Submission to Senate Community Affairs Legislation Committee Inquiry into Tobacco Advertising Prohibition

This submission was prepared by the VicHealth Centre for Tobacco Control on behalf of The Cancer Council Australia, National Heart Foundation, VicHealth Centre for Tobacco Control, Action on Smoking and Health (ASH) Australia and Australian Council on Smoking and Health.

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VicHealth Centre for TOBACCO CONTROL

The Cancer Council Australia

Heart Foundation

ASH Action on Smoking and Health

ACOSH

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In this submission, we address each of the three terms of reference of the inquiry in turn.

Term of reference (a)
The provisions of the Commonwealth Electoral Amendment (Preventing Smoking Related Deaths) Bill 2004

The Commonwealth Electoral Amendment (Preventing Smoking Related Deaths) Bill 2004 aims to prevent the provision of public election funding to any individual, group or party that accepts a gift from a tobacco manufacturer, distributor or retailer (defined as "a person who derives substantial revenue from the manufacture, distribution or retail of tobacco products"[1]). It is "[a] Bill for an Act to amend the Commonwealth Electoral Act 1918 to deny election funding to political candidates accepting gifts derived from tobacco smoking, and for related purposes". The Bill is essentially designed to address the issue of political donations by the tobacco industry influencing, having the capacity to influence, or being seen to influence, the making of policy.

The risks of political donations

The problem of donations to politicians and political parties – whether by corporations, unions, other groups or individuals – and their capacity to influence the making of policy has long been an issue of controversy in democratic systems across the world. The practice has been recognised to create a number of risks.

First, private political donations give rise to the risk that money will actually buy political influence. A study of the United States Congress carried out in the early 1990s found that the more tobacco money a member received, the less likely the member was to support legislation designed to reduce the harm caused by tobacco. Of a number of variables taken into account, the amount of tobacco money received was the variable most strongly and consistently associated with a lack of support for legislation designed to reduce the harm caused by tobacco, even after taking account of controls for additional factors such as district location and party. The study concluded that tobacco industry contributions to members of the US Congress strongly influenced the federal tobacco policy process.[2]

The second major risk is that of a *perception* of influence being "bought", leading to widespread mistrust and dissatisfaction with political representation.[3] When payments to political parties or candidates are seen to coincide with support for donors' interests or favourable policy outcomes, there is a very strong risk that outside observers will come to believe that the process of government is being influenced by donations, and that policy outcomes can be sold to those who can afford them, regardless of what is in the interests of the community as a whole.

Third, if private funding of a political party or an election candidate affords better access to politicians and party machines – as is generally acknowledged – this means that those with deep pockets will very likely enjoy better opportunities to develop a profitable relationship with

1 Note that it may be necessary to define the term "substantial revenue" in the Bill to reflect the comments of the Hon Duncan Kerr in his First Reading speech on the Bill that "[t]he notion of `substantial revenue' means the bill will not apply to those whose revenue from the retailing of tobacco is only incidental to their supply of other retail products – for example supermarkets, corner stores and petrol stations".

2 Stephen Moore, MD, MPH, Sidney M. Wolfe, MD, Deborah Lindes, Clifford E. Douglas, JD. Epidemiology of Failed Tobacco Control Legislation. JAMA, 19 October 1994, 272, 15, at 1171-1175.

3 Alan Doig. Politics and Sleaze: Conservative Ghosts and Labour's Own Brand. Parliamentary Affairs, 1 April 2003, 56, 2, at 322-333.

influence-wielding politicians, and make representations in an informal setting, than other constituents who lack the means to buy this type of access.

Fourth, by accepting donations from industry groups or other private sources, it is hard to see how politicians can avoid conflicts of interest in situations where the interests of their other constituents may require them to make decisions that will hurt their donors. Where parties are used to, and perhaps depend on, receiving donations from certain quarters, clearly a strong incentive exists to avoid adopting policies that harm the interests of the donors concerned. And the bigger the donations, the greater the potential impact.

In summary, these issues raise the concern that, in accepting donations from particular organisations and individuals, political parties and politicians may in fact limit, or at least be seen to be limiting, their capacity or their will to represent all of their constituents fairly and evenly, and so uphold the principles of democratic representation. Ideally, political battles should be fought over policy issues – on the merits of arguments – and not on the basis of who can afford to, or who is willing to, pay for outcomes.

The special case of the tobacco industry

While all of these considerations are of relevance to debate about political donations generally, they take on a particular resonance in the context of the tobacco industry. The tobacco industry is like no other industry. It sells products that are harmful when used exactly as intended by the manufacturer, have no safe level of use, are addictive, and have no identified therapeutic benefit. The overwhelming majority of the tobacco industry's customers commence using their products in childhood, and the overwhelming majority would prefer not to be using their products but continue to do so primarily because of addiction. Tobacco kills approximately 19,000 Australians prematurely every year – over 50 a day – and has taken over 700,000 lives prematurely since 1950. It costs the Australian community over $21 billion a year.

The goal of the tobacco industry is, of course, to maximise its profits. This is so notwithstanding that the industry knows that the more products it sells (and the more money it makes), the more people it will addict, and the more people it will kill. The tobacco industry opposes, and has always opposed, every measure that would be effective in reducing the death, disease and social costs caused by tobacco – because every such measure would also reduce its profits. Stronger health warnings would reduce smoking rates and thereby reduce the death, disease and social costs caused by tobacco. But they would also reduce tobacco industry profits. Stronger restrictions on tobacco industry advertising would also both reduce the death, disease and social costs caused by tobacco, and reduce the tobacco industry's profits. So, too, would greater funding of mass media tobacco education campaigns and comprehensive cessation assistance programs.

Unlike other industries, there is no space in which the interests of the tobacco industry coincide with those of the rest of the community. There is no safe level of smoking. There is no optimal level of tobacco use. Most tobacco use occurs because of addiction. Every dollar of profit to the tobacco industry imposes costs – both individual and social – on the rest of the community. Any influence the tobacco industry can bring to bear on the policy process benefits only the tobacco industry – and costs the rest of the community. Policy considerations – whether economic, public health or legal – operate against the tobacco industry. It can only push its interests through other means – hence the attraction of trying to buy outcomes.

In addition to the matters we set out above in respect of the risks of political donations generally, acceptance of political donations from the tobacco industry assists the tobacco industry in

its efforts to create a perception of legitimacy. This has always been vitally important to the industry, as it has always sought, and continues to seek, to take the minds of the community away from what it is – an industry that profits from the sale of addictive drug delivery devices that kill people – and so to prevent it from being regulated as it would be regulated if it were universally seen for what it is.

False arguments about tobacco industry "legality"

The argument is often made that, as long as the tobacco industry is legal, there can be nothing wrong with accepting political donations from it. Putting aside for the time being the issues raised above in respect of the lack of commonality of interest between the tobacco industry and the rest of the community, this argument is fundamentally misconceived. Only the *conduct* of an industry can be judged to be "legal" or "illegal", not the industry per se[4]. And there are strong arguments that much past and present tobacco industry conduct has been and remains unlawful, including under trade practices law and the criminal law. In our response to term of reference (c), we set out arguments that the tobacco industry has engaged, and continues to engage, in conduct that contravenes the *Trade Practices Act 1974* (Cth). Similar arguments have been made with respect to breaches of the criminal law.[5] The corollary of this is the argument that the money donated by the tobacco industry is effectively ill-gotten gains, or proceeds of crime. It is clearly inappropriate that politicians and political parties should accept such money, particularly where public health organisations argue serious past and ongoing failures of law enforcement against the tobacco industry.

Use of third parties to channel funds and other techniques to circumvent regulations

We also think it is important to give careful consideration to the way in which the channelling of funds from the tobacco industry to political parties and politicians might be achieved in the face of legislation such as the Bill proposes. If the tobacco industry is simply able to use intermediaries to make donations, or resort to other techniques, the Bill may, in practice, be of little effect.

4 Jonathan Liberman and Jonathan Clough. Corporations that Kill: The Criminal Liability of Tobacco Manufacturers. (2002) Vol 26 Criminal Law Journal, 223 at 225-7.

5 Ibid.

Term of reference (b)
The exposure draft of the Tobacco Advertising Prohibition (Film, Internet and Misleading Promotion) Amendment Bill 2004

The effects of tobacco advertising and the need to prohibit it

Tobacco advertising is a powerful medium by which the community, and young people in particular, are provided with images of smoking. Tobacco advertising normalises cigarette smoking and associates it with attractive role models and glamorous images.[6] It imbues tobacco products and smoking with particular meanings that are far removed from the reality of harm and addictiveness.

Through both its direct and indirect advertising, the tobacco industry associates cigarette smoking with athletic prowess, sexual attractiveness, professional success, adult sophistication, independence, adventure and self-fulfilment. This constant barrage of misleading messages appeals to young people and encourages them to take up a behaviour that is harmful to their health.[7]

The overwhelming majority of research shows that tobacco advertising not only leads to an increase in consumption but that young people, the source of replacement smokers, are heavily influenced by that advertising. The tobacco industry continues to vigorously fight effective advertising restrictions and questions this research. It asserts that the purpose of tobacco advertising is to encourage current adult smokers to switch brands. This claim has been examined and, based on the economic evidence, dismissed.[8]

> *Cigarette advertising appears to affect young people's perception of the pervasiveness, image and function of smoking. Since misperceptions in these areas constitute psychosocial risk factors for the initiation of smoking, cigarette advertising appears to increase young people's risk of smoking.*[9]
>
> ...
>
> *The images typically associated with advertising and promotion, convey the message that tobacco use is a desirable, socially approved, safe and healthful, and widely practised behaviour among young adults, whom children and youths want to emulate. As a result, tobacco advertising and promotion undoubtedly contribute to the multiple and convergent psychosocial influences that lead children and youths to begin using these products and to become addicted to them.*[10]

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6 Hastings, G., MacFadyen, L. & Stead, M. 1997, Tobacco marketing: shackling the pied piper, British Medical Journal, pp. 439-440.

7 Hammond, R. 2000, Tobacco advertising and promotion: The need for a coordinated global response, The World Health Organisation, Geneva.

8 Ibid.

9 US Department of Health and Human Services. Preventing Tobacco Use Among Young People. A report of the Surgeon General. Public Health Service, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, Atlanta, Georgia, 1994.

10 Lynch B, Bonnie R (eds) Growing Up Tobacco Free. Committee on Preventing Nicotine Addiction in Children and Youths, Division of Biobehavioural Sciences and Mental Disorders, Institute of Medicine. National Academy Press, Washington DC, 1994.

...

Adolescents who had a favourite cigarette advertisement and/or possessed or were willing to possess a smoking promotional item have been found to be more likely to experiment and take up smoking in the future than those who did not.[11]

The US Surgeon General has noted a number of ways in which tobacco advertising and promotion may affect the consumption of tobacco products.[12] These include:

- Encouraging children or young adults to experiment with tobacco products and initiate regular use;
- Acting to reduce current tobacco users' motivation to quit;
- Acting to encourage former smokers to resume smoking; and
- The ubiquity and familiarity of tobacco advertising and promotion may create an environment in which tobacco use is seen as not only acceptable but likely to be without hazard.

The tobacco industry has been highly innovative in publicising its products and its brands, particularly in an effort to target young people. Although many forms of advertising are prohibited, tobacco companies still manage to spend millions of dollars marketing their products (including in ways mentioned below). The World Bank recently concluded that "bans on advertising and promotion prove effective, but only if they are comprehensive, covering all media and all uses of brand names and logos."[13]

It was considerations such as these that led to the inclusion within the Framework Convention on Tobacco Control ("FCTC") of very strong provisions dealing with tobacco advertising, promotion and sponsorship.

Article 13 of the FCTC states:

1. Parties recognize that a comprehensive ban on advertising, promotion and sponsorship would reduce the consumption of tobacco products.

