UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

UNITED STATES OF AMERICA, **Plaintiff,**	
v.	**Civil Action No. 99-2496 (GK)**
PHILIP MORRIS USA INC., *et al.*, **Defendants.**	

DECLARATION OF RICHARD DALE HURT, M.D.

1. My name is Richard Dale Hurt, and I am over the age of 18.
2. I have been involved in medical education and research for over 25 years. I received my M.D. in 1970 from University of Louisville. I have been a Professor of Medicine at the Mayo Clinic in Rochester, MN since 1995, Director of the Nicotine Dependence Center since 1987, and Program Director of General Internal Medicine Research Fellowship since 2003. I have served as a staff physician in the Division of Primary Care Internal Medicine since 1976 and was Chair of the Division from 1987 to 1997.
3. My first exposure to the internal tobacco company documents that eventually formed the first set of documents at the Minnesota Depository was through my work as a consultant and expert witness for the State of Minnesota and Blue Cross & Blue Shield of Minnesota in the Minnesota tobacco litigation, which was filed in 1994. Since the documents became publicly available at the Minnesota Depository, I have visited the facility multiple times and have developed a research team to review documents there intermittently over the past nine years, beginning in 2001. From my visits and those of

my research team, I have published extensively using the tobacco industry documents housed in Minnesota.

4. To date, I have published 175 peer-reviewed medical or public health articles relating to tobacco dependence and treatment, among other topics. Of those publications, over 20 co-authored published works have focused on what are, in my view, the tobacco industry's efforts to undermine the public health by misleading the public and policy makers about the harms caused by its products. These publications have relied on documents housed at the Minnesota and/or Guildford Depositories.
5. Several of my co-authored publications that relied on research based on boxes of documents housed at the Minnesota Depository have been instrumental in contributing to the medical community's understanding of what I consider to be deceptive and misleading behavior on the part of the Defendants.
6. For example, my publication with CR Robertson, *Prying Open the Door to the Tobacco Industry's Secrets About Nicotine: The Minnesota Tobacco Trial, JAMA* 280(13):1173-1181 (1998) (attached as Ex. 1), revealed that, for decades, the tobacco industry internally acknowledged that nicotine is an addictive drug, cigarette design alterations and manipulations perpetuate and enhance nicotine addiction, and that 'health-conscious' smokers were led to believe that the use of so-called 'low tar' or 'low nicotine' products were safer and an alternative to quitting. This publication relied solely on trial exhibits that were deposited in the Minnesota Depository and released to the public as an isolated collection when the Minnesota Depository opened its doors in April 1998.
7. My publication with ME Muggli and DD Blanke, *Science for Hire: A Tobacco Industry Strategy to Influence Public Opinion on Secondhand Smoke*, Nicotine & Tobacco

Research 5:303-314 (2003) (attached as Ex. 2), directly contributed to exposing what I believe to be the deceptive nature of the Defendants' coordinated global efforts to influence public opinion on the devastating harms of secondhand smoke exposure through the lawyer-managed 'ETS Consultancy Program.' Documents unearthed from the Minnesota Depository were critical to this publication. This paper emerged from my research team's review of about 200,000 pages of documents that were de-privileged by the Minnesota court and placed into the Minnesota Depository in a separate collection beginning in June 2000.

8. In our publication, *Open Doorway to Truth: Legacy of the Minnesota Tobacco Trial*,. Mayo Clinic Proceedings 84(5):446-456 (2009) (attached as Ex. 3), my co-authors and I state that, in our view, "Only a few single events in the history of public health have had as dramatic an effect on tobacco control as the public release of the tobacco industry's previously secret internal documents." This publication reviews the genesis of the public release of the internal tobacco documents, the history of the Minnesota and Guildford Depositories created by the 1998 Minnesota tobacco settlement, and what in my view is the tremendous scientific and policy impact directly made possible by the tobacco documents – including more than 500 peer-reviewed scientific publications relating to the tobacco documents and the first public health treaty negotiated under the auspices of the World Health Organization, the Framework Convention on Tobacco Control, which came into force in 2005.

9. I continue to use the documents in educating medical students, residents, and providers in the United States and across the globe on what I have come to know as the tobacco industry's efforts to addict our patients and further their misleading fraudulent practices

on the public. For example, from 2004 on, I have delivered a presentation entitled, "Cigarettes – A Modern Epidemic but a Pandemic for the Ages" where I use the tobacco industry's documents to educate medical learners and professionals about the industry's tactics to addict consumers and its role in creating the current tobacco epidemic. I have given this presentation at meetings in numerous states and territories including: West Virginia, Texas, Puerto Rico, Minnesota, Kentucky, North Carolina, Alaska, and Pennsylvania to name a few, as well as at international meetings in Uruguay, France, Brazil and Israel. I have also given a presentation on secondhand smoke exposure in many states and countries showing documents uncovered in the Minnesota and Guildford Depositories, including at international meetings in the British Virgin Islands, Mexico, and Spain.

10. When the Minnesota Depository was opened to the public in April 1998 (and the Guildford Depository in February 1999), more than 33 million pages of once-secret internal documents became available for public review (26 million in the Minnesota Depository and about 7 million in the Guildford Depository). I understand that the volume of material housed at the Minnesota Depository has nearly doubled from 11,400 boxes in Oct 1998 to currently 23,041 boxes.

11. I understand that the Minnesota Depository is used by researchers, journalists, students, litigants and advocates from around the world working to expose the tobacco industry's knowledge about its products and its worldwide efforts to undermine the public health. My understanding is that the Minnesota Depository continues to be used in this manner to this day and based on my research experience in this field, I expect that such research efforts at the Minnesota Depository will continue in the future.

12. My knowledge of these Minnesota Depository materials has facilitated my personal contributions to several committees and organizations related to tobacco dependence and treatment. These include my service as the Chair of the Tobacco Endowment Advisor Committee of the Minnesota Partnership for Action Against Tobacco at the Minnesota Department of Health, as well as my service on the Advisory Committee of the UCSF Center for Tobacco Control Research & Education & Legacy Tobacco Documents Library; the Executive Board of the Society for Research on Nicotine and Tobacco; the AMA Adolescent Smoking Cessation Advisory Board; and the Cessation Advisory Panel of the American Legacy Foundation.
13. My knowledge of the tobacco industry internal documents from the Minnesota Depository has also been critical to testimony I have provided to local, state and national legislative bodies. For example, in 2005 I testified on the adverse health effects of secondhand smoke before the Rochester City Council and in 2006 before the Olmsted County Board of Commissioners. In addition, I testified before the Minnesota House Health and Human Services Committee in St. Paul, Minnesota,. In these presentations, I supplemented the science on the adverse health effects of secondhand smoke with what the tobacco industry knew on this issue using quotes and images from the documents housed at the Minnesota Depository.
14. Based upon my experience, I believe that the Minnesota Depository is unique and essential among the available resources to access tobacco documents, including the tobacco document websites maintained by the tobacco companies and the Guildford Depository maintained by BATCo. Of critical importance, is the oversight role that the

Minnesota Depository plays in protecting the contents of the documents housed there and helping researchers navigate issues, as much as they can as a neutral third party.

15. A vivid example arose during 2004-2005, when our research team was engaged in a document review of all BATCo boxes produced to the Minnesota Depository. From 2002 to 2005 our research team reviewed nearly 400 boxes of documents produced by BATCo in various lawsuits, including about 360 boxes produced in this action, *United States v. Philip Morris USA, et. al*. The research team reported to me that it had identified numerous problems with document collection and notified Depository staff of the issues. Concurrently, our team hired the vendor Night Owl Document Management Service to scan photocopies of the documents and, through that process, additional problems with inconsistencies between indices and actual hard copies of the documents and missing pages were identified.

16. Through the review and scanning process of these documents, the Depository staff helped our research team preliminarily sort out the issues by being an intermediary between our team and BATCo. For example, the Depository staff was able to correct mistakes, at our request, by working with BATCo's local legal counsel to insert pages of documents that should have been in the boxes of documents, but were not. Further, when BATCo began pulling documents out of the document collection, claiming that they were inadvertently produced, and preventing us from scanning such documents, the Depository staff ensured that those documents did not leave the facility and that there was a complete record of the documents in dispute.

17. In 2006, we sought relief from the Minnesota court to order BATCo to cease interfering with our team's use of and access to the documents, and to compel BATCo to produce

documents to the Depository in accordance with the 1998 Minnesota Consent Judgment. I understand that the Minnesota court did not address the merits of our claim because it held that Mayo Clinic lacked standing to enforce the Minnesota settlement.

18. If this situation had instead revolved around documents that were supposed to placed online at one of the tobacco company's websites, I believe that neither our research team, nor the broader research community who rely on these documents, would have ever known of the documents' existence or that a tobacco company was removing large volumes of documents from public access. In my view, the oversight role that the Minnesota Depository has played in ensuring the integrity of the document population (in this instance, by addressing problems in the boxes produced by BATCo, and calling attention to BATCo's efforts to remove documents from the Depository) is essential to ensure that the document collections provided by the Defendants are as accurate and complete as possible for the research community.

19. I have also had direct experience with the vulnerability of the contents of BATCo's Guildford Depository, where there is no third-party oversight to ensure the integrity of the collection.

20. In December of 2001, I accessed an audio-tape recording of a BAT marketing conference at the Guildford Depository and requested (and obtained) a copy. The audiotape included a marketing proposal to sell single cigarettes in developing countries. The presenter on the audiotape, a BAT employee, states, " . . . the brand image must be enhanced by the new packaging . . . if you just say, this is a cheap cigarette for you dirt poor little black farmers . . . they're not going to go for it." Another conference participant states, "We could sell them to the Palestinians if we made the plastic hard enough that you could rip

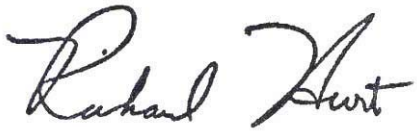
the end off and put your shells in them . . . " and, referring to the United States market, the same participant states, "When we see stick sales in the inner city, they aren't farmers, but they are poor and black."

21. In January 2004, I requested access to the same audiotape again, but the entire side of the tape containing the above discussion was no longer there. After bringing this to the Guildford Depository staff's attention, I was told that the tape would be replaced in the collection. I am not asserting that the Guildford Depository staff intentionally deleted the contents of the audiotape. Indeed, there would have been little point to their doing so, because, the previous year, a co-author and I published some of the above excerpts in a letter to a scientific journal. ME Muggli & RD Hurt, *Listening Between the Lines: What BAT Really Thinks of Its Consumers in the Developing World,* Tobacco Control 12:104 (2003) (copy attached as Ex. 4). However, I do believe that without an accountability mechanism in place to systematically and routinely ensure the integrity of internal tobacco industry record collections, as I understand is the case at the Minnesota Depository, their contents are vulnerable. Likewise, I believe that this type of essential third-party oversight is not likely possible on the tobacco companies' document websites.

I hereby sign this declaration under penalties of perjury pursuant to 28 U.S.C. § 1746.

Dated: March 24, 2011

Respectfully submitted,



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

The Minnesota Tobacco Trial

Richard D. Hurt, MD; Channing R. Robertson, PhD

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.

JAMA. 1998;280:1173-1181

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.[1-6] 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 entered 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.[1-6] Although documents relating to cigarette marketing to children[7-10] and describing involvement of tobacco company legal counsel in controlling certain aspects of company research[11-14] 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.[16-19] 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]

From the Nicotine Dependence Center, Mayo Clinic and Mayo Foundation, Rochester, Minn (Dr Hurt), and the School of Engineering, Department of Chemical Engineering, Stanford University, Stanford, Calif (Dr Robertson).

