Administration control of cigarette design, marketing, and promotion. In addition, proposed legislation must not include provisions that allow the industry to continue to label and promote their "light" and "low-tar" products, thus continuing the low-tar, low-nicotine scam. Finally, the industry should be prohibited from imposing their sophisticated advertising and promotion techniques on citizens of other nations. The tobacco pandemic has already spread far beyond US shores, and every effort must be made to curtail it.

When the breadth and depth of tobacco industry actions are understood, it becomes evident that allowing a tobacco settlement that honors the industry demands for legal and financial immunity would be a public health disaster of epic proportions and would allow the industry to continue to promote its deadly product throughout the 21st century. Congress must use its power to stop the carnage of more than 400 000 Americans dying each year of cigarette-related diseases. That is the equivalent of 3 fully loaded 747 aircraft crashing daily for 365 days a year with no survivors. Were that to be occurring, does anyone seriously doubt that Congress would act decisively? The important question is, does Congress have the conscience and the political will necessary. We can only hope so. The health of millions depends on it.

We would like to acknowledge Attorney General Hubert H. Humphrey III, who stood by his principles for full disclosure and full accountability, and Michael Ciresi and Roberta Walburn for their legal brilliance and indefatigable work ethic that brought about the successful conclusion of the trial and the disclosure of the industry documents. We also want to thank Rhonda Baumberger for the preparation of the manuscript.

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