2. Each Party shall, in accordance with its constitution or constitutional principles, undertake a comprehensive ban of all tobacco advertising, promotion and sponsorship. This shall include, subject to the legal environment and technical means available to that Party, a comprehensive ban on crossborder advertising, promotion and sponsorship originating from its territory. In this respect, within the period of five years after entry into force of this Convention for that Party, each Party shall undertake appropriate legislative, executive, administrative and/or other measures and report accordingly in conformity with Article 21.

3. A Party that is not in a position to undertake a comprehensive ban due to its constitution or constitutional principles shall apply restrictions on all tobacco advertising, promotion and sponsorship. This shall include, subject to the legal environment and technical means available

11 Pierce J, Choi W, Gilpin E, Farkas A, Berry C. Tobacco industry promotion of cigarettes and adolescent smoking. JAMA, 1998; 279:511-515.

12 US Department of Health and Human Services. Reducing the Health Consequences of Smoking: 25 Years of Progress. A Report of the Surgeon General. Rockville, Maryland: US Department of Health and Human Services, Public Health Service, Centres for Disease Control, Centre for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health. DHHS Publication No (CDC) 89-8411.

13 The World Bank. Curbing the Epidemic: Governments and the Economics of Tobacco Control. In: Development in Practice. Washington, DC: The World Bank; 1999.

to that Party, restrictions or a comprehensive ban on advertising, promotion and sponsorship originating from its territory with cross-border effects. In this respect, each Party shall undertake appropriate legislative, executive, administrative and/or other measures and report accordingly in conformity with Article 21.

4. As a minimum, and in accordance with its constitution or constitutional principles, each Party shall:

*(a) prohibit all forms of tobacco advertising, promotion and sponsorship that promote a tobacco product by any means that are false, misleading or deceptive or likely to create an erroneous impression about its characteristics, health effects, hazards or em*issions;

(b) require that health or other appropriate warnings or messages accompany all tobacco advertising and, as appropriate, promotion and sponsorship;

(c) restrict the use of direct or indirect incentives that encourage the purchase of tobacco products by the public;

(d) require, if it does not have a comprehensive ban, the disclosure to relevant governmental authorities of expenditures by the tobacco industry on advertising, promotion and sponsorship not yet prohibited. Those authorities may decide to make those figures available, subject to national law, to the public and to the Conference of the Parties, pursuant to Article 21;

(e) undertake a comprehensive ban or, in the case of a Party that is not in a position to undertake a comprehensive ban due to its constitution or constitutional principles, restrict tobacco advertising, promotion and sponsorship on radio, television, print media and, as appropriate, other media, such as the internet, within a period of five years; and

(f) prohibit, or in the case of a Party that is not in a position to prohibit due to its constitution or constitutional principles restrict, tobacco sponsorship of international events, activities and/or participants therein.

5. Parties are encouraged to implement measures beyond the obligations set out in paragraph 4.

Similar considerations led to a very strong recommendation from the House of Representatives Family and Community Affairs Committee's recent Inquiry into Substance Abuse in Australian communities in relation to tobacco promotion and marketing. The House of Representatives Family and Community Affairs Committee's report records (recommendation 48):

> *The Committee recommends the Commonwealth, State and Territory governments work together to ensure that all remaining forms of promotion of tobacco products be banned, including advertising, incentives to retailers, sponsorships and public relation activities.*

The need to amend the Tobacco Advertising Prohibition Act 1992 (Cth)

The *Tobacco Advertising Prohibition Act 1992* (Cth) *("TAP Act")* has now been in operation for more than 10 years. While it has played an important role in limiting the exposure of the Australian public to tobacco advertising through more traditional mass media forms of marketing, it has been largely ineffective in limiting exposure through other channels of communication to which the tobacco industry has increasingly been turning since the

commencement of the Act. In addition, the exposure of the public to the promotion of smoking in the popular media remains an ongoing concern.

In our view, the Act should be substantially amended to ensure that it better achieves its fundamental object, stated in section 3 of the Act:

> *(1) This Act is intended to limit the exposure of the public to messages and images that may persuade them:*
>
> *(a) to start smoking, or to continue smoking; or*
>
> *(b) to use, or to continue using, tobacco products.*
>
> *(2) The object is to improve public health.*

On World No Tobacco Day, 31 May 2002, the Parliamentary Secretary to the Minister of Health and Ageing, the Hon Trish Worth MP, announced that the government would conduct a review of the Act. The Issues Paper released by the Department of Health and Ageing for the review in August 2003 said that the review would "consider whether the Act has met its objective of limiting exposure of the public to messages and images that may persuade them to start or continue smoking". The review is also to "consider whether the objectives of the Act should be expanded to take into account new and emerging advertising and sponsorship practices". In October 2003, we made a detailed submission to the Department in which we outlined the forms of advertising in which the tobacco industry continues to engage (such as event and venue promotions; affinity marketing (connecting tobacco products with other popular brands); marketing at the point of sale; promotions through the pack; direct marketing; value-added promotions; Internet marketing; and advertising in international magazines), discussed the problem of tobacco advertising in the popular media, and made the case for legislative change. In our view, this Review process should result in substantial legislative change.

The Tobacco Advertising Prohibition (Film, Internet and Misleading Promotion) Amendment Bill 2004 attempts to deal with a few of the many ongoing tobacco advertising issues that must still be addressed. We here make comments on the main objects of the Bill, but we stress that the Bill only seeks to deal with a very few of the issues that concern us, and more substantial amendments to the Act will therefore be required. We do not comment here about any drafting issues. We intend to provide such comments to Senator Allison directly.

Application of the Act to the Internet

We agree that the definition of "publish a tobacco advertisement" should be amended to make it clear that it applies to publication via the Internet. While we think that Internet publication is likely to be covered by the wording of section 10(1)(e) ("by any means (including, for example, by means of a film, video, computer disk or electronic medium)"), it appears from the discussion in the Issues Paper, released in August 2003 by the Commonwealth Department of Health and Ageing for the review of the *Tobacco Advertising Prohibition Act 1992* (Cth), that some people are of the view that Internet publication is not covered. That being the case, it would be preferable to make this clear in the legislation.

Product placement

We agree that product placement in film, television programs and computer games should be prohibited. At present, this is addressed by the coverage of "publish a tobacco advertisement" and "broadcast a tobacco advertisement", and the fact that the "accidental or incidental" exception

does not apply where a publisher or broadcaster has received a direct or indirect benefit for the publication or broadcast. But, again, it appears from comment that has been made in the media over some time now that there are those under a misapprehension that product placement is not prohibited, and it would be helpful to make this explicit in the legislation. We also agree that it would be useful to make the demanding, soliciting, offering or accepting of a benefit in return for product placement an offence, and we agree with the higher penalties proposed for all classes of product placement offences.

Regulation of Internet sales

We agree that the sale of tobacco products over the Internet should be regulated, but we are not persuaded that a total ban on Internet sales is necessary (which we think would be the effect of the prohibition on offering products for sale). Instead, we think a strict regulatory framework is required to deal with these sales.

First, we think that there should be a prohibition on Internet sales from *overseas* for personal use to Australians, and on purchases for personal use by Australians from overseas via the Internet. Otherwise, products in Australia cannot be regulated in accordance with Australian law on health warnings, contents information, and other areas (such as product composition) that might be regulated in the future, and Australians will be drawn to Internet sites hosted overseas that are more difficult to regulate than those based in Australia. Internet sales from overseas should be allowed only to persons in the tobacco trade, who may need to do business in this way. Of course, business transactions are increasingly being administered on-line, and we have not seen a persuasive argument that these ought to be prohibited.

Second, we think that the Act should provide that only factual information may be communicated to an Australian via the Internet by a person in the tobacco trade, i.e. plain, one colour information about price, availability and characteristics of products; no trademarks, designs, depictions, etc. should be used. Further, such information should only be made available on secure sites, i.e. to registered users, with reasonable steps required before registration, namely:

- opening of access accounts by means of a valid credit card;
- requiring applications to open an access account to be accompanied by some other form of ID by which the age of the person wishing to open the access account can be reasonably ascertained;
- placing a prominent notice on the site that persons under 18 should not access it;
- including a procedure in the registration process for the Internet access account through which the person wishing to open the account confirms that they are not under the age of 18.

We think that obligations should be imposed on Internet content hosts (for Australian-hosted material) to take down material within 24 hours of notification by the Commonwealth Department of Health and Ageing; and on Internet service providers (for non-Australian hosted material) on notification by the Department to take reasonable steps to deny access to end-users.

It should be an offence for a person to refuse full access to a website to a *TAP Act* regulator, including by providing a password where necessary for access. It should be an offence to provide access to offending material knowingly or recklessly – so, if any person (and not only the Department) has advised an Internet content host or Internet service provider of offending material and they have not responded appropriately, they would be guilty of an offence. The requirements of legislation should be included within the Internet Industry Association code where appropriate.

Definition of "tobacco advertisement"

We agree that the definition of "tobacco advertisement" should be amended to ensure that it covers the sorts of techniques that the tobacco industry has used to try to get around the precise wording of the definition, such as colours and colour schemes. We agree that there should be a set of catch-all words at the end of the definition to put the coverage of the term beyond doubt and to put an end to efforts to find ways through and around the definition. We support the use of words such as "or any other image, message or communication" as is proposed.

Publicity given to tobacco industry sponsorships

We agree with the proposal insofar as it would prohibit events and activities co-sponsored by the Commonwealth being publicly sponsored by tobacco manufacturers, distributors or retailers (provided that "tobacco retailers" are limited to retailers whose predominant retailing activity is the retailing of tobacco products").

We think, however, that there may be some difficulties in seeking to prohibit the Commonwealth from co-sponsoring events or activities with tobacco manufacturers, distributors or retailers under any circumstances. It may be problematic to prescribe an absolute rule that could operate to prevent funding being provided, or reduce the funding that is provided, to some useful events and activities. We would, instead, focus on the publicity given to tobacco industry sponsorship of such events, which is, of course, a powerful form of tobacco industry marketing.

Under section 10(5) of the *TAP Act*, "the publication of an acknowledgment of assistance or support" is specifically exempted from the Act if it complies with regulations made under the Act. This has allowed the tobacco industry to have itself publicly associated with a number of worthy causes and events. Examples include Philip Morris' sponsorship of the Covent Garden Opera Scholarship in 2001 and 2002, the Breaking Point Domestic Violence conference in February 2003 (co-sponsored with the Commonwealth Government), and the 150th anniversary of the Victorian Royal Botanic Gardens.

We do not argue that the tobacco industry should be prohibited from providing funds to such causes and events – it is essentially up to each individual and organisation to decide whether to take tobacco industry money or not (subject to the specific issue of political donations, to which we also refer in this submission). But we consider it contrary to the public interest for a tobacco company, and its products, to gain publicity that links them with worthy causes or particular imagery, feelings, values or ideals, and works to cultivate associations far removed from the realities of harms and addictiveness. The Covent Garden Opera scholarship sponsorship provides a good example. In an article that appeared in *The Australian*, "A fiery response to smoke sponsor", the CEO of VicHealth, Dr Rob Moodie, was quoted as saying: "How do you sing without a larynx or voice box?".

Thus we are not saying that the tobacco industry should be prohibited from providing funds to worthy causes (to which the Commonwealth may also wish to provide funds). But the section 10(5) exception should be removed to prevent the use of that exception to achieve publicity that is against the object of the Act, and every other provision of the Act.