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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,"[20] 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.[16]

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,[2] 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[1,3,4]] 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."[23]

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."[24] 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 absorption 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.[24]

The addictive potential of a drug is enhanced by delivery systems that cause it to reach the brain more quickly,[25] 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."[26]

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").[28]

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."[28]

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

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."[29] 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."[30] 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."[31] Others were more blunt, such as a 1983 B&W memo that stated, "Nicotine is the addicting agent in cigarettes."[32]

Further understanding of the addictive process is shown in a 1979 BAT document summarizing a survey of 2018 smokers.[33] 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.[33]

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.[34]

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.[35] 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?)."[37] 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.[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."[43]

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 Industry 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

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.[44]

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."[44]

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."[12] 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.[43]

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."[48] Johnson's opinion was that "we are in a nicotine rather than a tobacco industry."[49] 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."[50]

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."[48] 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.[51]

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.[52]

Apparent changes in crop processing in the early 1980s caused the industry some concerns. H. E. Guess[53] 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,"[54] and a 1982 report from Lorillard documents a significant long-term effort to investigate adding nicotine to cigarettes from exogenous sources.[55]

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.[56] (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.[57] 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[59] 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.[60]

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."[60] 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[61] 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].[62]

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."[62] 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."[62] Further on the review stated that "the industry must come forward with evidence to show that its products, present and prospective, are not harmful."[62] 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 [total 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, MARLBORO and WINSTON.[63]

A December 1976 Lorillard document outlined the impression most people had (and still have) about low-tar, low-nicotine 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."[28]

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."[39] 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."[39] 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.[39]

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 low-tar cigarettes.[64] 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.[64]

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.[65]

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

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.[68]

Surveys conducted as recently as 1996 indicate that more than two thirds of American smokers are unaware that there are ventilation holes in cigarettes.[69-71] Even regular, full-flavor cigarettes such as Winston "Reds" have had ventilation holes in the filters since the early 1980s.[72] 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.[73]

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.[67] The outcome of the conference summarized the new approach to marketing: "All work in this area should be directed towards providing consumer reassurance 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.' "[68]

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?[74]

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.[75]

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.[76] 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.[77]

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.[78]

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."[79]

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]

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 additional nicotine 'kick' could be easily obtained through pH regulation."[84] 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."[85] 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.[86]

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."[87]

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."[89] 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.[90]

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."[80] 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.[91]

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.[92] 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.[86]

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.[93]

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."[94] 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 important letters or documents have to be sent, please send to home—I will act on them and destroy."[95] While we can call for honesty and truth from the industry,[96] 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.[15] 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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Review

Science for hire: A tobacco industry strategy to influence public opinion on secondhand smoke

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A review of internal tobacco company documents reveals that members of the tobacco industry and its corporate attorneys created an international scientific consultants program to influence public opinion on environmental tobacco smoke (ETS). This program was shaped as a "product" to protect the industry from international threats of smoking restrictions. Additionally, this program was used to promote a scientific backdrop supporting the industry's position on ETS that differed from regulatory agencies and published scientific research. In this report, we detail the pervasive nature of the so-called ETS Consultants Program, outline the wide range of activities undertaken by the consultants, and highlight the role of the industry's corporate attorneys in creating and managing this program. We suggest heightened monitoring of industry-created scientific organizations, further tobacco document research, and wide dissemination of such work.

Introduction

Previous internal tobacco company document research showed the tobacco industry's worldwide scientific campaign aimed against policies addressing environmental tobacco smoke (ETS) and efforts to undermine U.S. regulatory agencies (Muggli, Forster, Hurt, & Repace, 2001). The industry went to great lengths to confront the ETS issue in the United States and worldwide by creating an impression of legitimate, unbiased scientific research while consistently concealing its role. The recruitment of researchers by lawyers to an international ETS Consultants Program was integral to the industry's ETS strategies. One previously reported internal tobacco company document revealed that the ETS Consultants Program aimed to "pay…scientists on an international basis to keep the ETS controversy alive" (Boyse, 1988; Chapman, 1997a, b).

Although other reports have described tobacco industry tactics aimed at influencing research and the scientific debate on ETS (Barnes & Bero, 1996, 1997, 1998; Barnes, Hanauer, Slade, Bero, & Glantz, 1995; Bero, Galbraith, & Rennie, 1994; Hirschhorn, Bialous, & Shatenstein, 2001; Ong & Glantz, 2001), the current review highlights previously secret and now deprivileged internal documents dated from approximately 1988 to 1993 relating specifically to a lawyer-created ETS Consultants Program. The documents show that the tobacco industry and its attorneys created this program as a "product" to protect the industry from international threats of smoking restrictions and to promote a scientific backdrop supporting the industry's position on ETS that differed from regulatory agencies and published research (Glantz & Parmley, 1991; Hackshaw, Law, & Wald, 1997; Hirayama, 1981; National Cancer Institute, 1999; Repace & Lowery, 1985; Steenland, 1992; U.S. Department of Health and Human Services, 1986; U.S. Department of Health, Education and Welfare, 1979; U.S. Environmental Protection Agency, 1992).

Methods

The settlement of the 1998 litigation brought by the Minnesota Attorney General and Blue Cross and Blue Shield of Minnesota against the tobacco industry required the defendants to maintain and provide public access to previously secret internal documents.

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In addition, the defendants were ordered to produce to the Minnesota Tobacco Document Depository, located in Minneapolis, copies of all documents produced in any subsequent smoking and health litigation in the United States.

This article is based on a review of documents from three sources: (a) deprivileged documents produced to the Minnesota depository beginning in June 2000, (b) documents previously reviewed detailing the industry's strategies to undermine the scientific reports on ETS (Muggli et al., 2001), and (c) documents from the British American Tobacco depository located near Guildford, England.

A separate collection of deprivileged documents is housed in 84 boxes at the Minnesota depository. All documents in each box produced from the following companies were searched: American Tobacco Company, British American Tobacco Company, British American Tobacco Industries, Brown & Williamson Tobacco Company, Council for Tobacco Research, Lorillard Tobacco Company, Philip Morris Incorporated, R. J. Reynolds Tobacco Company, and the U.S. Tobacco Institute.

A focused search of documents related to the ETS Consultants Program was performed at the British American Tobacco depository. The index to these documents was searched by the fields *file user* and *file owner*. Approximately 400 files owned or used by key British American Tobacco scientists and public relations personnel were reviewed.

Findings

Overview of ETS Consultants Program

In its most unrefined form, the ETS Consultants Program was viewed internally as a "product."

> In its basic research programme and its mobilisation of scientific consultants and engineers in each…market, S & T PME [Science and Technology, Philip Morris Europe] is producing a "product" – scientists and scientific knowledge – for use by the PM [Philip Morris] company president in each market. In each market, it would be the responsibility of the company president to use this product to [the] best advantage in resisting smoking restrictions in his market (Remes, 1988).

In essence, the industry set out to manufacture the appearance of a wide scientific opinion that ETS "presents no scientific health risks to smokers" (Remes, 1988). At a minimum, the campaign was meant to offset the growing evidence of the health risks associated with ETS and to create an illusion of division within the scientific community. The hired scientists would "produce research or stimulate controversy in such a way that public affairs people in the relevant countries would be able to make use of, or market; the information" (Boyse, 1988).

To create the appearance of scientific independence, the program employed established scientists—sometime described by the industry as "whitecoats" (Rupp, 1988)—who would appear to have no affiliation with the industry.

> It has been apparent to the industry for some time that we do not have sufficient credibility to put forward a position on ETS (or any other issue for that matter) unless we can identify independent scientists who are saying the same thing. If independent scientists back up our position, it becomes more credible, not only to the general public and the media, but to politicians and other decision-makers…. Although it is essential for the industry to speak up about its positions, there are some things that are better left to independent scientists to express ("Industry ETS consultancy programmes," n.d.).

The role of "independent" experts was played by scientists "who had no previous connection with tobacco companies" (Boyse, 1988).

This program required concealment of the industry's role in organizing and directing the scientists.

> For this type of program it is absolutely essential to ensure that administration of the programme and contact with the consultants is made quite independently of the tobacco industry, and that no tobacco industry executives have direct contact with them ("Industry ETS consultancy programmes," n.d.).

The industry's attorneys would therefore "serve as an intermediary between PM [Philip Morris] and the scientific consultants and engineers in each market" (Remes, 1988).

Accordingly, ETS Consultants Programs were set up in the industry's operating regions in the United States, Europe, Asia, and South and Central America. The U.S. program began on an ad hoc basis in 1987 and later evolved into a large network of scientists who were used regularly inside and outside the United States (Whist, 1989). The European ETS Consultants Program was functioning by 1988 (Wells, 1988); the Asian program was developed in 1989 (Rupp & Billings, 1990) and the Latin America program in 1991 ("Regional public affairs plan and budget," n.d.). Documents as recent as 1997 and 1998, which discuss the activities of Latin American ETS consultants employed by the program from its

inception, were found at the Minnesota depository (Davies, 1997, 1998a, b, September 10, 1998; "Technical activity summary," 1998).

Although the exact scale of the worldwide program is not certain, the documents show that it was extensive. By 1988, early in the program's evolution, 81 consultants had been assembled, according to one Philip Morris document (Whist, 1988). The program included consultants in Argentina, Australia, Brazil, Chile, China, Costa Rica, Ecuador, France, Germany, Guatemala, Hong Kong, Indonesia, Italy, Japan, Korea, Malaysia, Norway, the Philippines, Singapore, Spain, Sweden, Taiwan, Thailand, the United States, the U.K., and Venezuela (Boyse, 1988; "Industry ETS consultancy programmes," n.d.; "Meeting of BAT and PMI representatives" 1992; "Regional public affairs plan and budget," n.d.; Remes, 1989; Rupp, 1988).

The range of activities was extraordinary. In 1989, 2 years after the program began, Philip Morris vice president Andrew Whist reported to Philip Morris International president Geoffrey Bible (later to become CEO of Philip Morris) that:

> …several hundred specific activities or events have been completed. These have included numerous press briefings, repeated briefings of important government officials, the publication of a number of review articles on ETS, several air quality monitoring studies, convening of a number of scientific conferences, submissions of comments on smoking restriction proposals being considered in a number of scientific countries, testimony before a variety of legislative bodies, preparation and submission of affidavits and offers of proof in cases involving claims concerning ETS, publication of a book…that seeks to put ETS into proper perspective, drafting of two additional books on ETS and indoor air quality issues, and approximately 100 separate presentations at major international scientific meetings challenging the unwarranted health claims that have been made concerning ETS (Whist, 1989).

The total cost of the worldwide program is difficult to ascertain, but the 1993 annual budget for the European, Asian, and Latin American programs alone was US$3 million – a sum described as "a substantial decrease" from the prior year ("Preliminary 1994 consultants program proposal," 1994). Philip Morris solely supported the European program, whereas financial responsibility for the Asian and Latin America programs was initially shared among Philip Morris, British American Tobacco, Japan Tobacco, Inc., R. J. Reynolds, Brown & Williamson, and Rothmans ("Preliminary 1994 consultants program proposal," 1994).

The ETS Consultants Program targeted critical regions—particularly those where smoking restrictions threatened the industry (Whist, 1988)—and was tailored to particular markets. Rather than "exporting" existing scientists who were already working for the program in the United States or elsewhere ("Industry ETS consultancy programmes," n.d.), local scientists were recruited in each major market. This was done partly to control expenses and to reduce the burden on the original group of consultants. More important, having a roster of consultants in place worldwide allowed the industry to respond quickly to local threats and created credibility that was achieved by exploiting the reputations of established local scientists ("Industry ETS consultancy programmes," n.d.; Rupp & Billings, 1990).