In its report to the Senate, tabled on 30 April 2002, the Commission, subject to stating that it was investigating whether the tobacco industry had engaged in misleading and deceptive conduct in marketing products as "light" and "mild", and issues relating to document destruction that had emerged from the *McCabe v British American Tobacco Australia* case, dismissed the concerns that the organisations had expressed. On reading the Commission's report, the organisations were concerned to find that the Commission's report was replete with mischaracterisations of the arguments that had been put by the organisations and basic factual and legal errors. On 15 May 2002, the organisations provided the Commission with a response to the Commission's report, in which the organisations' complaints about the Commission's report were detailed. While some meetings between representatives of the Commission and representatives of the organisations followed the submission of the May response, the Commission has taken no action, and, overall, the organisations do not believe that the Commission has at any stage genuinely addressed their concerns or explained to them why it has chosen not to act on them. The Commission has not seemed interested in meeting with international experts whom the organisations have been able to make available to the Commission to support their allegations, including experts who have been pivotal to successful litigation against the tobacco industry in the US, and it has failed to explain why the organisations' legal concerns have not been pursued.

The Commission's position has come as a surprise to the organisations, given the Commission's reputation for willingness to enforce the Act in a variety of areas and against a wide range of corporations. The organisations have never understood the Commission's lack of interest in this area. Recent public statements by the Chairman and CEO of the Commission in respect of the likely cost of litigation against the tobacco industry and the need for specific funding for such a course may, in retrospect, go some way to explaining the Commission's position.

In our view, the conduct of the tobacco industry in Australia represents a public health disaster and a consumer protection scandal. The industry has now begun to be held to legal account for its conduct in the United States, through litigation by both governments and individuals, and made to pay for some of the damage it has caused to individuals and to the community as a whole, but, so far, it has not been brought to account in Australia. Given the size and wealth of the tobacco industry, in our view, in Australia, only well-resourced litigation by a strong public agency will be able to bring the industry to account and achieve the important public policy outcomes that successful litigation against the tobacco industry would bring. In Australia, it is unrealistic to leave the task of bringing the tobacco industry to legal account, and enforcing the *Trade Practices Act 1974* (Cth) against it, to dying individuals and their families. All attempts at litigation against the tobacco industry thus far by individuals in Australia have shown that the industry can simply overpower individual litigants – it can win cases without the merits of the claims ever being tested.

In our view, if appropriate action is not taken by the Commission under the Act, it is unlikely that the tobacco industry will be brought to account for its conduct in Australia. Not only will this see the Act go unenforced against the tobacco industry, it will also ensure that the community bears enormous costs that, in our view, should properly be borne by the tobacco industry, and could be recovered through successful litigation.

Conduct in contravention of the Act

In our view, the tobacco industry has engaged in, and continues to engage in, a wide range of conduct that has contravened, and continues to contravene, the Act, and that has caused, and continues to cause, great harm to Australian consumers and to the Australian community as a whole. In its report to the Senate, the Commission referred to the fact that there have been

health warnings on cigarette packs for quite some time now (since 1974) and that people are generally aware that smoking is harmful, and said:

> Because of these warnings it is difficult to suggest that consumers could be misled or deceived that smoking was safe by reason of the availability of cigarettes, or by reason of an alleged failure by the tobacco companies to warn consumers about the dangers of smoking.
>
> Any failure by tobacco companies to disclose information of this kind must be considered with the surrounding facts and circumstances. For this reason it can be argued that the presence of warning labels means that tobacco companies are not representing that cigarettes are safe.

In our view, such an approach reflects a complete failure to come to terms with the conduct of the tobacco industry and its many long-term contraventions of the Act. It has never been the law that a tobacco manufacturer cannot contravene the Act unless it represents that its products are safe. Whether or not the tobacco industry has represented that its products are "safe" is not the central issue.

In our view, the tobacco industry has engaged in a wide range of conduct that involves contraventions of the Act. That conduct includes:

1. False and misleading statements about, and false and misleading advertising of, tobacco products over a long period of time during which the tobacco manufacturers sought to deny or downplay evidence of the harms and addictiveness of smoking, notwithstanding that documents that have come to light through litigation and a US Food and Drug Administration investigation in the US reveal that they have known of these harms since at least the early 1950s and of the addictiveness of nicotine since at least the early 1960s. Such conduct has played a significant role in encouraging people to use the tobacco manufacturers' products, and to suffer harm by doing so, and has been at the heart of successful legal claims in the US, both by individuals and state governments.

2. Misleading and deceptive conduct in the failure to inform consumers of the harms caused by smoking that are not specifically required to be disclosed on cigarette packs. We are concerned, in particular, about two categories of conditions:
   - those where the nature of what is lost by the person suffering the condition is substantially different from what is lost in the case of the conditions of which consumers may be "generally" aware. These include conditions which injure women's reproductive health (such as reduced fertility, early menopause and cervical cancer), impotence in men, blindness, miscarriage and sudden infant death syndrome (SIDS); and
   - those where the early detection and treatment of the condition may make the difference between dying as a result of the condition and surviving it – such as bladder cancer or colorectal cancer.

   The question here is not whether consumers are deceived into believing that smoking is safe. It is whether the information that would allow them to make informed decisions about the harms they face, and promptly attend to the signs of harm when they first materialise, is properly communicated to them.

   The organisations' submission to the Commission included a lengthy discussion of the way that "silence" is treated by the Courts in the context of section 52 of the Act, and the

jurisprudence which has developed to focus on the "reasonable expectation" of consumers of the disclosure of information; ie in this case: Would consumers, to whom tobacco companies have marketed and advertised their products for decades, and to whom they continue to market and advertise (albeit now through more limited means than in the past), have a reasonable expectation that tobacco companies would inform them that smoking increases their risks of suffering damage to reproductive health, impotence, blindness, miscarriage and sudden infant death syndrome, and conditions such as bladder cancer and colorectal cancer, where early detection and treatment may make the difference between life and death? The submission makes the case that the ongoing manufacture, sale, marketing and advertising of cigarettes, in the absence of the disclosure of this information, is misleading and deceptive. It provides both judicial and academic authority for that case.

3. The marketing of products described as "low-tar", "light" and "mild", in the knowledge that consumers believe these products to be less harmful than "regular" cigarettes, and to discourage them from trying to give up cigarettes, while the manufacturers know, and have known, that they are and were not less harmful and have actively sought to design them to ensure that the amount that smokers would take in when smoking would be substantially different from the amounts that machine-testing would show. Examples of evidence to this effect, in respect of conduct within the British American Tobacco and Philip Morris groups of companies, that has emerged in the US are included in Appendices One and Two.

   The Commission has, at intervals, over the last three or so years stated that it is investigating this issue to determine whether to bring proceedings under section 52 of the Act. It is now more than three years since this investigation commenced in February 2001. It is difficult for us to accept that this issue has ever been a serious priority for the Commission, given the length of time that has passed without any action. We hope that the Commission is genuinely examining this issue, but the perception has developed that any time the Commission is questioned or criticised, or knows it is about to be questioned or criticised, with respect to its failure to do anything about tobacco, it simply states that it is still investigating this issue.

4. The design and precise engineering of products in ways that make them more addictive and thus harder to quit.

   The tobacco industry has long known of the addictiveness of nicotine and its importance to the industry's profits, and has for a long time designed tobacco products to enhance and capitalise on this addictiveness. In an article published in the Journal of the American Medical Association (JAMA) in February 1997, Kessler et al (of the US Food and Drug Administration) wrote of the "disclosure of thousands of pages of internal tobacco company documents revealing that the tobacco manufacturers know that nicotine causes significant pharmacological effects, including addiction, and design their products to provide pharmacologically active doses of nicotine"[14].

14 Kessler, Barnett, Witt, Zeller, Mande, Schultz, The Legal and Scientific Basis for FDA's Assertion of Jurisdiction Over Cigarettes and Smokeless Tobacco, JAMA, February 5, 1997 – Vol 277, No. 5.

Documents released in the US over the last ten or so years evidence both of these matters within the BAT and Philip Morris groups of companies: knowledge of addictiveness, and design of products to capitalise on addictiveness. A sample of these documents is set out in Appendices Three, Four, Five and Six.

Four further Appendices (Appendices Seven through Ten) dealing with these issues are attached.

Appendix Seven is an expert report of William A. Farone, Ph.D., submitted in the case of *United States v. Philip Morris Inc, et al.* on November 15, 2001. Dr Farone was Director of Applied Research for Philip Morris Inc. in Richmond, Virginia, between 1977 and 1984. In part C of his expert report, titled "Cigarettes are designed by the tobacco industry to develop and create addiction", Dr Farone states that tobacco products "are designed to induce addiction, and thus to ensure lifelong customers – who engage in lifelong self-administration of lethal doses of toxic substances that are delivered along with nicotine". He then explains, in detail, how the products are designed to achieve these goals. Then, on pages 24-26, Dr Farone explains the use of ammonia which is "significant because it increases nicotine delivery levels, which … are important to create, maintain and satisfy nicotine addiction".

Appendix Eight is the JAMA article referred to above, by Dr David Kessler (former US Food and Drug Administration Commissioner) et al. On pages 406-7, under the heading, "Manufacturer statements, research, and actions", the authors set out what was then "newly disclosed evidence showing that tobacco companies expect their products to be used by consumers for pharmacological purposes and have designed their products to be pharmacologically active". The evidence "included 3 decades of tobacco industry statements, research, and actions". "The record before the agency showed that several methods of enhancing nicotine delivery are commonly used in the manufacture of commercial cigarettes." These include: tobacco blending "to raise the nicotine concentration in low-tar cigarettes"; "the use of filter and ventilation systems that by design remove a higher percentage of tar than nicotine"; and "the addition of ammonia compounds that increase the delivery of "free" nicotine to smokers by raising the alkalinity or pH of tobacco smoke".

Appendix Nine is the transcript of testimony given by Dr Kessler to the US House of Representatives Sub-Committee on Health and the Environment, Committee on Energy and Commerce on 25 March 1994, published under the title "Statement on nicotine-containing cigarettes". On page 150 Dr Kessler says: "The history of the tobacco industry is a story of how a product that may at one time have been a simple agricultural commodity appears to have become a nicotine delivery system."

Appendix Ten is a transcript of further evidence given to the Sub-Committee by Dr Kessler on 21 June 1994 in relation to the genetic and chemical manipulation of nicotine content, published under the title, "The control and manipulation of nicotine in cigarettes".

Conclusion

In short, the conduct of the tobacco manufacturers has involved, and in many cases, continues to involve, attempting to take consumers' minds away from the true realities of harm and addictiveness through a wide range of marketing techniques and the disputing of scientific evidence, keeping all information from consumers except that specifically required to be

disclosed by regulations, and designing products in ways that make them more addictive and harder to give up – while knowing that the overwhelming majority of their customers commence using their products in childhood, and that the overwhelming majority would prefer not to be using their products but continue to do so because of addiction.

The Commission's failure to take action

The Commission has, thus far, failed to take any steps with regard to these issues. It has either ignored the allegations, mischaracterised them, or sought to dismiss them with narrow and unjustified readings of the Act and, in one case, by basic legal error. Each of these complaints has been communicated to the Commission.

The reference to basic legal error is a reference to an error in the Commission's report to the Senate, in which it dismissed the possibility of action against the tobacco industry for failing to disclose to consumers that the nicotine delivered by cigarettes is addictive in the period between it first becoming so aware (which the record shows was in the early 1960s, at the latest) and the mandatory label referring to addiction being introduced, by saying that any application would be time-barred because warnings of addiction had been introduced in 1995 and the statutory limitation period had already expired.

This was a basic legal error – the statutory time limitation period referred to by the Commission only begins to run once a cause of action accrues. The law is clear that a cause of action accrues not when a contravention of the Act occurs, but when loss or damage is suffered as a result of such contravention. The introduction of a warning about addiction in 1995 is therefore of little relevance to the time limitation period. A person who, for example, commenced smoking before 1995, while the tobacco industry was choosing not to disclose its knowledge of the addictiveness of nicotine, and who became addicted to cigarettes, would have either three or six years (depending on when their cause of action accrued) to bring a claim from the time they suffered damage as a result of smoking. Many of these people would have become sick in the last six years, and would still be within their statutory time limitation period. Many will become sick in the future – their time limitation period has not yet begun to run. The reference to applications now being "time-barred" was simply wrong.

The organisations made this point to the Commission in their response of May 2002. In October 2003, the Commission admitted this error to the Senate, but it has shown no interest in pursuing the matter notwithstanding that it had claimed it could not be pursued on the basis of its erroneous position that the time limitation period had expired.

The Commission has also persisted with a very narrow reading of section 51AB of the Act (unconscionable conduct in connection with the supply or possible supply of goods and services), insisting that it can only apply where there is a direct relationship between the manufacturer and consumer, and that, because there is no such direct relationship between tobacco manufacturers and consumers – the relationship being between retailer and consumer – the section cannot apply to the conduct of tobacco manufacturers. Yet there is nothing in section 51AB or any case law applying or interpreting it that requires it to be so confined.

Section 51AB(1) states:

> *A corporation shall not, in trade or commerce, in connection with the supply or possible supply of goods or services to a person, engage in conduct that is, in all the circumstances, unconscionable.*

Sub-section (6) states:

> *A reference in this section to the supply or possible supply of goods does not include a reference to the supply or possible supply of goods for the purpose of re-supply or for the purpose of using them up or transforming them in trade or commerce.*

The relevant legal question, according to these two sub-sections, is, therefore, whether the relevant conduct is "in connection with the supply or possible supply of goods or services to a person". There is no requirement in the section that the conduct be engaged in by the person who actually physically supplies the goods to the end consumer. The conduct must be in connection with the supply or possible supply to the consumer, ie it must be operative at the point of supply/purchase. Referring to sub-sections (5) and (6), Goldring and Maher, in an article titled 'What is Unconscionability?' (1994) 1 Competition and Consumer Law Journal 230 at 234, write: "These subsections show an intention that the section is to apply principally for the benefit of the *ultimate* consumers of goods or services of a non-commercial character." (emphasis added)

The purpose underlying the inclusion of sub-sections (5) (which provides that the goods in question must be for domestic or personal use) and (6) is to limit the application of section 51AB. However, their inclusion is not designed to limit the bringing of an action by the ultimate consumer – rather they are designed to preclude the bringing of an action by a person who is not the ultimate consumer, such as a retailer, who has recourse under section 51AC (unconscionable conduct in business transactions). This conclusion is reinforced by the Explanatory Memorandum to the Act which introduced section 51AB, para 87 of which states:

> "The section is limited to unconscionable conduct in relation to consumer type purchases by virtue of sub-sections (5) and (6)."

Thus, the intention is to apply section 51AB to "consumer type purchases". A person making a "consumer type purchase" should be protected from unconscionable conduct. That means unconscionable conduct which is operative at the point of purchase – its precise origin is of less import than its effect.

The notion of unconscionable conduct is of particular importance in this context given the meaning of the word "unconscionable"[15], and the fact that the relationship between the tobacco manufacturers and their consumers relies, in most cases, on the creation and exploitation of addiction. As we have said, there is nothing in the Act or case law that says that a corporation cannot engage in unconscionable conduct under section 51AB unless it actually supplies the goods or services to the ultimate consumer.

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15 In Hurley v McDonald's Australia Ltd (2000) ATPR 41-741, Heerey, Drummond and Emmett JJ said at 40,584 that they should not be taken to agree with the trial Judge's approach, which equated the concept of unconscionable conduct in section 51AA with that in sections 51AB and 51AC. Their Honours continued at 40,585: "For conduct to be regarded as unconscionable, serious misconduct or something clearly unfair or unreasonable, must be demonstrated - Cameron v Qantas Airways Ltd (1994) 55 FCR 147 at 179. Whatever "unconscionable" means in sections 51AB and 51AC, the term carries the meaning given by the Shorter Oxford English Dictionary, namely, actions showing no regard for conscience, or that are irreconcilable with what is right or reasonable - Qantas Airways Ltd v Cameron (1996) 66 FCR 246 at 262. The various synonyms used in relation to the term "unconscionable" import a pejorative moral judgment - Qantas Airways Ltd v Cameron (1996) 66 FCR 246 at 283-4 and 298." In Garry Rogers Motors (Aust) Pty Ltd v Subaru (Aust) Pty Ltd (1999) ATPR 41-703, Finkelstein J said, in relation to s.51AC, at 43,016: "I take as the measure of unconscionability, conduct that might be described as unfair."

Thus, while the term "unconscionable" in section 51AB cannot be precisely defined, it is clear that it looks at notions of unfairness, unreasonableness and lack of conscience.

What proceedings could achieve

In our view, there is substantial scope for proceedings brought by the Commission in relation to these issues to have very real, practical effects.

The Court's powers to grant remedial injunctions

First, section 80 allows the Federal Court, on the application of the ACCC, to grant an injunction "in such terms as the Court determines to be appropriate", where, inter alia, the Court is satisfied that a person has engaged in misleading or deceptive or unconscionable conduct. The Court can make both orders requiring a party to refrain from certain conduct, and orders requiring a party to do something. Section 80 confers a broad power on the Court - it allows the Court to grant an injunction "in such terms as [it] determines to be appropriate". The breadth of this power, as long as it is exercised within the scope and purposes of the Act, has been repeatedly emphasised by the Federal Court. For example, in *ACCC v. Z-tek Computer Pty Ltd* (1997) 148 ALR 339 Merkel J said at 343 that: "The width of the power conferred by s 80 and its public interest character obviously give the court great amplitude in determining appropriate injunctive orders in a particular case."

In *Truth About Motorways* [2000] HCA 11, Gummow J at [80] described the mandatory injunction sought in that case as "apt to counterbalance the injury to the public interest" allegedly sustained by the relevant conduct. Thus, in exercising its powers under section 80, the court looks to protect the public interest, including by making orders designed to undo the damage, or "counterbalance the injury", done to the public interest by the contravening conduct.

We think that, given the past and ongoing conduct of the tobacco industry, section 80 would support a broad range of mandatory and prohibitive injunctions against the tobacco industry, including:

- requiring the tobacco industry to provide the funding for, without controlling the content of, consumer education / corrective advertising required to adequately inform consumers of the magnitude and full range of the health risks of smoking;
- requiring the tobacco industry to provide assistance to consumers addicted to their products and wanting to give up;
- prohibiting the use of misleading terms such as "light" and "mild";
- prohibiting the use of trade marks, logos and imagery which, through misleading communications of the past, have been imbued with meaning that is substantially at odds with the harmful, addictive reality of tobacco products;
- requiring the industry to disclose all information within its power, custody or control in respect of the health risks of smoking;
- requiring the industry to disclose all information within its power, custody or control in respect of the addictiveness / physiological effects of tobacco products, and the ways in which addictiveness / physiological effects are affected by methods of product manufacture and design;
- requiring the industry to disclose all information within its power, custody or control in respect of steps it has taken to encourage or induce consumers to use its products.

Each of these orders would flow rationally and reasonably from the contravening conduct – as a way of counterbalancing the injury done to the public interest.

Recovery of damages by individuals and expenditure by the Commonwealth

Second, any proceedings brought by the Commission would play a very substantial role in assisting individuals who had claims to pursue those claims, and, in so doing, also assist in the recovery of public expenditure on tobacco-related disease. Under the *Health and Other Services (Compensation) Act* 1995, successful litigants are required to reimburse the Commonwealth for Medicare expenditure, nursing home benefits and residential care subsidies. The *Social Security Act 1991 (Cth)* contains similar provisions that allow the Commonwealth to recover social security payments including sickness allowance, disability support pension, and age pension. Given the enormous health care and social security costs caused by tobacco-related disease, successful recovery by individuals could return to the public purse large amounts of public expenditure that should, in our view, properly be borne by the tobacco industry.

Recovery of public expenditure could be maximised if legislation of the kind referred to above were extended to include both the recovery of expenditure under the Pharmaceutical Benefits Scheme (PBS), and expenditure incurred by the States for care provided in public hospitals. The former was presumably not included in the *Health and Other Services (Compensation) Act* 1995 on the basis that it was not possible at that time to retrospectively identify, on the PBS database, prescriptions dispensed for a particular individual. As patients' Medicare numbers are now included on PBS prescriptions, it would now be possible to determine, for an individual, government subsidies for PBS prescriptions.

The most recent estimate of the magnitude of potentially recoverable expenditure for health care for tobacco-related disease is $1.044 billion each year[16]. This estimate includes Medicare, nursing home, PBS and hospital expenditure. However, recoverable health care expenditure may be as much as three times this estimate, in view of the most recent US Surgeon General's report on smoking[17]. This exhaustive report confirmed that smoking is associated with many diseases for which an association had previously been suspected. When the US Surgeon General's estimate of the annual cost of medical care attributable to smoking is extrapolated to the Australian population, and adjusted for medical care price differences, an estimate of $3.472 billion per year is obtained for recoverable health care expenditure. An estimate of the likely magnitude of recoverable social security expenditure for tobacco-related disease is not available for Australia.

Proceedings by the Commission could assist in this regard in two primary ways. Any finding made by a court in proceedings under section 80 could be used by a person bringing a proceeding for damages under section 82 or section 87 of the Act. Or the Commission could use its powers under section 87 to bring a representative proceeding on behalf of individuals affected by the tobacco industry's conduct.

We are not suggesting that every dollar of these amounts would actually be recovered or that every individual who potentially has a claim will bring one and will do so successfully. Rather, we are highlighting the fact that very substantial sums of public money are potentially at stake, and that very significant recovery should be possible through strong, well-resourced legal proceedings.

16 D Collins and H Lapsley, Counting the cost: estimates of the social costs of drug abuse in Australia in 1998-99, Canberra: Commonwealth Department of Health and Ageing; 2002.

17 US Surgeon General, The Health Consequences of Smoking: A report of the Surgeon General, 2004, http://www.cdc.gov/tobacco/sgr/sgr_2004/index.htm

Conclusion

In our view, the Commission has, thus far, failed to enforce the *Trade Practices Act 1974* (Cth) against the tobacco industry, and it has not provided a satisfactory explanation for this failure. The Commission's failure to enforce the Act against the tobacco industry has, in our view, been an important factor in allowing the tobacco industry to operate as if it were above consumer protection law, and, in so doing, to cause great harm to individuals and enormous costs to the Australian community as a whole. Strong enforcement of the Act against the tobacco industry would deliver significant public policy and public health benefits, and facilitate the recovery of large amounts of public expenditure on health and social security costs, which will otherwise continue to be borne by the Australian taxpayer, rather than the tobacco industry, which is primarily responsible for them.