> [O]ften it is necessary for scientists to respond rapidly to what may appear to be minor local issues e.g. misleading newspaper articles. This is something a local scientist can do quite naturally, but it looks suspicious if someone from another country does it. Of course, the tobacco industry can respond, but it will have less credibility and in some countries we may prefer to leave independent scientists to respond to protect us from a potential legal backlash ("Industry ETS consultancy programmes," n.d.).

By retaining local scientists, the industry also gained access to valuable political connections.

> Local scientists are useful because they have political contacts in a country that international experts will never match. If a government is proposing to introduce restrictions on smoking in public places they are more likely to be influenced by a prominent scientists in their own country who they may have known for some time and with whom they may have worked on other issues than with some otherwise obscure U.S. scientist ("Industry ETS consultancy programmes," n.d.).

The role of attorneys

Although the ETS Consultants Program was controlled by the industry's attorneys, some thought had been given initially to entrusting the program to scientists.

> …[T]here is a dispute within PM [Philip Morris] between the scientists and the public relations people about who should spearhead the drive. Scientists think it should be scientists—PR

> [Public Relations] people think it should be lawyers. So far, lawyers are winning (Sachs, 1988).

The lawyers indeed won. The idea of putting scientists in charge of the "science" was quickly abandoned, in recognition that "it would not be appropriate to hand it over to a scientist to manage as the project is actually being carried out for public affairs reasons!" ("Industry ETS consultancy programmes," n.d.).

From its inception, the international ETS Consultants Program was overseen by the Washington, D.C., law firm of Covington & Burling (Boyse, 1988; "Industry ETS consultancy programmes," n.d.; Remes, 1988), one of the United States largest law firms (Covington & Burling Web site, at www.cov.com) and long-time counsel to Philip Morris and the Tobacco Institute. Covington & Burling was so central to the ETS Consultants Program that, as the European program began in 1988, the law firm proceeded "to set up an office in London to coordinate their European activities," according to a British American Tobacco report (Boyse, 1988; Rupp, 1988).

Although Covington & Burling is a law firm, the documents suggest its lawyers representing the tobacco industry functioned more as public relations strategists and less as legal advisors. According to a 1990 document, outside attorney and later Philip Morris senior vice president Steven Parrish cautioned that "Covington and Burling, although they are lawyers, are being used as corporate affairs consultants" and that "just because they may have written or approved a document does not mean the document has legal clearance" (Newsom, 1990). An anonymous, undated report from British American Tobacco files, entitled "Industry ETS Consultancy Programmes," similarly acknowledged that "[o]n the tobacco front," Covington & Burling "act as much as a public relations agency as they do to provide legal advice" ("Industry ETS consultancy programmes," n.d.).

Despite this conclusion, and despite the fact that the program was being run "for public affairs reasons," the author of this British American Tobacco report approved the selection of Covington & Burling to run the program.

> It is…necessary to select an external organization to manage the programme. There are not many possibilities for doing this. A public relations agency would clearly be inappropriate, and anyway would have no idea of how to interact with scientists. There is no scientific version of a public affairs agency, and anyway it would not be appropriate to hand it over to a scientist to manage as the project is actually being carried out for public affairs reasons!
>
> The only option is to select a group of people who have expertise in both the scientific arena and public affairs arena, and who can be trusted by the industry to manage the programme in accordance with their wishes. The only such groups of people are U.S. lawyers ("Industry ETS consultancy programmes," n.d.).

As program coordinators, Covington & Burling offered several advantages beyond public affairs expertise. First, they separated the industry from the scientists it secretly employed: The law firm would "serve as a buffer between the companies and the consulting scientists, providing both distance and some opportunities for work product protection" (Wells, 1988).

Second, by controlling the process of screening, recruitment, and training, Covington & Burling helped ensure that the paid consultants said nothing to contradict the industry's positions. Through a carefully staged screening process, likely candidates were drawn slowly into the program, being informed only gradually of its true nature (Boyse, 1991, August 1993; Covington & Burling, 1991, 1992; Covington & Burling London, 1990; Remes, 1989; Rupp, 1988; Rupp & Billings, 1990). Potential consultants were identified and screened for "anti-smoker" opinions before any contact was made. Those who passed this test were approached by intermediaries about their interest in "indoor air quality" and asked to critique 10 hr of reading from scientific literature, including "anti-ETS" articles. Only those who provided the right responses at this point were informed of tobacco companies' involvement (Boyse, 1988). Even an industry insider worried that this "rather oblique" approach "may appear to be somewhat less than honest to many scientists" (Boyse, 1988).

Once recruited, scientists were sent to training meetings organized by Covington & Burling (Rupp, November 23, 1992) and were assigned to study industry-approved training materials, to further ensure that their public statements would support the industry's positions. Experienced consultants provided "care and feeding" of new recruits. According to a 1993 communication, two experienced consultants from the United Kingdom were to be sent to Asia to teach newly hired Asian scientists:

> They will meet consultants in each market and then, with the consultants, meet with government officials, on in-door [sic] and air quality issues and policies as well as discuss and share some of the materials that have been developed in region and by consultants. Perry and Leslie [U.K. consultants Roger Perry and George Leslie] will, therefore, do the care and feeding, but also some practical training (showing the

> consultants how to deal with government officials), make some points (hopefully) that the consultants are unable or unwilling to make, as well as gather some intelligence directly from the government sources (Harris, 1993).

Several references in the documents report the extent to which the attorneys may have guided the scientific opinions of the consultants. After hearing Covington & Burling's initial explanation of the program, a British American Tobacco scientist reported internally that the hired scientists were to

> …operate within the confines of decisions taken by PM [Philip Morris] scientists to determine the general direction of research, which apparently would then be "filtered" by lawyers to eliminate areas of sensitivity (Boyse, 1988).

According to this British American Tobacco report, Covington & Burling attorney David Remes "was not prepared to elaborate on these areas of sensitivity or on the stage at which any filtering process would be carried out" (Boyse, 1988).

Brown & Williamson assistant general counsel J. Kendrick Wells later shed additional light on the attorneys' function, explaining that Covington & Burling was to establish groups of scientists

> …who will speak on the issue of ETS and who have been horse-shedded by John [Rupp of Covington & Burling] to ensure that their opinions support the industry's position on ETS and that their answers to the inevitable questions about the primary issue [active smoking] do not undercut the industry (Wells, 1988).

Wells reported asking Rupp why tobacco manufacturers should rely on a law firm to oversee their scientific consultants. According to Wells,

> John said it is important to have a law firm play the role of organizing because the firm can, in the process of organization and horse-shedding individual scientists, avoid product liability problems (Wells, 1988).

"Horse-shedding" is legal jargon for the practice of preparing witnesses to testify, especially with instructions about the proper method of responding to questions (Garner, 1995). According to one legal commentator, "horse-shedding" refers to the "'preparing' of witnesses" that "may embrace a multitude of other measures, including some ethical lapses believed to be more common than we would wish…. [T]he process often extends beyond organizing what the witness knows, and moves in the direction of helping the witness to know new things" (Frankel, 1995).

Finally, an advantage of entrusting the program to attorneys appears to have been the hope that even if the attorneys were engaged in nonattorney work, they might succeed in invoking the "attorney–client privilege of confidentiality," if necessary, to mask the connection between the tobacco industry and the participating scientists. This may explain references to "legal…reasons" (Remes, 1988) for having a law firm serve as an intermediary. Similarly, Covington & Burling apparently advised Brown & Williamson that, by acting as a buffer, it would provide "some opportunities for work product protection" (Wells, 1988)—a reference to the "attorney work product doctrine" protecting the confidentiality of certain written legal materials created by attorneys.

Activities of consultants

The ETS consultants undertook a variety of activities to further the industry's position on ETS (Covington & Burling, 1989; Covington & Burling London, 1990; "Regional public affairs plan and budget," n.d.; Rupp & Billings, 1990; Whist, 1988). Although previous research has reported on the industry consultants' activities (Glantz, Slade, Bero, Hanauer, & Barnes, 1996; Ong & Glantz, 2000; Remes, 1988; World Health Organization [WHO], 2000), the documents shed additional light on the breadth and sophistication of the program. For example, during the program's first 2 years of operation, consultants reportedly conducted 1150 "favorable T.V. and radio interviews," participated in 36 scientific conferences, published 43 scientific papers, began preparation of 33 additional papers, conducted 32 "scientific briefings" and 41 "political briefings," and published three books in multiple languages (Whist, July 11, 1989).

Using consultants to gain political influence Many of the consultants were selected for their political connections and influential positions (Proctor, 1990). One recruited consultant was described as a poor scientist and communicator; however, he had "built up extensive contacts in India and the Far East, including the UN [United Nations] and WHO personnel" and, it was thought, "his influence on some of these contacts might be useful" (Proctor, 1989). In at least one instance, a consultant felt his connections were "of decisive importance" in helping the industry defeat national ETS legislation (Rupp, 1992).

In 1992, despite the strenuous opposition of the tobacco companies, the Parliament of Argentina passed strong legislation to restrict smoking in

public places, and the legislation was sent to President Carlos Menem. The industry mounted a massive public opinion campaign to encourage Menem to veto the legislation (''Veto of anti-tobacco law,'' 1992) but was also able to have more direct influence. One of the industry's Latin American consultants, prominent Buenos Aires cardiologist, medical professor, and head of the Instituto de las Clinicas Cardiovasculares, Dr. Carlos Alvarez, was not only on the industry's payroll (''Latin American ETS project,'' 1994) but also a personal scientific and technical advisor to Menem (Covington & Burling, 1991). President Menem vetoed the law.

Covington & Burling attorney John Rupp visited Buenos Aires and reported to Philip Morris that:

> The reports we have received indicate that Dr. Carlos Alvarez played a very useful role in the larger industry efforts to defeat, and then convince President Menem to veto, the antitobacco [sic] legislation approved by the Argentine Parliament at the end of 1992. Dr. Alvarez's activities included conversations with Senators from both parties and a series of conversations with President Menem as well as President Menem's brother, who serves as President of the Argentine Senate. Dr. Alvarez also provided President Menem with a briefing package and covering letter that pointed out that the smoking restrictions that had been proposed lacked a solid scientific basis (Rupp, 1992).

Later, Rupp reported Alvarez' own assessment of his role in defeating the legislation:

> Dr. Alvarez expects to be paid for his efforts in connection with the Argentine antismoking legislation.... [H]is assumption is that the industry expects to compensate him for his efforts, which he believes to have been of decisive importance (Rupp, 1992).

The documents do not reveal whether, or how much, Dr. Alvarez was paid for his efforts. They do show, however, that Rupp considered Alvarez sufficiently valuable to recommend that Alvarez be paid an annual retainer of US$50,000 to ''present his views on ETS and indoor air quality issues to the President of the Republic and to other government officials on an informal basis and, should smoking restriction legislation be reintroduced, to become active in opposing such legislation'' (''Latin American ETS project,'' 1994).