Appendix One

Use of misleading 'light', 'mild, 'low tar' terminology within the British American Tobacco group of companies

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Use of misleading "light", "mild", "low tar" terminology within the British American Tobacco group of companies

12 January 1974
"Smoker adjusts his pattern to deliver his own nicotine requirements"
Notes from the Annual BAT Research Conference show that a BAT German study has shown that "whatever the characteristics of cigarettes as determined by smoking machines, the smoker adjusts his pattern to deliver his own nicotine requirements".[1]

13 February 1975
"The question as to whether such cigarettes are really safer does not matter"
An internal BAT memo written by R.M. Gibb to Dr. S. Green about Safer Cigarettes outlines "Product Development" (to cope with current governmental S&H [smoking and health] pressures). This is what our management really expects R&D to do. Things like marketable low tar and nicotine cigarettes ...The question as to whether such cigarettes are really safer does not matter, although privately even our Health people wonder whether low tar and nicotine cigarettes are a good idea. I think the research going on into the smoker's response to such modified cigarettes comprise genuine inquiry in the smoking and health field, examining what I call the 'involuntary moderation' concept of a safer cigarette".[2]

30 January 1976
"Many established smokers do compensate for changed delivery in an attempt to equalise nicotine delivery, when this is possible".
A BAT Research document entitled "Compensation for Changed Delivery" concludes that "many established smokers do compensate for changed delivery in an attempt to equalise nicotine delivery, when this is possible".[3]

14 April 1977
Alleviate anxiety over health "and enable the smoker to feel assured about the habit and confident in maintaining it over time".
P. L Short, from BAT writes a paper on " Smoking and Health: the Effect on Marketing", commenting that "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 claiming low deliveries, by the perception of low deliveries and by the perception of 'mildness'. Furthermore, advertising for low delivery or traditional brands should be constructed in ways so as not to provoke

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[1] S. Green, The Group Research & Development Conference at Duck Key, Florida, 1974, 12 January {1125.01}in "Chronology: Cigarette Design" – choose www.ash.org.uk, choose 'Links', 'Industry Documents', 'Chronologies', 'Cigarette Design'.
[2] R.M.Gibb, Memo to Dr.S.Green, 1975, 13 February [L&D RJR / BAT 23] in "Chronology: Cigarette Cigarette Design" – choose www.ash.org.uk, choose 'Links', 'Industry Documents', 'Chronologies', 'Cigarette Design'.
[3] BAT Group Research and Development Centre, Compensation for Changed Delivery, Report No.RD. 1300, Restricted, 1976, 30 January {Minn. Trial Exhibit 13,540} in "Chronology: Cigarette Cigarette Design" – choose www.ash.org.uk, choose 'Links', 'Industry Documents', 'Chronologies', 'Cigarette

anxiety about health, but to alleviate it, and enable the smoker to feel assured about the habit and confident in maintaining it over time".[4]

21 September 1977
Ways to develop cigarettes with deliveries to smoker different from machine delivery
A BAT memo outlines how "it should now be possible to design a number of cigarettes which would have the same smoking machine delivery but different deliveries to the compensating smoker. Broadly speaking, this could be achieved by developing cigarettes with a knowledge of the smoker's response to such factors as pressure drop, ventilation, irritation, impact, nicotine delivery, etc."[5]

14 April 1978
Smokers increase the volume of drawn smoke as standard deliveries reduced by manufacturer. We have not yet observed a smoker who smokes to the same patterns as a standard smoking machine".
A BAT report states that "we have found a trend within the department for smokers to increase the volume of smoke drawn from cigarettes as the standard deliveries have been reduced by manufacturers … we also observed … a degree of compensation for reduced delivery when a ventilated cigarette was smoked."

The report later states that "it can be assumed that, due to the interaction between smokers and the cigarettes that they smoke, cigarettes are unlikely to be smoked by people in the same way as a standard smoking machine. We have not yet observed a smoker who smokes to the same patterns as a standard smoking machine".[6]

27 June 1978
"In general a majority of habitual smokers compensate for changed delivery, if they change to a lower delivery brand."
David Creighton from BAT writes a paper on "Compensation for Changed Delivery": "It is generally accepted that a large number of habitual smokers are influenced in their smoking habit by the amount of nicotine that they draw from a cigarette. Over a period of time, during which they are learning to smoke effectively - that is so they do not make themselves feel ill, but do derive pleasure and satisfaction from smoking - they probably build up an association in their minds between the mouth sensations such as flavour, irritation and "impact" and the amount of smoke that gives them the satisfaction of smoking. This is a similar mechanism to Pavlov's dogs".

"Compensation may be defined as:- 'Subconscious changes made to the smoking pattern by a smoker in an attempt, which may or may not be successful, to equalise the deliveries of products which have different deliveries when smoked by machine under standard conditions"

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[4] "Document PSC044". . On TDO: http://tobaccodocuments.org/psc_who/PSC044.html.
[5] F. Haslam, Memo Re, Compensation, 1977, 21 September {Minn. Trial Exhibit 10,488} in "Chronology: Cigarette Design, www.ash.org.uk, choose "Links', "Industry documents', 'Chronologies', 'Cigarette Design' .
[6] D E Creighton, Measurement of the Degree of Ventilation of Cigarettes at Various Flow Rates, Report No RD. 1576, Restricted, 1978, 14 April, {Minn. Trial Exhibit 17,777} in "Chronology: Cigarette Design, www.ash.org.uk, choose "Links', "Industry documents', 'Chronologies', 'Cigarette

"Numerous experiments have been carried out in Hamburg, Montreal and Southampton within the company, as well as many other experiments by research workers in independent organisations, that show that generally smokers do change their smoking patterns in response to changes in the machine smoked deliveries of cigarettes."

"It is difficult to ignore the advice of Health Authorities who advise smokers to give up smoking or change to a lower delivery brand but there 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."[7]

[7] D. Creighton, *Compensation for Changed Delivery*, BATCo, 1978, 27 June [Minn 11,089] in "Chronology: Cigarette Design, www.ash.org.uk, choose "Links', "Industry documents',

Appendix Two

Use of misleading 'light', 'mild, 'low tar' terminology within the Philip Morris group of companies

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Use of misleading "light", "mild", "low tar" terminology within the Philip Morris group of companies

Phillip Morris

1974
"Generally, people smoke in such a way that they get more than predicted by machines."
An internal Philip Morris document titled "Some unexpected observations on tar and Nicotine and Smoker Behaviour says: "Generally, people smoke in such a way that they get more than predicted by machines."

Undated
Retain the FTC standardized test – "it gives low numbers"
"The FTC standardized test should be retained: (1) it gives low numbers; (2) it permits comparisons between brands."[1]

17 September 1975
No reduction in smoke intake by smoking Marlboro Light.
Barbro Goodman , from Philip Morris writes an internal memo to L Meyer, outlining that "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.

The report later states in its conclusions that "(t)he smoker data collected in this study are in agreement with results found in other project studies. The panelists smoked the cigarettes according to physical properties; ie. the dilution and the lower RTD of Marlboro Lights caused the smokers to take larger puffs on that cigarette than on Marlboro 85's. The larger puffs in turn increased the delivery of Marlboro Lights proportionately. In effect, the Marlboro 85 smokers in this study did not achieve any reduction in smoke intake by smoking a cigarette (Marlboro Lights) normally considered lower in delivery."[2]

October 1975
"Chang[e] the image of low delivery cigarettes so that smokers believe a flavourful cigarette can really be 'healthy'".
An internal Philip Morris research paper states: "One goal is to come up with a low delivery cigarette that will appeal to current low delivery cigarette smokers … Furthermore, some portion of current low delivery smokers may desire to switch to a more flavourful cigarette and others may follow as consumer experience results in

[1] Philip Morris Cos., Inc. "Human Smoking Behavior". 19832606. Bates: 2500126796-2500126862. On TDO: http://tobaccodocuments.org/bliley_pm/26987.html.
[2] L.F. Meyer, Inter-office memorandum to B. Goodman. Philip Morris USA, 1975, 17 September [Minn trial exhibit 11,564] in "Chronology: Cigarette Design, www.ash.org.uk, choose "Links',

changing the image of low delivery cigarettes so that smokers believe a flavorful cigarette can really be "healthy"".[3]

March 1977
"They may be smoking more ...to compensate for the decreases in the tar and nicotine delivery of their cigarettes".
William Dunn, a research scientist at Philip Morris co-authors a report: "We find that our smokers [were] smoking cigarettes in 1972 that delivered significantly less tar and nicotine than in 1968. At the same time they were smoking more cigarettes as well as more of the rod [farther down the tobacco portion] from each cigarette. These findings suggest ...that a tar and nicotine quota mechanism may be operative. That is, they may be smoking more ...to compensate for the decreases in the tar and nicotine delivery of their cigarettes".[4]

[3] Jones, B.; Houck, W.; Martin, P. "Low Delivery Cigarettes and Increased Nicotine/Tar Ratios, A Replication". Jan 1975. Bates: 1003288950-1003288967. On TDO: http://tobaccodocuments.org/ness/4428.html.
[4] R. Kluger, *Ashes to Ashes - America's Hundred-Year Cigarette War, the Public Health, and the*

Appendix Three

Knowledge within the British American Tobacco group of companies about the addictiveness of nicotine

Appendix Three

Knowledge within the British American Tobacco group of companies about the addictiveness of nicotine

13 February 1962

Nicotine "is a natural tranquilizer". If the increase in production of tranquilizer drugs continues, and if "such drugs become more freely available they will compete with nicotine".

"If the absorption of nicotine is made pleasant and attractive this enhances the benefits just as in the case of well prepared and well served food. However, the force of the habit or the strength of addiction is not such as to give any grounds for complacency in the face of alternative methods of stimulating the body to meet stress, and that is just where the danger lies since alternative methods are becoming available. In the last few years there has been a quite remarkable increase in the production of tranquilizer drugs, and while most of these need a doctor's prescription there is already one on free sale in Switzerland. If such drugs become more freely available they will compete with nicotine, which was a -- which is a natural tranquilizer, and will leave smoking primarily dependent on its psychological effects for the maintenance of the habit."[1]

30 May 1963

Body craves for renewed drug intake to restore physiological equilibrium

"In a chronic smoker the normal equilibrium in the corticotropin releasing system can be maintained only by continuous nicotine intake. It means that those individuals are but slightly different in their aptitude to cope with stress in comparison with a non-smoker. If nicotine intake, however, is prohibited to chronic smokers, the corticotropin-releasing ability of the hypothalamus is greatly reduced, so that these individuals are left with an unbalanced endocrine system. A body left in this unbalanced status craves for renewed drug intake in order to restore the physiological equilibrium. This unconscious desire explains the addiction of the individual to nicotine."[2]

17 July 1963

Large part of tobacco industry business is administration of nicotine

"It may be useful, therefore, to look at the tobacco industry as if for a large part its business is the administration of nicotine (in the clinical sense)".[3]

24 –27 October 1967

"Smoking is an addictive habit attributable to nicotine …"

BAT's 1967 Research Conference is held in Montreal. Draft minutes list "Assumptions made by R&D scientists": "Smoking is an addictive habit attributable

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[1] February 13th, 1962 BAT memo, "The Effects Of Smoking, Proposal For Further Research Contracts With Battelle," by Sir Charles Ellis, director of research. In 'Secret Tobacco Document Quotes', www.tobacco.org/Documents/documentquotes.html.

[2] May 30, 1963 report, *A Tentative Hypothesis on Nicotine Addiction* produced for the British-American Tobacco Company (Batco) by C. Haselbach and O. Libert of the Battelle Memorial Institute in Geneva Trial Exhibit 13433, in 'Secret Tobacco Document Quotes', www.tobacco.org/Documents/documentquotes.html.