The documents also suggest that Alvarez's political connections may have been used in other ways. A 1992 Covington & Burling report indicates that, as part of its efforts to prevent reenactment of the Argentine legislation, the industry considered having Alvarez host a series of dinner parties to urge Argentine officials and journalists to oppose smoking restrictions. John Rupp reported:

> Dr. Alvarez is prepared to host a series of dinners at his home, as well as other meetings as appropriate, with key government officials and important members of the Argentine press. The immediate occasion for such gatherings might be a series of visits to Argentina by (a) a current or former member of the United States Congress, (b) a consulting scientist for the United States, and/or (c) some other individual qualified to talk about the inappropriateness of smoking restrictions in view of other problems and challenges confronting Argentine policymakers.
>
> Dr. Alvarez would be responsible for issuing invitations to the gatherings. He would also act as the host, providing a few words of introduction for the United States guest and, following the guest's presentation, summarizing some of the main arguments against smoking restrictions. Throughout, every effort would be made to preserve the informality of the gatherings. If the guest on a particular occasion is a current or former member of the United States Congress, smoking restrictions might be only one of several topics addressed, with the political and/or economic situation in the United States perhaps taking top billing (Rupp, 1992).

A 1992 Covington & Burling report shows the industry also considered using Alvarez to monitor activities of the WHO Latin American Regional Office, the Pan American Health Organization (PAHO):

> Ms. de Otero [of manufacturer Tabacelera Nacional] and Mr. Antich [of Cigarerra Bigott] asked us to explore...what additional efforts might be made to obtain advance warning of initiatives on ETS planned by WHO/PAHO for the Latin Region. We agreed to discuss this issue with Dr. Alvarez, who may have contacts with PAHO representatives in Buenos Aires, and also to begin making discreet inquiries of PAHO Washington staff members with whom we have had contacts in the past (Rupp, 1992).

It is unclear whether these plans were implemented. This proposal is consistent, however, with previous

findings of the WHO in July 2000 relating to the tobacco companies' efforts to undermine tobacco control policy at the WHO, specifically plans to "persuade PAHO to take tobacco off their list of priorities" (WHO, 2000).

Many other ETS consultants offered invaluable political and professional connections to the industry. Among the European consultants alone, Covington & Burling counted the following sources of influence:

> *Political and scientific contacts*. One consultant is, for example, the advisor to a particularly relevant committee of the House of Commons. One is the executive director of a leading scientific society that considers workplace and related issues. Several are advisors to the European Community on scientific matters. Several have been members of the working groups of the International Agency for Research in Cancer [IARC].... One consultant is a medical advisor to several Middle Eastern governments. Another has numerous other governmental contacts throughout the world, including those who persuaded the Portuguese Minister of the Environment to open the Lisbon conference. Still another is [a] medical consultant to several British companies. Others hold major professorships in leading universities and technical schools. (Covington & Burling London, 1990)

Creating indoor air technical societies As a platform for its consultants, the program created Indoor Air International, or IAI.

> *Learned society*. Our consultants have created the world's only learned scientific society addressing the questions of indoor air quality. The society (Indoor Air International) is seeking memberships from all those interested in IAQ [indoor air quality] issues throughout the world. It will soon have its own periodic newsletter, in which ETS and other IAQ issues will be discussed in a balanced fashion to an audience of regulators, scientists, building operators, etc. It will also have its own scientific journal [Indoor Air International Journal].... The society will sponsor meetings and conferences...and thus can serve as an independent and accepted source of ideas and research regarding IAQ to the public and scientific community (Covington & Burling London, 1990).

Covington & Burling attorney Patrick Davies suggested describing IAI's mission "in general terms" as "a multidisciplinary organization" formed "to investigate the full range of indoor environmental problems," "run by an elected Council and Executive Committee," and "subject to the views of its membership." Conspicuously absent from the instructions was any mention of the tobacco industry (Davies, P., 1992). Nor was there any mention of tobacco industry ties in a 1993 IAI press release regarding the industry-sponsored IAI volatile organic compound conference in London (IAI, 1993). There was also an effort to keep tobacco industry scientists from having any involvement with consultants who were members of IAI.

> S & T [Philip Morris' Science and Technology in Neuchatel] should avoid direct involvement with consultants actively working with C & B [Covington & Burling]. C & B should not recruit as consultants any scientists actively working for S & T. It makes no sense to allow scientists to "double dip." There is a grave risk that IAI members may be compromised if they have a direct relationship with Philip Morris S & T (Andrade, 1991).

Scientists from the European and Asian regions of the program created a consulting group, Associates for Research in Indoor Air (ARIA) to offer "consulting services to companies and governments on IAQ issues" (Covington & Burling London, 1990). Coordinated by U.K. consultant George Leslie and created by consultant Francis Roe, ARIA was funded by Philip Morris through Covington & Burling (Thornton, 1989) and paid scientists to attend IAI conferences (Leslie, 1992; Untitled document, 1992). The management of ARIA was described as follows by an internal British American Tobacco scientist:

> Regarding structure, Leslie is the direct interface between Rupp and the scientists and funding of individual consultants is channelled through Leslie. However, Rupp maintains strong control over Leslie (Proctor, 1989).

Documents suggest that some of the IAI-funded attendees were unaware that ARIA was funded by the tobacco industry (Maerestetten, 1989).

Organizing and attending scientific conferences European ETS consultants played key roles in organizing indoor air quality and ETS conferences in Canada, Germany, Hungary, Italy, Sweden, and Switzerland (Covington & Burling London, 1990). In one year, European consultants attended or were scheduled to attend 34 scientific conferences across the globe (Covington & Burling, 1989). The Asian consultants attended or presented papers at an industry-organized conference at McGill University

in Montreal, Canada, and at conferences in Hong Kong, Indonesia, South Korea, the Philippines, Portugal, Switzerland, and Thailand (''Industry ETS consultancy programmes,'' n.d.; Rupp & Billings, 1990). Latin American consultants also attended conferences and presented papers throughout the world (Boyse, 1993; ''Regional public affairs plan and budget,'' n.d.; Rupp, 1992). The IAI cosponsored a conference in Beijing in 1994, and Covington & Burling reported spending $45,000 to have 14 Asian scientists participate (Rupp, 1993).

In addition to attending conferences, consultants in the program were paid to monitor third-party conferences (''Revised 1993 budget,'' 1992). It appears that an internal tobacco industry steering group selected the conferences to which consultants were sent. According to a Covington & Burling memo,

> We ask our consultants to cover all substantial scientific conferences where they can usefully influence scientific and public opinion. They also attend many other conferences on their own, as part of their ordinary scientific activities. The conferences we ask them to attend are selected after approval from [Philip Morris Europe scientist] Dr. Gaisch and with the advice of a small group of consultants, who serve as an informal scientific steering group (Covington & Burling London, 1990).

Covington & Burling reported that a 1990 conference in Lisbon, ''Indoor Air Quality and Ventilation in Warm Climates'' (1990), was organized by industry consultants but maintained a public appearance of independence.

> Our European consultants have organized and will conduct a major scientific conference in Lisbon next month on indoor air quality in warm climates. More than 100 scientists from throughout the world will attend, including some from the Asian consulting group.... The conference is sponsored by a Portuguese university and two international scientific groups—all quite independent of the industry, and all made possible by our consultants. (Covington & Burling London, 1990)

One of the more widely publicized conferences produced by the ETS Consultants Program was a 1989 ETS symposium at McGill University in Montreal, Canada, involving approximately 30 industry consultants (Covington & Burling London, 1990). This symposium was developed to ''neutralize'' anticipated scientific reports from the U.S. Environmental Protection Agency and a report from Rockefeller University.

> What we have been planning over the past several days is a major international symposium which would be both closed and private until the release, shortly after the symposium, of a monograph summarizing the proceedings. Our goal, of course, is to produce an impressive document that would have the potential of neutralizing two reports that are scheduled to be released near the end of this year—an ETS risk assessment that is being prepared by EPA and a detailed assessment of ETS health effects under preparation, at Rockefeller University, supervised by Professor Spitzer (an avowed anti-smoker). The EPA and Spitzer reports would cause substantial damage unless they are somehow countered (Whist, August 8, 1989).

The resulting ''Environmental Tobacco Smoke; Proceedings of the International Symposium at McGill University 1989'' disclosed that the conference was sponsored by a tobacco industry grant (Ecobichon & Wu, 1989). However, it was not disclosed that at least one-third of the conference participants were part of the ETS Consultants Program.

Consultants in the media

Consultants were expected to participate in media efforts, including responding to ''media articles misrepresenting the science of ETS or calling for smoking restrictions for scientifically unjustified reasons'' (''Latin American ETS project,'' 1994). Terms of consultants' employment included being referred to journalists at the industry's request and writing letters to editors.

> [The consultant] will be told that industry representatives may identify him to journalists as a local expert on ETS and indoor air quality measurements and invite them to contact him for comment on indoor air quality issues. If [the consultant] is not contacted by journalists directly, he will be expected to write letters to the editors of newspapers or magazines publishing ETS or indoor air quality articles (''Latin American ETS project,'' 1994).

Consultants were limited to three or four letters to the editor per year in order to prevent ''overexposure'' (''Latin American ETS project,'' 1994).

Consultants sometimes disclosed the industry's financial support when they submitted writings for publication (Hanners, 1998), but the documents provide examples of consultant's writings in publications without such disclosure. An article in the *Hong Kong Standard*, entitled ''Institute tries to clear air on smoking risks'' (1989), reported on an industry news conference, quoting industry consultant George Leslie

and Covington & Burling attorney John Rupp as among "independent speakers from the U.S. and Britain on the question of Environmental Tobacco Smoke." Leslie was described as the "Head of Associates for Research on Indoor Air U.K." and was reported to claim, "tobacco smoke was a negligible health risk compared to cooking, heating and air-control equipment." Rupp was described neither as the coordinator of the industry's ETS Consultants Program, nor as an industry attorney, but rather as "a senior U.S. scientific advisor and member of the American Civil Liberties Union" ("Institute tries to clear air on smoking risks," 1989).

A 1992 column in the London *Telegraph* similarly quoted longtime industry consultants Peter Lee (Lee, 1992, 1993, 1996) and Petr Skrabanek (ARIA, April 14, 1992, May 31, 1992; "Statement 029," 1992), who were described only as an "independent statistician" and a "senior lecturer in community health at Trinity College, Dublin," respectively (Lister, 1992). Covington & Burling attorney Charles Lister cited the column to Philip Morris as evidence of the value of the consultants program:

> The attached article in Sunday's *Telegraph* is one helpful response. I cannot help noting that all of the scientists and scientific evidence offered to support our position were nurtured by the European consultant program. The program cannot provide all of the answers, or win all of the battles, but surely the attachment again illustrates that it can provide significant help (Lister, 1992).

Consultants also were used to influence the scientific reporting of journalists in Latin America. A media symposium on indoor air quality was created to publicize the industry's position on ETS and that because most buildings use natural ventilation—open windows rather than air conditioning—smoking restrictions are not a solution for poor indoor air quality (Alfaro, n.d.; Davies, P., 1994). The *Centro Internacional de Estudios Superiores de Comunicación* (CIESPAL), a well-known academy for journalists in the Latin American region (CIESPAL, n.d.), sponsored the indoor air quality symposium in October 1993 in Quito, Ecuador. All of the symposium speakers were from the Latin American ETS Consultants Program (Boyse, August 17, 1993). The consultants reported to Covington & Burling that 40–60 journalists attended the symposium and that the media fallout was successful, "generating numerous articles in local newspapers" and that it was the "focus of several local television and radio programs" (Davies, 1993). Patrick Davies, a Covington & Burling attorney, reported that they would get "additional miles" out of the symposium because CIESPAL offered to publish and distribute the proceedings if the law firm would purchase 1000 copies of the book (Davies, P., 1993). Davies also commented in the same document, "CIESPAL would go a long way towards solidifying the consultant's positions as the regional experts to whom journalists should turn when the issue is indoor air quality."

Payment of the consultants

Previous reports have documented the tobacco industry's history of paying scientists to write letters to editors, minimizing the health effects of ETS—as much as $10,000 for one 8-paragraph letter to a journal drafted at least partly by industry lawyers (Hanners, 1998). However, it is difficult to ascertain the amounts paid to most consultants. If consultants were usually paid directly by Covington & Burling, then records of the payments may never have reached the files of the tobacco companies or may not have been produced in discovery. However, a 1990 Covington & Burling memo states that consultants were paid for the work they performed:

> [O]ur consultants are not on retainer, and therefore are not paid unless and until they actually perform work. As a result, a strong list of available consultants does not in fact mean the creation of unnecessary costs; it does mean wider choice and greater flexibility (Covington & Burling London, 1990).

Covington & Burling itself proposed paying annual retainer fees totaling $205,000 to 9 of the 15 Latin American consultants, in addition to payments to support Latin American research projects and other initiatives ("Latin American ETS project," 1994).

Conclusions

In this article we detail, for the first time, the pervasive nature of the tobacco industry's efforts to influence worldwide public opinion on ETS through the attorney-run ETS Consultants Program. This program was viewed internally as simply another "product" that was carefully organized to influence public opinion and was used by the industry in specific markets throughout the world. Scientists were hired primarily for their influence and contacts within their region and for their ability to influence decisions about proposed smoking restrictions. The industry deployed these consultants to oppose local tobacco control efforts and, in one instance, exploited the dual role of a scientist who served as an industry consultant and a presidential advisor.

Attorneys were put in charge not to render legal advice or services but to obscure the industry's involvement and control the scientists. By "filtering"

the scientists' activities and "horse-shedding" their opinions, attorneys were to guide the views they would express at scientific conferences and in public debates. Even industry insiders worried that "[t]he excessive involvement of external lawyers at this very basic scientific level is questionable" (Boyse, 1988). However, the ETS Consultants Program was not about science. It was about the subordination of real science to the industry's legal and political objectives.

We report here on documents previously protected by claims of attorney–client privilege. Clearly, claims of attorney–client privilege were to be used to withhold information about the program. Ironically, the attorney–client privilege is intended to foster honesty; by ensuring confidentiality, it encourages clients to communicate frankly with their attorneys and enables the attorneys to render candid advice (*Upjohn v. United States*, 1981). Here, privilege claims were used to perpetuate deception. The privilege of confidentiality applies only when attorneys act in their capacity as attorneys—not when they run a public relations campaign. As a special master appointed by the Minnesota trial court concluded after reviewing over 200,000 documents that the industry claimed as privileged,

> I specifically find that defendants have asserted claims of privilege over information generated by counsel acting in scientific, administrative or public relations capacities, but not in a legal capacity. That information is not privileged. ("Report of special master," 1998)

Although the documents described here provide insight into the ETS Consultants Program, it is not a complete picture. In the course of the Minnesota litigation, the public learned that executives of both Philip Morris and R. J. Reynolds may have destroyed, or "invalidated," at least some damaging documents (Osdene, n.d.; Senkus, 1969). A 1998 document describes the systematic destruction of internal tobacco industry documents (Tully, 1998). Though Philip Morris CEO Geoffrey Bible was quoted in 1998 as saying, "First and foremost, the company wants the truth told" (Shaffer, 1998), it is unlikely that the full story of the ETS Consultants Program will ever be fully disclosed even through reports of the program were made directly to Mr. Bible (Whist, July 11, 1989).

Limitations

Although the publicly available tobacco documents reviewed for this article represent an invaluable resource, there are several limitations to this work. First, the publicly available documents do not represent a complete set of correspondences and reports relating to ETS or the ETS Consultants Program. Although the documents we report here are picked from millions of pages, we assert that this does not invalidate our findings. Many of the documents were found in a separate deprivileged collection—a collection of documents already handpicked by industry lawyers to remain secret. These documents likely give a truer picture of the ETS Consultants Program than could have been obtained through other sources. Further, in order for our findings to be invalidated, other documents would have to contradict what we report here. We did not find such documents in the deprivileged set or in the files searched at the Guildford and Minnesota depositories. Furthermore, we believe that the documents we cite do not represent isolated communications but rather form a clear pattern over several years that involve high-level tobacco industry management. Second, the majority of the publicly available documents housed at the depositories are dated prior to 1995, although we see evidence of the ETS Consultants Program as recent as 1998. Third, these documents were collected in litigation pertaining to the defendants' actions in the U.S.A., whereas the ETS Consultants Program is international in scope. Fourth, often the consultants in the documents are not named; therefore, it is difficult to identify their published works. Fifth, interviews were not conducted to corroborate findings from the documents. Finally, many of the documents cited in this article represent reports from attorneys to their clients, and these reports may overstate, rather than minimize, the attorneys' accomplishments.

Recommendations

We recommend that further systematic document research be conducted to determine the tobacco industry's efforts to undermine public health initiatives worldwide. The public health community should increase its surveillance in an effort to rapidly expose the activities of scientists and organizations acting under the influence of the tobacco industry. We further recommend that findings from document research should be effectively and widely disseminated to the public in peer-reviewed journals, the media, testimony at governmental hearings, and oral presentations. In doing so, we may affect the extent to which the tobacco industry can influence public opinion about issues of extreme importance to the preservation of public health.

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REVIEW

Open Doorway to Truth: Legacy of the Minnesota Tobacco Trial

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More than a decade has passed since the conclusion of the Minnesota tobacco trial and the signing of the Master Settlement Agreement (MSA) by 46 US State Attorneys General and the US tobacco industry. The Minnesota settlement exposed the tobacco industry's long history of deceptive marketing, advertising, and research and ultimately forced the industry to change its business practices. The provisions for public document disclosure that were included in the Minnesota settlement and the MSA have resulted in the release of approximately 70 million pages of documents and nearly 20,000 other media materials. No comparable dynamic, voluminous, and contemporaneous document archive exists. Only a few single events in the history of public health have had as dramatic an effect on tobacco control as the public release of the tobacco industry's previously secret internal documents. This review highlights the genesis of the release of these documents, the history of the document depositories created by the Minnesota settlement, the scientific and policy output based on the documents, and the use of the documents in furthering global public health strategies.

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BAT = British American Tobacco; FCTC = Framework Convention on Tobacco Control; JAMA = *Journal of the American Medical Association*; LTDL = Legacy Tobacco Documents Library; MSA = Master Settlement Agreement; NCI = National Cancer Institute; PMI = Philip Morris International; RICO = Racketeer Influenced and Corrupt Organizations; TobReg = Study Group on Tobacco Control Regulation; TTC = transnational tobacco company; UCSF = University of California, San Francisco; WHO = World Health Organization

More than a decade has passed since Minnesota settled its litigation against the tobacco industry. The Minnesota settlement has been recognized as one of the most important public health events of the second half of the 20th century because it exposed the tobacco industry's long history of deceptive marketing, advertising, and research.[1] It has also been more than 10 years since the tobacco industry's individual settlements with the states of Mississippi (1997), Florida (1997), and Texas (1998) and since the signing of the Master Settlement Agreement (MSA) between 46 US State Attorneys General and the tobacco companies (1998). These agreements are the 5 largest settlements in the history of litigation.[2]

Before the Minnesota tobacco case, filed in 1994 by the Minnesota Attorney General and Blue Cross Blue Shield of Minnesota, successful litigation against the cigarette manufacturers had been almost universally unsuccessful. The "first wave" of suits from the 1950s to the 1970s were met by an industry that had adopted a "scorched earth" litigation strategy, outspending individual litigants by orders of magnitude while vehemently denying any association between their product and diseases such as lung cancer.[2] Through hundreds of cases between 1950 and 1970, the tobacco industry disclosed only a few thousand internal documents, thereby maintaining an impregnable wall of silence.[3] The first crack in this wall occurred during the "second wave" of tobacco litigation; this wave was marked by the 1983 Cipollone case, in which plaintiffs aggressively sought and received a small cache of damning documents.[4]

Other events converged in the mid-1990s to expose the tobacco industry's wrongdoing. In 1994, copies of internal documents from the Brown & Williamson Tobacco Corporation were leaked and were ultimately published in the *Journal of the American Medical Association* (*JAMA*) in 1995.[5] Although these documents were not numerous (4000 pages), they were selected because of their damning content and were sent anonymously to Stanton A. Glantz, PhD, a widely recognized tobacco control researcher. These documents became the basis not only for the articles in *JAMA* but also for the book *The Cigarette Papers*.[6] The publication of this book was a historic event and provided the deepest look inside the tobacco industry before the Minnesota litigation. In 1994, the US Food and Drug Administration, under the leadership of then-director David A. Kessler, MD, sought to regulate tobacco products by claiming not only that these products were drug delivery devices but also that the industry controlled and manipulated the form and quantity of nicotine contained within their products.[7] In addition, Jeffrey Wigand, PhD, a former vice president at Brown & Williamson, began to cooperate with the Food and Drug Administration and ultimately told his story on the television program *60 Minutes*.[8] The industry was further exposed in Congressional hearings chaired by Representative Henry Waxman (Democrat, California),

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TABLE 1. **Summary of the US Tobacco Settlements**

Type of relief	Multistate settlement agreement	Minnesota	Texas	Mississippi	Florida
Monetary	Payments made to settling states in perpetuity, totaling approximately $206 billion through 2025	Settlement payments totaling $1.3 billion for years 1998-2003; annual payments of approximately $200 million beginning in 1998	$15 billion over 25 y; additional $2.3 billion through 2003 for indigent health care costs	$3.4 billion over 25 y	$11.3 billion
Injunctive/equitable					
Prohibits marketing of tobacco to children and opposition to proposals/ rules/legislation intended to reduce tobacco use by children	Yes	Yes	Yes	No	Yes
Prohibits opposition to legislation or rules governing tobacco control	Yes	Yes	No	No	No
Prohibits the support of legislation that would preempt, override, abrogate, or diminish settlement beneficiaries' rights/recoveries under the settlement agreement	Yes	Yes	No	No	No
Requires disclosure of information about lobbying payments likely to affect public policy	Yes	Yes	No	No	No
Restricts tobacco companies' marketing practices (eg, ban of billboard and transit advertising of tobacco products)	Yes	Yes	Yes	No	Yes
Bans payment for inclusion of tobacco product placement in any motion picture made in the United States	Yes	Yes	No	No	No
Restricts merchandising of products with tobacco brand names or logos	Yes	Yes	No	No	No
Forbids material misrepresentations regarding the health consequences of using tobacco products	Yes	Yes	No	No	No
Prohibits anticompetitive practices	Yes	Yes	No	No	No
Halts operations of The Council for Tobacco Research–U.S.A., Inc	Yes	Yes	No	No	No
Dissolves The Tobacco Institute, Inc., and Center for Indoor Air Research	Yes	No	No	No	No
Most-favored-nation clause	Yes	Yes	Yes	Yes	Yes

during which chief executives were forever immortalized on videotape as they swore before Congress and the American people that nicotine was not addictive.[9] All of these events were damaging to the tobacco industry, but even collectively their legacy does not compare with that of the Minnesota tobacco trial, which changed the tobacco control landscape forever.