[3] A. Yeaman, 'Implications of the Battelle Hippo I & II and the Griffith Filter," 17 July 1963, Doc No

to nicotine and the form of nicotine affects the rate of absorption by the smoker … It was likely, moreover, that tobacco would be involved in legislation of a food or drug administration nature in respect both of product and of manufacturer." A hand-written note changes "addictive habit" to "habit". The completed minutes state that "There is a minimum necessary level of nicotine. Smoking is a habit attributable to nicotine. The form of nicotine affects the rate of absorption by the smoker".[4]

September 1969
"Nicotine has well documented pharmacological action."
D.J. Wood from R&D at BAT gives a presentation to company executives: "Nicotine has well documented pharmacological action. It is claimed to have a dual effect, acting both as a stimulant and a tranquilliser. It is believed to the responsible for the 'satisfaction' of smoking, using this term on the physiological rather than the psychological sense "[5]

29 March 1976
If nicotine delivery is reduced below a "threshold 'satisfaction' level", smokers "will question more readily why they are indulging in an expensive habit".
"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," Green, senior BAT scientist.[6]

19 May 1977
"[U]nable to stop (by and large) and … would basically prefer to stop (if they could)".
A memo from Dr. Jagger of BAT's Brazilian subsidiary Souza Cruz: "If you ask people why they carry out a practice which they are unable to stop (by and large) and which they would basically prefer to stop (if they could) it is reasonable to expect them to take considerable refuge in justifications – i.e. enjoyment, pleasure, taste, satisfaction, tension relief. etc".[7]

28 August 1979:
We "are searching explicitly for a socially acceptable addictive product". Should consider "the hypothesis that the high profits additionally associated with the tobacco industry are directly related to the fact that the consumer is dependent upon the product".
A BAT document outlines "Key Areas – Product Innovation over the Next 1- Years for Long-Term Development: "We have to satisfy the 'individual' who is either about to give up or has just done so, i.e., in other words, customers in danger of extinction ...we are searching explicitly for a socially acceptable addictive product involving: - A pattern of repeated consumption –A product which is likely to involve repeated

[4]BAT, R&D Conference, Montreal, Proceedings, 1967, 24 October {1165.01}; BAT R&D Conference Montreal, 1967, 24-27 October, Minutes written 8 November Minn. Trial Exhibit 11,332} in 'Chronology 1: Nicotine and addiction', www.ash.org.uk – choose 'Links', 'Industry documents' and then select 'chronologies'.
[5] D. Wood, Aspects of the R&DE Function, Notes for a Talk, Given at Chelwood, 1969, {1184.02}in 'Chronology 1: Nicotine and addiction', www.ash.org.uk – choose 'Links', 'Industry documents' and then select 'chronologies'.
[6] Lewan T, 'Dark Secrets of tobacco company exposed', Tobacco Control 1998; 7: 315-319.
[7] J. A. Jagger, Smoking Enjoyment -Dr. M. Oldman, CIA Souza Cruz Ind. E. Comercio, 1977, 19 May {Minn. Trial Exhibit 11,130} in 'Chronology: Nicotine and addiction', www.ash.org.uk – choose

handling – the essential constituent is most likely to be nicotine or a 'direct' substitute for it".

"...We also think that consideration should be given to the hypothesis that the high profits additionally associated with the tobacco industry are directly related to the fact that the consumer is dependent upon the product. Looked at another way, it does not follow that future alternative 'Product X' would sustain a profit level above most other product/ business activities, unless, like tobacco, it was associated with dependence."[8]

1 January 1980

Large numbers of people will continue to smoke "because they can't give it up. … They can no longer be said to make an adult choice."

Dr SJ Green writes: "It has been suggested that cigarette smoking is the most addictive drug. Certainly large numbers of people will continue to smoke because they can't give it up. If they could they would do so. They can no longer be said to make an adult choice".[9]

11 April 1980

BAT should "look at itself as a drug company"

"…BAT should learn to look at itself as a drug company rather than as a tobacco company.[10]

1980

"Smoking is addictive" and "many smokers would like to give up the habit if they could".

A 1980 BATCO document clearly acknowledges that "smoking is addictive" and that "many smokers would like to give up the habit if they could".[11]

8 August 1991

The "unique property of inhaled cigarette, the delivery of unchanged nicotine to the brain occurring a few seconds after taking a puff".

Linda Rudge, a BAT Information Scientist, writes about "Smoking Cessation Methods", commenting that: "Overall, most methods have achieved, at best, only moderate success because they cannot imitate the unique property of inhaled cigarette, the delivery of unchanged nicotine to the brain occurring a few seconds after taking a puff".[12]

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[8] BAT, Key Areas - Product Innovation - Over Next Ten Years For Long-term Development, 1979, 28 August [Minn 11,283] in 'Chronology 1: Nicotine and addiction', www.ash.org.uk – choose 'Links', 'Industry documents' and then select 'chronologies'.

[9] Dr S J Green, Transcript of Note By SJ Green, 1980, 1 January [pollock 129] in 'Chronology 1: Nicotine and addiction', www.ash.org.uk – choose 'Links', 'Industry documents' and then select 'chronologies'.

[10] BAT, "Brainstorming 11, What Three Radical Changes Might, Through the Agency of R&D, Take Place in this Industry by the End of the Century," 11 April 1980, Minnesota Trial Exhibit 11361, Bates no 109884190-91 in 'Trust Us: We're the Tobacco Industry', Campaign for Tobacco-Free Kids (USA), Action on Smoking and Health (UK), www.ash.org.uk/html/conduct/html/trustus.html.

[11] Derek Yach, Douglas Bettcher, 'Globalisation of tobacco industry influence and new global responses,' Tobacco Control 2000; 9: 206, 208.

[12] L. Rudge, Smoking Cessation Methods, 1991, 7 August {Minn. Trial Exhibit 12,392} in 'Chronology 1: Nicotine and addiction', www.ash.org.uk – choose 'Links', 'Industry documents' and

Appendix Four

Knowledge within the Philip Morris group of companies about the addictiveness of nicotine

Appendix Four

Knowledge within the Philip Morris group of companies about the addictiveness of nicotine

1969

The "primary motivation for smoking is to obtain the pharmacological effect of nicotine".

"[T]he primary motivation for smoking is to obtain the pharmacological effect of nicotine. In the past, we at R&D have said that we're not in the cigarette business, we're in the smoke business. It might be more pointed to observe that the cigarette is the vehicle of smoke, smoke is the vehicle of nicotine, and nicotine is the agent of a pleasurable body response."[1]

1972

"[I]t is likely that greater numbers smoke for the narcotic value that comes from the nicotine".

An internal Philip Morris memo by a company scientist says that: "A widely held theory holds that most people smoke for the narcotic effect (relaxing, sedative) that comes from the nicotine. The taste comes for the 'tar' delivery (particulate matter) delivery. Although more people talk about 'taste', it is likely that greater numbers smoke for the narcotic value that comes from the nicotine".[2]

1972

"No one has ever become a cigarette smoker by smoking cigarettes without nicotine. Most of the physiological responses to inhaled smoke have been shown to be nicotine related."[3]

14 February 1973

"[N]icotine is the active constituent of cigarette smoke. … Most of the physiological responses to inhaled smoke have been shown to be nicotine-related. … The cigarette should be conceived not as a product but as a package. The product is nicotine. …"

William Dunn Jr. of Philip Morris addresses a conference in the Caribbean: "The majority of the conferees would go even further and accept the proposition that nicotine is the active constituent of cigarette smoke. Without nicotine, the argument goes, there would be no smoking …No one has ever become a cigarette smoker by smoking cigarettes without nicotine. Most of the physiological responses to inhaled smoke have been shown to be nicotine-related …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

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[1] T. Osdene, 'Why One Smokes, First Draft, 1969, Trial Exhibit 3681, Bates Number 1003287836-48 in 'Trust Us: We're the Tobacco Industry', Campaign for Tobacco-Free Kids (USA), Action on Smoking and Health (UK), www.ash.org.uk/html/conduct/html/trustus.html.

[2] *The Guardia*n, Kool Cigarettes "Keep you High for Longest", 1996, 24 October, p15 in Chronology: Nicotine and addiction', www.ash.org.uk – choose 'Links', 'Industry documents' and then select 'chronologies'.

[3] Dunn WL Jr. Motives and incentives in cigarette smoking. Philip Morris, 1972. Trial exhibit 18089 in

nicotine ..Smoke is beyond question the most optimized vehicle of nicotine and the cigarette the most optimized dispenser of smoke".[4]

16 March 1983

"Tolerance" is one of the criteria of substance dependence according to the American Psychiatric Association's Diagnostic and Statistical Manual of Mental Disorders. "Tolerance to nicotine is a well established fact."

An internal Philip Morris document states that: "The third edition of the American Psychiatric Association's Diagnostic and Statistical Manual of Mental Disorders defines substance dependence as '…requires physiological dependence, evidenced by either tolerance or withdrawal'. The key word is either. We can successfully defend the absence of withdrawal under controlled experiments, but we cannot defend tolerance. Tolerance to nicotine is a well established fact".[5]

20 March 1984

"People continue to smoke because they find it too uncomfortable to quit."

A Report for Philip Morris into the "Cigarette Consumer" highlights how "People continue to smoke because they find it too uncomfortable to quit. Over 85 per cent of smokers agree strongly/ very strongly to 'I wish I had never began (sic) smoking'. Over 80 per cent claim to have had (sic) attempted to quit".[6]

1985

"[T]he majority of smokers wished they did not smoke …"

"I realize that research tells us that the majority of smokers wished they did not smoke and are, therefore, unlikely to be of much help to the industry ... My guess is that a large number of our smokers must take the view that, though they may try to quit, they will probably not be successful. Having faced up to the fact that they will probably continue to smoke, I cannot believe that they will willingly accept higher taxes on cigarettes"[7]

1992

Primary reason for smoking is "to deliver nicotine" to the body. Nicotine is a "physiologically active" substance.

"Different people smoke for different reasons. But the primary reason is to deliver nicotine into their bodies. Nicotine is an alkaloid derived from the tobacco plant. It is a physiologically active, nitrogen-containing substance. Similar organic chemicals include nicotine, quinine, cocaine, atropine and morphine. While each of these

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[4] Darnell, Alan. "Memorandum RE: Phillip Morris documents". 01 Sep 1987. On TDO: http://tobaccodocuments.org/landman/28340.html.

[5] J. L. Charles, Re Why People Smoke, Philip Morris, 1983, 16 March {Minn. Trial Exhibit 2536} in 'Chronology: Nicotine and addiction', www.ash.org.uk – choose 'Links', 'Industry documents' and then select 'chronologies'.

[6] Philip Morris, The Cigarette Consumer, 1984, 20 March {Minn. Trial Exhibit 11,899} in Chronology: Nicotine and addiction', www.ash.org.uk – choose 'Links', 'Industry documents' and then select 'chronologies'.

[7] 1985 PM document, "Smoking and Health Initiatives - P.M. International" (Bates numbers 2023268329 - 49.) in "Using the most addicted smokers". . On TDO: http://tobaccodocuments.org/landman/178716.html.

substances cab be used to affect human physiology, nicotine has a particularly broad range of influence."[8]

Undated

Without nicotine "the cigarette market would collapse … and we'd all lose our jobs and consulting fees"

"Without the chemical compound, the cigarette market would collapse, P.M. would collapse, and we'd all lose our jobs and consulting fees".[9]

[8] PMI. "re: Philip Morris Draft Report Regarding Proposal for a 'Safer' Cigarette". 1992. On TDO: http://tobaccodocuments.org/ness/9583.html.

[9] Philip Morris Cos., Inc. "Human Smoking Behavior". 19832606. Bates: 2500126796-2500126862.

Appendix Five

Control of nicotine delivery within the British American Tobacco group of companies

Appendix Five
Control of nicotine delivery within the British American Tobacco group of companies

7 August 1964
The kick of a cigarette is "a product of the quantity of nicotine in the smoke and the speed of transfer of that nicotine from the smoke to the blood-stream."
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 blood-stream."[1]

30 September 1966
Increased smoker response "is associated with nicotine reaching the brain more quickly". The higher the pH, the greater the percentage of extractable nicotine.
"[I]t would appear that the increased smoker response is associated with nicotine reaching the brain more quickly."... The report later states that "it appears reasonable to assume that the increased response of a smoker to the smoke with a higher amount of extractable nicotine may be either because this nicotine reaches the brain in a different chemical form or because it reaches the brain more quickly.[2] The report goes on to say that, for both tobacco and smoke, the higher the pH, the greater the percentage of extractable nicotine.

30 September 1966
"Free nicotine" reaches the brain faster, and gives a more addicting "kick"
Dr JD Backhurst, who delivered the report on 30 September 1966, at BAT's laboratory in Southampton, England, had confirmed that nicotine exists in two chemical forms—not one, as had been generally assumed. The first is the "bound" form, which the body has trouble absorbing. The other is the "free" form, which passes instantly through the mouth, throat and lungs and into the bloodstream. Free nicotine reaches the brain faster, and, Backhurst demonstrated, gives the smoker a more addicting "kick."[3]

29 March 1976
Danger of reducing nicotine below a threshold "satisfaction" level
"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," wrote Green, the senior BAT scientist, on 29 March 1976".[4]

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[1] Anderson HD. Potassium carbonate. Memo to R. P. Dobson, BAT, August 7, 1964. Trial exhibit 10356 in Hurt R.; Robertson C, 'Prying Open the Door to the Tobacco Industry's Secrets About Nicotine: The Minnesota Tobacco Trial', Journal of the American Medical Association, October 7, 1998-Vol 280, No. 13, p. 1173.