Although the terms of the massive tobacco settlements included large monetary awards and unprecedented public health relief (Table 1), the legacy of the Minnesota trial is

TABLE 2. **Overview of Tobacco Document Sources**[a]

	Guildford depository	Minnesota depository	Internet
Legal instrument	Minnesota settlement: one-time deposit of materials produced to Minnesota plaintiffs	Minnesota settlement: tobacco defendants required to deposit materials in Minnesota within 30 days of production to the plaintiffs, provided defendants do not claim privilege over the documents or the records are not subject to any protective order	MSA: Tobacco defendants required to place materials online within 45 days of production to the plaintiffs, provided defendants do not claim privilege over the documents or the records are not subject to any protective order
Contents	British American Tobacco materials (documents, videotapes, audiotapes) up to circa 1995	Materials of all US-based defendants[b] (documents, videotapes, audiotapes, slides, DVDs, CDs, oversized materials, hard drives, other electronic storage media) up to circa 2003	All documents of US-based defendants[b] up to circa 2003 *Industry Web site* Tobacco Archives: www.tobaccoarchives.com *Main nonindustry Web sites* LTDL: http://legacy.library.ucsf.edu/ TDO: http://tobaccodocuments.org/
Estimated volume of materials	6-7 million pages of documents, 500 videotapes and audiotapes	60 million pages of documents, 20,000 other media materials (documents, videotapes, audiotapes, slides, DVDs, CDs, oversized materials, hard drives, other electronic storage media)	We were unable to verify estimates for document collections online. However, the online collections should contain what is deposited in Minnesota with the exception of other media collections, which are available only in Minnesota
Closing date[c]	At least until end of February 2009	At least until end of December 2008	June 30, 2010

[a] LTDL = Legacy Tobacco Documents Library; MSA = Master Settlement Agreement; TDO = Tobacco Documents Online.
[b] US-based defendants include Philip Morris USA, Inc (now Altria Group, Inc); R.J. Reynolds Tobacco Company (now Reynolds American, Inc); Brown & Williamson (now Reynolds American, Inc); Lorillard Tobacco Company; The Tobacco Institute, Inc (disbanded by the MSA); and The Council for Tobacco Research–U.S.A., Inc (disbanded by the Minnesota settlement and the MSA).
[c] Pending the outcome of the tobacco defendants' appeal of the final order in the United States' Racketeer Influenced and Corrupt Organizations case, which (among other things) established additional obligations for public document disclosure on the part of the tobacco defendants until September 2021.[11,12]

the public disclosure of millions of pages of previously secret internal documents from the tobacco industry and the continued disclosure of such documents produced during discovery in US smoking and health litigation from 1998 to 2008. For the first time in history, the Minnesota settlement also allowed public access to the files of UK tobacco giant British American Tobacco (BAT). The MSA also required large tobacco companies to maintain their letter-sized records on the Internet and to deposit any oversized or electronic media in Minnesota until June 2010. To date, these legal settlements have resulted in the release of approximately 70 million pages of documents, thousands of audiovisual files, and hundreds of other electronic media files. No other comparable dynamic, voluminous, and contemporaneous document archive exists. We would argue that the use of these documents in furthering public health goals based in science, policy, and litigation—the 3 fronts on which the tobacco industry had successfully escaped accountability for decades—has been nothing short of astounding.

The first peer-reviewed article based on tobacco companies' internal documents introduced during the Minnesota trial by the plaintiffs' witnesses was published 10 years ago in *JAMA*.[10] The article and the authors' testimony focused on nicotine addiction, pH manipulation, and low-tar/low-nicotine cigarettes. Since then, several hundred peer-reviewed articles have been published. We summarize the multiple legacies of the Minnesota trial and the MSA by highlighting the effect that these internal documents from the tobacco industry have had on tobacco control around the world.

CREATING "SKELETONS" IN THE CLOSET: THE DOCUMENT DEPOSITORIES

The terms of the Minnesota settlement provided for the creation of 2 publicly accessible document depositories: one in Minneapolis, MN (Minnesota depository) and the other in Guildford, England, near London (Guildford depository) (Table 2). The Minnesota depository contains materials from all defendants, whereas the Guildford depository contains only materials produced to the Minnesota plaintiffs from the defendant BAT.[13] At their sole expense, the settling tobacco industry defendants were obligated by the Minnesota settlement to allow public access to the litigation depositories for 10 years.[13] After the Guildford depository had been open to the public for only a year, BAT's public relations firm reported to the company that its depository was a "skeleton" in the company's closet,[14] in part because of the public airing of its internal documents relating to cigarette smuggling, price fixing, control of scientific research by attorneys, and political attacks against the World Health Organization (WHO).[15]

When the depositories were opened to the public in May 1998 (Minnesota) and February 1999 (Guildford), approximately 35 million pages of once-secret internal documents were available for public review.[3] Since the settlement in

1998, the number of pages of tobacco industry documents available for public review has nearly doubled because (1) the Minnesota settlement mandated that all of defendants' previously unproduced documents in any US civil smoking and health litigation during the following 10 years be placed into the Minnesota depository[13] and (2) the MSA required the settling tobacco defendants to place oversized and electronic media into the Minnesota depository.[16] In one case alone, the US Racketeer Influenced and Corrupt Organizations (RICO) case against the tobacco industry, *United States v Philip Morris USA, Inc., et al*, the tobacco defendants were forced to produce an additional 26 million pages of documents.[17]

The Minnesota depository currently houses approximately 60 million pages, and the Guildford depository, approximately 6 to 7 million pages. The Minnesota settlement, in combination with the terms of the MSA, has also made publicly available approximately 20,000 other media materials (audiotapes, videotapes, CDs, DVDs, slides, maps, oversized paper materials, microfilm, and external storage devices such as hard drives). Before the Minnesota litigation, US tobacco companies had produced only a relatively small number of documents during several decades of litigation, and BAT had never produced a single document in a smoking and health action.[3]

For decades, the tobacco industry had engaged in "scorched earth" litigation tactics aimed at building a nearly impregnable wall around the industry. Included in the industry's litigation tactics were abuses of the attorney-client privilege doctrine as a means of keeping scientific documents secret.[3] In Minnesota, the industry faced a brilliant legal team representing the State and a wise, no-nonsense veteran judge who held both sides accountable. In fact, we think that the courageous rulings of the judge, the Honorable Kenneth J. Fitzpatrick, resulted in revelations about this industry that no one could have anticipated.[18] Viewed in this context, the sheer volume and breadth of the documents and electronic media available for public review as a result of the Minnesota settlement and the MSA are staggering.

Although the Minnesota litigation resulted in previously unimaginable access to millions of tobacco industry records, substantial barriers have prevented public access to the depositories' contents during the past 10 years. Although the Minnesota depository was administered by an independent third-party paralegal firm,[19] BAT was allowed to manage the daily operations of the Guildford depository.[20] In doing so, the company violated the spirit of the Minnesota settlement, a fact documented by both the legislative and judicial branches of government and by journalists and academicians.[15,17,21-24] Operations at the Minnesota depository were also affected by BAT's conduct with respect to its obligations to make certain litigation documents publicly available. In 2006, Mayo Clinic sought legal relief for its research team from BAT's interference with document research conducted at the Minnesota depository. Mayo sought to compel BAT to produce documents that Mayo thought BAT was obligated to produce into the depository in accordance with the Minnesota settlement and to order BAT to cease interfering with Mayo investigators' use of and access to documents.[25] The court did not address the merits of Mayo's claim because it held that Mayo, which was not a party to the Minnesota litigation, did not have legal standing to enforce the Minnesota settlement.[26] Although the 10-year public access provision of the Minnesota settlement was an ingenious instrument for furthering the discovery of revelations regarding the industry's behavior, users of the depositories have ultimately been unable to seek relief from disruptions to research and issues related to document access at the depositories.[27]

Now that 10 years have passed, whether the depositories will close as stated in the Minnesota settlement or will remain open with the addition of new documents is unclear. The Minnesota settlement provided that the Minnesota depository would be in operation for 10 years from May 8, 1998,[13] and that the Guildford depository would be maintained for a period of 10 years after its opening on February 22, 1999.[13] Accordingly, the Minnesota depository was set to close on May 8, 2008, and the Guildford depository, on February 22, 2009. However, the final order in the RICO case against the tobacco industry requires that the defendants maintain the Minnesota and Guildford Depositories until September 2021.[11] Were that decision to be upheld, it would enforce the disclosure of contemporary documents about the tobacco industry's activity, especially because the "light" cigarette case ruling by the Supreme Court of the United States will undoubtedly result in the filing of new litigation against the industry. The tobacco defendants have appealed the case; oral arguments were heard by the United States Court of Appeals for the District of Columbia in October 2008.[12] A decision is expected in early 2009.

DIGITIZING THE DOCUMENTS

Tobacco Defendants Based in the United States

Although the Minnesota settlement required the tobacco defendants to deposit their hard-copy documents in depositories, the MSA obligated the settling tobacco parties to make their documents available online until June 30, 2010.[28] In effect, most of the documents produced by US-based defendants and placed into the Minnesota depository have also been posted on industry-created Web sites, with the exception of oversized and electronic materials that the MSA requires to be deposited in Minnesota.[16]

The tobacco industry's Web sites, developed under the MSA,[29] were initially perhaps easier to search than were the hard-copy documents at the depositories[30]; however, these electronic files have proved to be difficult to use because of impaired search functions, inconsistencies between the tobacco entities' Web sites, and inaccessibility to images. Furthermore, tobacco industry Web sites allow their managers to track user searches.[27] In response to the limited search capability of tobacco industry sites, the research community sought to make tobacco document images more accessible and useable and to create permanent images on the Internet. After the MSA required the settling tobacco defendants to provide the National Association of Attorneys General with a "snapshot" of each of their Web sites in July 1999,[29] the images were available to the research community, which devised other means of enhancing document access.

Computer programs called *spiders* have been used to identify images and indexing information on the tobacco defendants' Web sites. These programs allow the ongoing collection of documents as defendants add new documents to their Web sites in response to litigation. Beginning in 1999, Tobacco Documents Online (http://tobaccodocuments.org/) standardized the available document descriptions to allow for uniform searching and offered previously unavailable and invaluable searching tools such as full-text searching (made possible by optical character recognition, or OCR, which converts images into text) and the ability to systematically collect and annotate documents.[31] Before the availability of Tobacco Documents Online's enhanced search tools, researchers could not conduct full-text searches and instead had to rely on the indexed fields that were coded for each document (eg, author, title, date).

Similarly, the University of California, San Francisco (UCSF) Library, which had already been posting internal documents from the tobacco industry on the Web,[32] began offering researchers more user-friendly options for searching the documents than those provided by the industry sites. In 2002, UCSF, supported by a $10-million grant from the American Legacy Foundation, launched the Legacy Tobacco Documents Library (LTDL), which allows comprehensive, user-friendly, full-text searching. In addition to offering enhanced searching tools, LTDL will remain a permanent online collection.[33] Additional collections of tobacco company documents are also available online.[34,35]

British American Tobacco

Because BAT was not a party to the MSA's requirement of online production of documents, digitizing the documents produced by BAT has been challenging.[15] After almost 8 years of efforts by researchers and staff from the London School of Hygiene and Tropical Medicine, Mayo Clinic, and UCSF, with expenditures of $3.6 million, 6 to 7 million pages of BAT documents from both depositories were digitized and made publicly accessible at LTDL.[36] Although the expenditures for document acquisition and accessibility by the public health community have been substantial, they pale in comparison to what the tobacco industry has probably spent on operations aimed at managing internal documents. For example, at the time of the Minnesota litigation, one of the tobacco defendants alone, R.J. Reynolds Tobacco Company, disclosed to the Minnesota plaintiffs' lawyers that it had spent $90 million to create its document index.[37]

INFLUENCE OF THE TOBACCO DOCUMENTS

The response of the tobacco control community to the release of the documents has been profound. However, comprehensive document research would not have occurred without the availability of mechanisms for researching and disseminating the findings from the documents on their public release in Minnesota.

Faced with a treasure trove of documents previously hidden from public view but in an inaccessible format, in 1998 US President Bill Clinton issued an executive memorandum mandating that the Department of Health and Human Services address the issue of how to make the documents more accessible and how to expose relevant content.[38,39] The Department turned to the National Cancer Institute (NCI), which issued a Request For Proposals from the scientific community.[40] Since 1999, NCI's initiative has resulted in 17 peer-reviewed research grants with a total expenditure of $23.2 million (Michele Bloch, MD, PhD, Medical Officer, Tobacco Control Research Branch, Behavioral Research Program, NCI, written communication, June 2008).

During the past 10 years, more than 500 publications (453 peer-reviewed journal articles, 32 books or book chapters, and 51 reports) relating to the tobacco documents[41] have been published across diverse disciplines. The topics of these publications can be categorized as follows: industry science and ethics, secondhand smoke, industry strategy and tactics, ingredients and product design, litigation, marketing, regional issues, economics, youth-related activities, and document research and commentary.[41] Examples from nearly every aspect of the tobacco industry's operations have been reported. Publicity surrounding these publications has undoubtedly influenced public opinion about the unscrupulous behavior of the tobacco industry and has furthered health policy goals, in part by denormalizing smoking as an acceptable behavior and discrediting the tobacco industry as a stakeholder in health policy.[42,43] In addition to academic publications, the release of the tobacco documents has generated several seminal public health reports from the WHO and its regional offices[2,44-46] and from civil society organizations.[47,48]

Although the impact of the Minnesota litigation has seemingly been centered in the United States, acknowledgment of its impact on tobacco control throughout the world is growing. There is general agreement that many of the advances in tobacco control during the past 10 years have their roots in Minnesota. Although public disclosure of tobacco documents is a creation of US litigation, many tobacco industry defendants are transnational companies. Consequently, the public release of the documents has had a global impact. The release of correspondence between parent companies and foreign subsidiaries has allowed a glimpse into the operations of transnational tobacco companies (TTCs). Accordingly, tobacco control advocates, researchers, and litigants working outside the United States have made extensive use of the documents to support their own health policy efforts.

Although the following is not a comprehensive accounting of the extraordinary efforts of the global tobacco control community, we offer a few examples of individuals and organizations that have used the documents to effect health policy change outside the United States. In 2007, Pascal A. Diethelm, president of the Swiss antismoking group OxyRomandie and vice president of the National Committee Against Smoking, France was given the 2007 International Tobacco Industry Document Research and Advocacy Award for using the documents to reveal the consulting relationship between Philip Morris International (PMI) and a researcher at the University of Geneva, Ragnar Rylander.[49] Rylander did not disclose his ties to the tobacco industry in his publications on secondhand smoke. Once this became known through the documents, the University rebuked him and also adopted a policy of no longer allowing its scientists to accept tobacco industry funding. In the statement announcing this policy, the University noted that "The huge mass of tobacco industry documents that has been made public as a result of judgements pronounced by American tribunals against this industry shows that these companies have attempted to manipulate public opinion for decades, and that the targeted recruitment of a large number of scientists has been a privileged instrument of this disinformation plot." In Nigeria, Akinbode Oluwafemi, on behalf of Environmental Rights Action/Friends of the Earth Nigeria, searched and used the documents to support the April 2007 lawsuit filed by the Lagos State Government in conjunction with Environmental Rights Action seeking legal relief from the industry's efforts to target young people.[50] In Finland, Heikki Hilamo has used the documents to produce extensive peer-reviewed publications and books in English and Finnish on topics such as product liability and industry interference with tobacco control.[41] In 2003, Professor Gérard Dubois[51] of France published a landmark document exposing the tobacco industry's playbook.

The use of documents by individuals and organizations working to effect policy in their own countries has also occurred in Brazil,[52] Indonesia,[53] and Austria.[54] Furthermore, civil society organizations have used the documents in advocacy efforts to combat the tobacco industry's influence across the globe.[47,55-57] Researchers from approximately 70 countries have published regional tobacco document analyses.[58] Efforts from the $500-million multipronged tobacco control campaign, which is funded by New York Mayor Michael Bloomberg[59] and the Bill and Melinda Gates Foundation[60] and which focuses on reducing the prevalence of smoking in low- and middle-income countries, have relied on revelations from tobacco documents. For example, the global tobacco control campaign funded by the Bloomberg Initiative (WHO's MPOWER package [**m**onitor tobacco use and prevention policies; **p**rotect people from tobacco smoke; **o**ffer help to quit tobacco use; **w**arn about the dangers of tobacco; **e**nforce bans on tobacco advertising, promotion and sponsorship; and **r**aise taxes on tobacco]) highlights documents produced to Minnesota plaintiffs and addresses the importance of revealing tobacco industry tactics.[61] Had it not been for the Minnesota litigation and the subsequent release of documents, only a small fraction of these events would have taken place in the past decade.

TOBACCO DOCUMENTS AND THE WHO

Document disclosures resulting from the Minnesota litigation have had an extraordinary influence on the global regulation of the TTCs under the leadership of the WHO. In the late 1990s, former WHO Director General Gro Harlem Brundtland launched a landmark inquiry into the tobacco industry's efforts to undermine global tobacco control, as evidenced by tobacco documents made public in Minnesota.[44] The 2000 WHO expert report concluded:

> At the most fundamental level, this inquiry confirms that tobacco use is unlike other threats to global health. Infectious diseases do not employ multinational public relations firms. There are no front groups to promote the spread of cholera. Mosquitoes have no lobbyists. The evidence presented here suggests that tobacco is a case unto itself, and that reversing its burden on global health will be not only about understanding addiction and curing disease, but, just as importantly, about overcoming a determined and powerful industry.[44]

The WHO's regional offices also directed substantial resources into mining the tobacco documents that were made public in Minnesota.[58]

In direct response to the WHO inquiry, the 54th World Health Assembly (WHA) passed resolution *WHA54.18 Transparency in Tobacco Control*[62] in 2001. This resolution urges WHO member states to monitor and to inform its membership about industry affiliations with its member-

ship, as well as to communicate information about identified efforts of the industry to subvert health policy.[62] As stated by the WHO, the documents were instrumental in developing the WHO Framework Convention on Tobacco Control (FCTC)[63]:

> The tobacco industry made a big strategic mistake in Minnesota that is reverberating around the world.…[The Minnesota plaintiffs'] plan was to bury the industry in its own documents by forcing disclosure of the truth about what the industry knew, when they knew it, and what they did to hide the truth from the public. The Minnesota team doggedly pursued the industry documents (including several trips to the US Supreme Court) and eventually forced the industry to turn over the material Minnesota needed to make its case.…*Today, the WHO Tobacco Free Initiative is using these documents to help develop the Framework Convention on Tobacco Control as well as national tobacco control efforts around the world.* They are an invaluable resource and probably the most important and lasting result of the tobacco litigation in the United States. The truth will set us all free.[64] [Emphasis added]

WHO's comprehensive findings, based on its inspection of the tobacco documents, have proved invaluable in FCTC treaty negotiations. The disclosed documents could be shared with policy makers to inform them of the tobacco industry's efforts to circumvent health policies and to assist them in removing the industry as a stakeholder in the ratification process. Furthermore, in spite of the interference of the tobacco industry in the development of the FCTC,[65] several FCTC articles (Article 5.3, 12.C, and 20.4C) are designed to protect tobacco control initiatives from the tobacco industry's decades-long mission of subverting and obfuscating public health measures.[63]

Finally, to date, 161 countries are Parties to the FCTC. Several guidelines, which are aimed at assisting Parties in meeting their obligations under the treaty, have thus far been developed. As of this writing, the Conference of the Parties has adopted strong guidelines in Article 5.3 (protection of public health policy with respect to tobacco control from the commercial and other vested interests of the tobacco industry), Article 8 (protection from exposure to tobacco smoke), Article 11 (packaging and labeling), and Article 13 (advertising, promotion, and sponsorship).

Former Director General Brundtland also made the regulation of tobacco production a high priority for WHO by appointing the Scientific Advisory Committee on Tobacco Product Regulation. This committee was subsequently elevated to the status of a standing committee and in 2003 was renamed the WHO Study Group on Tobacco Control Regulation (TobReg). With its prominent status as a standing committee, the WHO TobReg is positioned to develop meaningful standards for tobacco product regulation around the world well into the future. These standards will have a substantial impact in developing countries that lack the expertise and resources to develop their own standards. Many TobReg members have been associated with the tobacco documents, including Channing Robertson, PhD, who was the second witness in the Minnesota trial. The TobReg issued its report, *The Scientific Basis of Tobacco Product Regulation*, in 2007.[66]

TOBACCO DOCUMENTS IN LEGISLATIVE AND PARLIAMENTARY INVESTIGATIONS

The internal documents of the tobacco industry have also been used in parliamentary and legislative hearings. In July 1999, the UK House of Commons Health Select Committee[24] reviewed documents made public by the Minnesota settlement, set forth nearly 60 recommendations for reducing the health burden of tobacco use, and urged the government to act on its recommendations.[24] In the United States, tobacco documents have informed policy makers about the TTCs' internal strategies regarding "reduced-risk" products. In the 2003 congressional investigation of "reduced-risk" tobacco products, documents produced to the Minnesota depository disclosed correspondence from a senior tobacco company researcher who opined that the technology did not and will not exist to manufacture a "reduced-risk" product (a cigarette low in tobacco-specific *N*-nitrosamines), even while members of the tobacco industry were simultaneously touting the potential health benefit of such products.[67]

LITIGATION

The publicly available internal corporate records of tobacco companies are also a valuable resource for litigation efforts. In particular, Minnesota's document discovery allowed access by every litigant in cases brought after the Minnesota settlement to 35 million pages of internal records and thousands of documents stripped of privilege by the Minnesota court through its application of the crime-fraud exception to the doctrine of privilege.[37] The importance of the Minnesota settlement has been so great that a description of the landscape of global tobacco control has suggested that, "quite simply, 'when the history of tobacco . . . is written, there is going to be before the Minnesota case and after the Minnesota case.'"[68]

The US case against the tobacco industry was extremely document-intensive, as noted by the court,[62] and may be "the largest piece of civil litigation ever brought."[69] In *United States v Philip Morris*, the government proved its case.[70] However, a 2005 decision of a Scottish court, *McTear v Imperial Tobacco Ltd*, determined that the defendant tobacco company was not liable for the death of the plaintiff (who had smoked 2 packs per day) from lung

cancer and that "there was no scientific proof of causation between the plaintiff's smoking and his death from lung cancer."[71] The plaintiff in *McTear* was denied legal aid and, as a result, lacked the financial resources that may have allowed her access in court to the sort of documents available to the plaintiffs in the Minnesota and RICO cases.[71] This contemporaneous example makes apparent the importance of plaintiffs' access to documents such as those made public by the Minnesota settlement. However, it should be pointed out that disclosure laws differ from one country to the next; for example, these laws are more restrictive in the United Kingdom and less restrictive in the United States. This is one aspect of the US legal system that makes litigation a far more powerful regulatory tool for promoting product safety than it may be in other countries.[43] Furthermore, the cost of failed suits in the United Kingdom falls to the plaintiff; this regulation discourages plaintiffs who are less well financed, even when they have a strong case.