[2] Blackhurst JD. Further work on "extractable" nicotine. Report issued by I.W. Hughes, BAT, September 30, 1966. Trial exhibit 17825 in Hurt R; Robertson C, 'Prying Open the Door to the Tobacco Industry's Secrets About Nicotine: The Minnesota Tobacco Trial', Journal of the American Medical Association, October 7, 1998-Vol 280, No. 13, p. 1173.

[3] in Lewan T, 'Dark Secrets of tobacco company exposed', Tobacco Control 1998; 7: 315-319.

7 April 1982

Offer high nicotine deliveries so that, with a minimum of effort, smoker can take the dose to meet immediate needs

"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.... 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.""[5]

12 November 1984

Nicotine "may be presented to the smoker in at least three forms". "Free base forms" are "considerably more 'active'".

"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'."[6]

A further BAT report recognises that if cigarette's nicotine level: " 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".[7]

"Certainly the nicotine level of B&W (Brown & Williamson, the US subsidiary of BAT) cigarettes…was not obtained by accident….[W]e can regulate, fairly precisely, the nicotine and sugar levels to almost any desired level management might require."[8]

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."[9]

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[5] Brooks GO. Smoker compensation study. Memo to William Telling, BAT, April 7, 1982. Trial exhibit 13668 in Hurt R; Robertson C, 'Prying Open the Door to the Tobacco Industry's Secrets About Nicotine: The Minnesota Tobacco Trial', Journal of the American Medical Association, October 7, 1998-Vol 280, No. 13, p. 1173.

[6] Riehl T, McMurtrie D, Heemann V, et al. Project SHIP: review of progress, November 5-6, 1984. BAT, November 12, 1984. Trial exhibit 10752 in Hurt R.; Robertson C, 'Prying Open the Door to the Tobacco Industry's Secrets About Nicotine: The Minnesota Tobacco Trial', Journal of the American Medical Association, October 7, 1998-Vol 280, No. 13, p. 1173.

[7] Quoted in *Report of Special Master: Findings of Fact, Conclusions of Law and Recommendations Regarding Non-Liggett Privilege Claims, Minnesota Trial Court File Number C1-94-8565*, 1998, 8 March, {Minn. Plaintiff's Exhibit 56 (1) B&W 660913609, p 620} in 'Chronology 1: Nicotine and addiction', www.ash.org.uk – choose 'Links', 'Industry documents' and then select 'chronologies'.

[8] Quoted in Report of Special Master: Findings of Fact, Conclusions of Law and Recommendations Regarding non-Liggett Privilege Claims, Minnesota Trial Court File Number C1-94-8565, 8 March 1998 Minnesota Plaintiff's exhibit 56(1) BATCo 1026303333, p. 336; B. Griffith, Letter to John Kirwan, BAT, 1963 in 'Trust Us: We're the Tobacco Industry', Campaign for Tobacco-Free Kids (USA), Action on Smoking and Health (UK), www.ash.org.uk – choose 'Links', 'Industry documents' and then choose Trust Us: We're the Tobacco Industry'.

[9] Cigarette design. BAT, undated document. Trial exhibit 11973 in Hurt R.; Robertson C, 'Prying Open the Door to the Tobacco Industry's Secrets About Nicotine: The Minnesota Tobacco Trial', Journal of

Appendix Six

Control of nicotine delivery within the Philip Morris group of companies

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Control of nicotine delivery within the Philip Morris group of companies

3 June 1960
Philip Morris studies the effect of adding nicotine to increase nicotine content of cigarettes
"A method for increasing the nicotine content of cigarettes was discussed. The results to date show an increase in the smoke delivery of total alkaloids proportional to the amount of nicotine maleate added." [1]

1 February 1965
Determine minimum "nicotine drip" to keep smokers "hooked".
An internal memo written by a Philip Morris researcher reads: "Determine minimum nicotine drip to keep normal smokers 'hooked'"[2]

8 November 1990
Philip Morris scientists show "optimal cigarette nicotine deliveries for producing the most favourable physiological and behavioural responses."
Three Philip Morris scientists state that they "have shown that there are optimal cigarette nicotine deliveries for producing the most favourable physiological and behavioural responses".[3]

9 June 1995
Philip Morris discovered it could reduce the tar, but increase the nicotine
Victor DeNoble, research scientist at Philip Morris, says that one of the most important research findings in relation to nicotine was that "[t]he company began to realise that they could reduce the tar, but increase the nicotine, and still have the cigarette be acceptable to the smoker".[4]

Philip Morris' use of ammoniated sheet corresponding to dramatic increase in sales
According to RJ Reynolds, "Philip Morris began using ammoniated sheet material in 1965 and increased use of the sheet periodically from 1965 to 1974. This time period corresponds to the dramatic sales increase Philip Morris made from 1965 to 1974".[5]

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[1] Quoted in *Report of Special Master: Findings of Fact, Conclusions of Law and Recommendations Regarding Non-Liggett Privilege Claims, Minnesota Trial Court File Number C1-94-856*5, 1998, 8 March, {Minn. Plaintiff's Exhibit 74 (1), PM 1001919941, p941} in Chronology: Cigarette Design, www.ash.org.uk, choose 'Links', "Industry Documents', 'Chronologies', 'Cigarette Design'.
[2] P. Pringle, *Cornered – Big Tobacco at the Bar of Justic*e, Henry Holt and Company Inc, 1998, p247.
[3] Quoted in *Report of Special Master: Findings of Fact, Conclusions of Law and Recommendations Regarding Non-Liggett Privilege Claims, Minnesota Trial Court File Number C1-94-856*5, 1998, 8 March, {Minn. Plaintiff's Exhibit 72 (1), PM 2028813366, p366} in Chronology: Nicotine, www.ash.org.uk, choose 'Links', "Industry Documents', 'Chronologies', 'Nicotine and addiction'.
[4] P. Hilts, G. Collins, "Records show Philip Morris studied influence of nicotine", New York Times, 8 Jume 1995, p.1.
[5] RJ Reynolds, Ammoniation, Undated, {Minn. Trial Exhibit 13,141} in Chronology: Cigarette Design,

Appendix Seven

Expert report of William A. Farone, Ph. D. Nov 15, 2001, former Director of Applied Research for Philip Morris

EXPERT REPORT

OF

WILLIAM A. FARONE, Ph.D.

November 15, 2001

Submitted in:

United States v. Philip Morris Inc., et al.
Civ. No. 99-2496 (GK)

I. Background and Qualifications

My name is William A. Farone. I am a professional scientist with a background in engineering. I have training and experience in the cigarette industry. My Curriculum Vitae is attached. I am currently President and Chief Executive Officer of Applied Power Concepts, Inc., in California. In 1976 I joined Philip Morris USA, then a subsidiary of Philip Morris Inc., in a staff position reporting to the Vice-President of Research & Development. From 1977 to 1984 I was Director of Applied Research for Philip Morris Inc. in Richmond, Virginia. I hold a Ph.D. in physical chemistry, a M.S. in chemistry and a B.S. in chemistry with honors. I have published over 60 papers in the areas of physics, chemistry, biotechnology and management techniques, and made over 60 technical presentations addressing similar area. I hold a number of chemical, electrical and biotechnology patents.

I joined Lever Brothers in 1967 and was made Director of Scientific Research in 1972. Other positions with that company are reflected in my curriculum vitae. As Director of Scientific Research, I acted as the government regulatory agency liaison, which involved filings of New Drug Applications, OTC panel submissions, Food Additive Petitions and other submissions to the Food and Drug Administration ("FDA"), Federal Trade Commission ("FTC"), Consumer Product Safety Commission ("CPSC"), and the Environmental Protection Agency ("EPA"). As a result, I am familiar with the research and claim support required by the FDA and FTC to support product claims and have had extensive experience in research and testing of products for human use and consumption. I was also responsible for new and existing product research for household products, toiletries, foods and personal products in the areas of

physical chemistry, toxicology, biochemistry, microbiology, process engineering and organic chemistry. At Lever Brothers, biological -- or animal -- testing was important, indeed required to ensure the safety of the products being sold for human use and to obtain marketing approval. Equally important was "whole product" testing, or testing the product "as sold." This was important -- and properly required -- to ensure that the combined effect of the product components were not harmful.

In 1975, I left Lever Brothers to become Vice President of Research and Development at PVO, International, a company involved in development and manufacture of chemical products for the food, cosmetics, toiletries, medical supplies and detergent industries. While with PVO, I maintained a research program for development of new products and provided technical support to the marketing group.

I was approached by Philip Morris in 1975, and invited to join the company in a senior staff position in order to learn the background in all the ongoing research programs and then to become a Director of Research. This lead to my becoming Director of Applied Research in 1977. I accepted the offer believing that I was to direct efforts 1) to help Philip Morris diversify away from dependence on the cigarette business and 2) to help develop "safer" cigarette products, as evidenced by the results of standard toxicological tests. During my tenure with Philip Morris, I supervised five divisions with approximately 150 persons. I and my staff developed new technologies and processes which could, if implemented, change the nature of cigarette making, including producing cigarettes that demonstrated less toxicity in toxicological testing, and thus had the potential to be less hazardous for smokers. Despite the potential advances facilitated by

these technologies during my tenure at Philip Morris, many of these technologies were not put to commercial use in the manufacture of cigarettes despite the fact that they were economically and technically feasible.

I left Philip Morris in 1984, following which I formed Applied Power Concepts. The work of this company is described more fully in my curriculum vitae. In 1994, I was contacted by representatives of FDA and was asked to provide information regarding the tobacco industry's use of cigarette manufacturing and design processes to regulate the levels and delivery of nicotine in cigarettes. In the decade prior to my acquiescence to the government's request for information, I was not involved in any litigation or regulatory proceedings involving Philip Morris or the other defendants in this action in any capacity. I did, however, maintain my interest in cigarette technology and my company pursued the improvement of a carbon monoxide reduction catalyst similar to one which we developed at Philip Morris.

Since my testimony before the FDA, I have been requested to testify in a number of lawsuits against Philip Morris and/or some of the other defendants in this action. I have testified as a fact and expert witness in cases against tobacco manufacturers and in other matters.

II. Scope of Testimony

In addition to the expert testimony described herein, I understand I may be asked to testify and provide opinions regarding the analysis and conclusions of other experts in this case,

and I may also testify in this case as a fact witness on matters I observed during my years of employment with Philip Morris. These matters include, without limitation, descriptions of research projects conducted at Philip Morris, discussions of developing and possibly marketing a less harmful cigarette, the reasons for not doing biological testing, and not marketing less harmful cigarettes, the risk in litigation of certain research, the destruction or concealment of certain documents, the consensus view of Philip Morris scientists of the dangers of smoking, the addictiveness of smoking, the manipulation of nicotine and marketing to children.

III. Basis of Report

This report is based on my experience with Philip Morris, my contact with others who work in the tobacco industry, my employment and experience outside the tobacco industry, my education and training and my review and knowledge of tobacco industry documents. These documents include Philip Morris documents that concern research on cigarette design and manufacture that occurred while I was at Philip Morris, but are documents to which I first gained access well after I left Philip Morris.