Nonetheless, the documents have had, and probably will continue to have, a great impact on tobacco-regulation litigation throughout the world, as predicted by commentators after the initial release of these documents.[72] Within 2 years after the 1998 US tobacco settlements, tobacco litigation of some type had been filed in Australia, Bangladesh, Brazil, Canada, China, Finland, France, Germany, India, Ireland, Israel, Japan, the Marshall Islands, Norway, Oman, Pakistan, Peru, Poland, South Korea, Spain, Sri Lanka, Switzerland, Uganda, and the United Kingdom.[2] Currently, many cases are pending in countries other than the United States. In Brazil, for example, a case filed against PMI in 1995, *The Smoker Health Defense Association (ADESF) v Souza Cruz, S.A. and Philip Morris Marketing, S.A.*, was decided for the plaintiffs, but the appeal was pending as of December 2008.[70] The government of British Columbia brought suit against PMI in 2001, seeking recovery of past and future costs associated with a "tobacco related wrong."[73] The trial in that case, *British Columbia v Imperial Tobacco Ltd., et al*, is set to begin in September 2010.[73] In 2007, the Nigerian government filed a lawsuit for recovery of health care costs against BAT, PMI, and others, seeking US $22.9 billion in damages for costs incurred by treating their citizens for tobacco-related illnesses.[74] According to media coverage of the case:

> A lot of their case is based on documents found at the British American Tobacco Documents Archives. BAT was required to make their internal documents public after a lawsuit won by the American state of Minnesota. Now many of these documents are for public use online, maintained by the University of California, San Francisco, Mayo Clinic and London School of Hygiene and Tropical Medicine. In this archive there are documents in which BAT reveals that they were aware of the fact that few Nigerians know the health risks of cigarette smoking and, in fact, many Nigerians believe that smoking may even be healthy.[50]

Litigation against tobacco manufacturers is also currently pending in Israel, Spain, Columbia, Nigeria, Argentina, and Turkey.[73]

A final example of the influence of the tobacco documents released under the Minnesota settlement on other litigation is the recent 5-to-4 ruling by the US Supreme Court in *Altria Group, Inc. v Good*, which allows filings against tobacco manufacturers of cases that allege deceptive marketing of "light" and "low-tar" cigarettes.[75] The topic of "low-tar" or "light" cigarettes was central to the testimony of 1 of the authors of the current review (R.D.H.), and the industry's knowledge of the false health claims made about these products had not been previously entered into the public record. Had most members of the US Supreme Court agreed with the industry, the case would have ended the approximately 40 pending "light" cigarette cases and could have barred future cases involving deceptive health-related claims of any kind. As noted by legal scholars, "even the state lawsuits that resulted in the $246 billion Master Settlement Agreement 10 years ago would arguably have been barred" if the industry had prevailed at the Supreme Court.[76]

UNANTICIPATED DOCUMENT FINDINGS

Although a primary goal of the Minnesota litigation was "to expose the industry's decades-long campaign of deception by revealing the industry's secret research in smoking and health, addiction and nicotine manipulation,"[77] the documents revealed much more than the industry anticipated. The tobacco defendants' plan to overwhelm the Minnesota plaintiffs with truckloads of documents backfired, as reported by the WHO:

> The idea—what lawyers call "papering"—was to simply bury the relevant material in a lot of trash. They forgot that winters are long in Minnesota and did not realize that the Minnesota team would look through all the paper.…And while 99.9% of the material that the industry produced in Minnesota was irrelevant to the Minnesota trial, it had great relevance to other tobacco control issues.… Indeed, the documents reveal industry subversion of not only the scientific but also the political process all over the world.[63,64]

Documents released in Minnesota expanded public knowledge of information that had not been previously available to the public in existing sources. First, the documents, through reports published by journalists, researchers, and civil society organizations, paved the way for holding the companies accountable for their role in the global illicit tobacco trade and provided information that has proved crucial to the development of effective counterstrategies against this trade.[48,78-88] In 2008, for ex-

ample, Canada's largest cigarette manufacturers pleaded guilty to aiding and abetting tobacco smuggling and agreed to pay CanD$1.15 billion for defrauding the Canadian government of unpaid taxes. Also, in a different case, without admitting guilt and in return for dropping smuggling-related litigation against Philip Morris, the company agreed to pay US $1.25 billion to the European Commission, the executive branch of the European Union.[89] Article 15 of the WHO FCTC, the world's first public health treaty, makes provisions for measures aimed at combating the illicit tobacco trade. Parties to the FCTC are currently negotiating a supplementary treaty aimed at ending this practice.[65]

A second area highlighted by the Minnesota settlement was the extent to which lawyers concealed and destroyed documents. Although before the Minnesota case went to trial there had been glimpses of what the tobacco industry had been hiding in its files,[5,6,90-96] after more than 20 trial court orders and more than 5 appeals Minnesota's successful application of the crime-fraud exception to the attorney-client privilege and work-product doctrine resulted in the release of an additional 39,000 explosive documents.[39] These most secret documents, previously protected by attorney-client privilege, provided evidence of the industry's systematic destruction and concealment of information, including abuses of the attorney-client privilege doctrine.[97,98] The judge in *United States v Philip Morris, et al,* the Honorable Gladys Kessler, who found the major tobacco companies guilty of violating certain provisions of the RICO statute in August 2006,[99] summarized the tobacco industry's conduct related to suppression of information:

> The evidence is clear that on a significant number of occasions, Defendants did in fact suppress research and destroy documents to protect themselves and the industry….By destroying evidence, Defendants make it virtually impossible to know what materials existed prior to their destruction.[100]

Finally, in September 2008, the UK's Royal College of Physicians called for an end to smoking in the United Kingdom in 20 years, a call that would have been unfathomable just 10 years earlier.[101]

CONCLUSION

Few single events in the history of public health have had as dramatic an effect on global tobacco control as the public release of the tobacco industry's internal documents in the Minnesota tobacco trial and through the MSA. The tobacco industry's own words have reverberated through court rooms, public hearings, and media outlets across the globe, and this decade of truth has forever affected health policy worldwide. In fact, one of the legacies of the tobacco documents may be the end of cigarettes as a prevalent and legal commodity.

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PostScript

LETTERS

Letters intended for publication should be a maximum of 500 words, 10 references, and one table or figure, and should be sent to the editor at the address given on the inside front cover. Those responding to articles or correspondence published in the journal should be received within six weeks of publication.

Listening between the lines: what BAT really thinks of its consumers in the developing world

In an audio recording of the "Structured Creativity Conference" held in Hampshire, UK in June 1984, British American Tobacco (BAT) adds context to the written report of marketing and product applications.[1] Employees are taped brainstorming creative ways to push their product in light of future marketing constraints and social pressure towards a smoke-free society. Project proposals included the following: low sidestream smoke cigarettes,[2] "front end lift" cigarette design to give the smoker more "impact" on the first puffs,[3] pleasant smelling sidestream smoke,[4] and nicotine inhalers—"Forget about smoking . . .GO FOR A QUICKEEK. No tar with nic, is what makes the body kick."[5]

One of the most interesting proposals came from Ian Ross from a Finland subsidiary, who later became the head of international brand business at BATCo in the early 1990s. Ross's proposal, the "LDC (less developed counties) Project",[6] called for individually heat sealed cigarettes designed to lengthen the shelf life of cigarettes in arid climates found in Africa and the Middle East. This rather ingenious idea for stick sales would be sold to tobacco vendors in reels with visible brand imaging, containing 200 cigarettes that could be pulled off along perforations one at a time.

What the 80 or so page written report did not include, the audiocassette captured with clarity. The taped conversations of the BAT conference participants offered rarely obtained loose discourse regarding product design proposals and a derogatory discussion of the people intended for end product use.

Ross relays that he wants to make "stick purchases seem like a consumer benefit" by supplying "factory sealed and factory freshness" every time. As for marketing the heat sealed stick product, Ross states: " . . .[T]he brand image must be enhanced by the new packaging . . .if you just say, this is a cheap cigarette for you dirt poor little black farmers . . .they're not going to go for it."

Ross also discusses the target group—"urban", "male", between 18–30, and "aspiring lower middle" socioeconomic class—and says: "I have not gone into psychographics . . .I have no idea what the psychographics of the average black farmer is."

Another conference participant ruminates, "We could sell them to the Palestinians if we made the plastic hard enough that you could rip the end off and put your shells in them..."

This discourse, not found on the written presentation, between the BAT marketing and product development personnel was obviously not meant for public consumption, nor is it new information that the tobacco industry targets the developing world. A patent search in the UK resulted in no individually heat sealed cigarette applications.

What is of great interest to those of us who spend our time searching through page after page of internal tobacco industry documents is the significant difference between what is written and what is said. David Schechter, the former BAT lawyer, recently explained the "mental copy rule" to the US Department of Justice, which assumed that anything one would write could end up being used publicly or legally against the company.[7] This leads to the obvious question: Are we overlooking important research tools in the form of non-written material?

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Eclipse: does it live up to its health claims?

We read the recent article by Slade *et al*[1] with great interest and agree that reasonable regulation focused on the development and appropriate evaluation of potential reduced risk cigarettes is warranted. Furthermore, we agree with Slade *et al* that the results of our evaluation indicate that Eclipse may offer potential benefits to smokers. However, we disagree with several of the other conclusions drawn by the authors.

The article challenges the merits of Eclipse and questions the fundamental differences between Eclipse and other cigarettes. It is not possible within the context of this letter either to fully describe the scientific data that has been developed to characterise Eclipse or to address many of the criticisms of Eclipse raised in Slade's article. However, we briefly address pertinent issues below and encourage interested parties to independently evaluate all of the available information.

Slade *et al* have inaccurately represented the claims that RJ Reynolds Tobacco Company (RJRT) has made regarding Eclipse. No cigarette is without risk, including Eclipse. Our advertising for Eclipse states: "The best choice for smokers who worry about their health is to quit. But Eclipse is the next best choice for those who have decided to continue smoking." Our advertising also makes it clear that RJRT does not claim that Eclipse presents less risk of cardiovascular disease or complications with pregnancy.

In the absence of any existing regulatory standard, RJRT assessed Eclipse's risk reduction potential using a four step scientific methodology that included chemical testing and analysis, biological and toxicological testing, human testing, and independent scientific verification. In general, the evaluation strategy utilised was consistent with strategies outlined by the Institute of Medicine Committee that addressed this subject.[2] RJRT has conducted an extensive comparative evaluation of Eclipse and has presented this research at scientific meetings in the both the USA and internationally. The results of these and other studies may be reviewed on the Eclipse website (www.eclipsescience.com).

In addition, much of this research has been published in the peer reviewed literature. The weight of the evidence from this research clearly shows that, compared to other cigarettes, Eclipse may present smokers with less risk of cancer, chronic bronchitis, and possibly emphysema. An independent panel of scientific experts reviewed the science and reached conclusions consistent with RJRT's claims.[3]

RJRT's comparative studies were conducted using Kentucky reference cigarettes (K1R5F and K1R4F) and leading low "tar" and ultra low "tar" commercial brand styles. Combined, the cigarettes selected for comparison to Eclipse are representative of the vast majority of cigarettes sold in the US market.[4–6] By contrast the entire market segment of the very low yielding ultra low "tar" cigarettes used by Slade *et al* as a comparison collectively represent less than 1% of the market. Furthermore, one of the two cigarettes selected as a comparison (Now Box) does not have a measurable US Federal Trade Commission (FTC) "tar" yield.