IV. Discussion

A. Cigarettes are addictive and hazardous when used as intended

I understand and scientifically conclude that cigarettes are extremely hazardous when used as intended. They cause lung cancer and cancer of other organs, chronic obstructive pulmonary disease, and cardiovascular disease, among other conditions. I accept as scientifically valid the epidemiology expressed in the Surgeon General's reports of l989 through 1998. Tobacco-induced

deaths make up at least 35% of all fatal conditions in males ages 35 to 69. Analyzing a study by the American Cancer Society on the death rates from smoking, the report concludes that between 40% and 50% of regular cigarette smokers will eventually be killed as a consequence of their addiction.

In addition, cigarettes are addictive when used as intended. Nicotine in cigarettes is a primary cause of addiction, a fact recognized by defendants decades ago. Based on the scientific studies reviewed by the FDA in 1995, the conclusions of which I have further analyzed, 85% (77% to 92%) of cigarette smokers become addicted to nicotine.

Modern cigarette products have failed to incorporate feasible modifications which would have materially enhanced their safety without unduly compromising their utility.

B. Defendants have long known that cigarette smoke delivers carcinogens

Cigarette smoke contains hazardous levels of carcinogens and harmful substances. Over 40 compounds in cigarette smoke are known carcinogens. These include compounds from chemical groups such as the polyaromatic hydrocarbons (including benzo(a)pyrene), N-Nitrosamines, aromatic amines, aldehydes, and other organic and inorganic compounds.

The research conducted on disease-causing agents in cigarette smoke was extensive. The industry found classes or grouping of chemical compounds that related to "biological activity."

The term "biological activity" was adopted by the industry for their products to encompass all of the chemical effects of mutagenicity, carcinogenicity and teratogenicity. It became known that nitrosamines, especially tobacco-specific nitrosamines, were among the worst compounds in tobacco smoke, followed by various carcinogenic aldehydes and then various polynuclear aromatic hydrocarbons (PAHs) . Of lesser importance, but still studied extensively and linked to a significant number of deaths annually, is the unintentional but avoidable inclusion of excessive radioactive isotopes in and on tobacco. Defendants' agreement not to compete among themselves on health issues and not to conduct meaningful biological research stifled development and use of technologies which would remove these hazardous components and produce a safer cigarette.

While defendants publicly proclaimed a lack of evidence to establish a relationship between smoking and disease, research from various cigarette manufacturers and that which was secretly conducted by the industry-funded and controlled Tobacco Industry Research Council (later called the Center for Tobacco Research) and the Tobacco Institute proved and confirmed the large amount of other scientific evidence that cigarette smoke was mutagenic and teratogenic, and that it was biologically active on numerous toxicological protocols designed to evaluate safety and carcinogenicity. However, the industry did not truthfully report these tests or the knowledge that it obtained from them to the public. The tobacco industry deliberately did not perform animal or cell testing on branded cigarettes as sold so that the public could reasonably determine whether "low tar" products represented as less harmful, for example, Carlton, Now and Cambridge, were in fact likely to be less hazardous than high tar products such as Marlboro

and Winston.

C. Cigarettes are designed by the tobacco industry to develop and create addiction

While I was at Philip Morris, it was clear to me that the modern cigarette is designed and manufactured as meticulously and thoroughly as drug products are by pharmaceutical companies. Indeed, the type and quality of research at Philip Morris, and the level of understanding about the biochemical and pharmacological properties of its products, was as sophisticated as any I encountered at Lever Bros.

From my work and experience at Philip Morris, and from my professional training, it is my view that the modern cigarette combines several technologies specifically designed and intended to make it more inhalable and addictive. In particular, the development of cigarette making machines that create and use "fine cut" tobacco and the use of casings and flavorings have made the cigarette smoke more inhalable and thus more addictive. Defendants' products are designed to induce addiction, and thus to ensure lifelong customers -- who engage in lifelong self-administration of lethal doses of toxic substances that are delivered along with nicotine.

Ensuring delivery of an dose of nicotine sufficient to create and sustain addiction was a design criterion of the modern cigarette, achieved through

(a) manipulation of nicotine levels via technology and blend selection;

(b) increasing nicotine in the gas phase and/or free nicotine;

(c) decreasing particle size through combustion chemistry;

(d) increased inhalability through tobacco processing;

(e) specification of flavorants, additives, and smoke chemistry to promote easy inhalability and thus rapid nicotine absorption;

(f) development of high-porosity paper, low-pressure drop filtration, rapid burning tobacco, and other characteristics to facilitate rapid and repeated product use; and

(g) marketing, advertising, promotion, and packaging to initiate and sustain addictive use patterns in youth and adults.

Documents show that, at the same time defendants made public statements that nicotine was not addictive and smoking was a choice, they were very aware that nicotine was the reason people smoked and that smokers would adjust their smoking habits to attain their desired "dose" of nicotine. Nicotine was recognized as critical to the continued success of a brand, and a variety of technologies, including blending different varieties of tobacco, using expanded tobacco, and designing specialized filters, were used to ensure that actual delivery levels of nicotine (as distinct from those reported by FTC measurements) occurred at doses necessary to ensure addiction. Based on my personal experience, my review of the documents, my knowledge of industry terminology and manufacturing processes, it is clear that the defendant manufacturers believed that smoking and nicotine was addictive whether or not it satisfied a specific technical definition

they chose to adopt for the purposes of confusing the public. Only recently have some defendants begun to admit that the overwhelming preponderance of scientific evidence proves that smoking is addictive, while still producing company executives and scientists who refuse to acknowledge that nicotine is the addicting agent.

The intentional design of cigarettes to create and sustain addiction sentences a majority of foreseeable users to premature death and disability from the product. While most smokers may be aware of some relation between smoking and disease and smoking and addiction, the actions of the tobacco industry have sought to minimize the true nature of those relationships in order to get people to start smoking and to discourage them from quitting.

The unusual combination of an addictive drug and various carcinogens, mutagens, teratogens and toxic chemicals makes a cigarette a unique and uniquely harmful consumer product. As smokers become dependent on nicotine and the other added pharmacologically active agents, their ability to stop smoking and reduce their intake of the toxic chemicals is reduced.

D. Defendants' agreement not to compete among themselves on health issues prevented them from providing accurate and complete product information

Medications and other industrial and commercial products that present dangers to the user generally include product information data sheets. Defendants could have provided similar

information to consumers, particularly as any one company developed innovations which reduced levels of carcinogenic components of smoke. These product information data sheets would have fit easily into packs and cartons of cigarettes, and could have provided detailed information on medical risks of cigarette smoking. Documented differences in levels of hazardous components of smoke could be presented to enable the potential user to decide whether to use the product. Such sheets could have also provided information on the proper number of puffs per cigarette and proper puff duration so as not to exceed the levels of tar and nicotine stated on the package. Users could also be told how to smoke cigarettes to avoid occluding the ventilation holes.

The cigarette manufacturers could have provided, and could provide now, adequate directions to foreseeable users in several forms, including directions printed on the outside of packs, a direction sheet included within a pack or carton, directions for use published with advertisements, television or radio announcements with directions (prior to the ban on cigarette advertising on television), and/or directions published to physicians, authors, interest groups, government agencies, and others.

These directions for use would instruct foreseeable users in how to use tobacco products in such a way that their risks for disease might be reduced. Providing information of this sort, however, would be inconsistent with an agreement not to compete on health issues.

E. The Gentlemen's Agreement

To my knowledge, none of the defendants have conducted meaningful in-house biological research on cigarettes "as marketed." During my tenure as Director of Applied Research at Philip Morris, I repeatedly recommended such research be conducted. Biological testing of products as marketed is critical to development of less hazardous products. Without meaningful biological research on the product as marketed, it is not possible to determine what effect the product as sold may have on users. It is and was well known that pyrolysis of tobacco and the additives creates a complex mix of thousands of chemicals. I considered biological research to be the responsible approach to this product and essential to development of a cigarettes that demonstrated lower levels of toxicity on well-accepted toxicological tests. I was told by my colleagues and superiors that there was an agreement with other tobacco manufacturers that none would conduct biological research internally and that Philip Morris's biological research on the health effects of cigarettes would be conducted by an overseas entity called the Institute for Biological Research ("INBIFO") in Cologne, Germany.

I was also told that the industry had agreed that, within the United States, biological research, normally an area of competitive significance not disclosed to competitors, would only be conducted jointly by the industry under the control of TIRC/CTR. To my knowledge, such testing was predominantly done on prototype or "reference" cigarettes, not on as-sold products. When any testing was done on as-sold products, the identity of the product was coded and concealed. Subsequent to formation of the TIRC (later CTR), the manufacturers ceased to individually pursue in- house biological research until very recently; instead, this normally

competitive activity was conducted, if at all, by CTR. Although I was hired to develop a less hazardous cigarette, I was never provided with any reports which showed the results of this biological research. Since I left Philip Morris, however, I have learned that research I considered necessary to development of safer products was shared with Philip Morris' "competitors." I was told by my colleagues at Philip Morris that biological research had been conducted but that I was not permitted to see this research or know the results, despite my position as Director of Applied Research. Although my co-workers at Philip Morris would not disclose this research to me, it was disclosed to employees of Philip Morris' "competitors."

Based upon my personal knowledge and review of documents, the defendants were concerned that competition among them on health-related issues could result in liability in litigation brought by individual smokers and might also prompt regulation by the FDA. Although the defendants intended cigarettes to deliver nicotine and thereby foster addiction, they concealed this information to avoid regulation, in part because they knew their products were hazardous. By their agreement not to conduct meaningful in-house biological research, the defendant manufacturers effectively ensured that none of their competitors would acknowledge the adverse effects of smoking or the addictiveness of nicotine. All of the defendants recognized that an admission of this sort would result in efforts by the FDA to regulate nicotine as a drug. In the case of such regulation, any manufacturer which was positioned to immediately provide research required by the FDA would have a substantial competitive advantage by being the first in line. Therefore, by their agreement that they would not conduct in-house biological research,

the defendants ensured that none of them would generate information that could provide a basis for FDA regulation, and ensured that, should FDA successfully assert regulatory authority, none would be positioned to gain a competitive advantage from early submissions to FDA.

I have reviewed numerous documents from tobacco manufacturers, including Philip Morris, Reynolds, Brown & Williamson and B.A.T., Lorillard, Liggett, and from industry-supported studies. Based on my review of these documents, and my experience and training, I conclude that the manufacturers had a longstanding agreement not to publicly conduct meaningful in-house biological research on as-marketed products. This "gentlemen's agreement" among manufacturers had the effect of eliminating, or secreting, biological research that was necessary to improve the safety of the product.

F. The tobacco manufacturers failed to use available technology to produce cigarettes that demonstrated less toxicological activity and were thus potentially less hazardous

Any claim by defendants that they have had a long standing and continuous goal to eliminate from marketed products smoke components that are of concern to the scientific community is false. The tobacco companies have gone to great lengths to conduct hundreds of millions of dollars of confidential research on the relationship between smoking and health and on the effects of nicotine. This research began in earnest in the 1950s and intensified in the 60s and 70s. As this research began to provide further evidence for disease causation and addiction, much

of it was stopped or moved to foreign shores where it could be effectively hidden. Numerous technological innovations were available to defendants to reduce the harm from cigarettes but those were not developed, not pursued or exploited.

The cigarette manufacturing industry is a highly sophisticated industry with the ability to use advanced product design technology to produce cigarettes that could, if desired, reduce tar and maintain nicotine. Defendants have collectively refused to incorporate technology that would cause significant reductions in potent chemical toxic materials and often patented technologies that could be used in cigarettes to potentially reduce diseases caused by smoking. The technology to do so has been available and improved over decades.

In my view, it is technologically feasible today to design a cigarette which would not cause an increase in cancer, emphysema, asthma, heart failure or other smoking-related diseases. To my knowledge, none of the manufacturers has done this, although Philip Morris investigated the possibility in the early 1970's. During the course of this research many potential product concepts were discovered that could have been used to potentially reduce the risk associated with smoking but were not. The measures discussed above, in addition, could have been adopted and would have affected the product users' awareness of the risks associated with the product.

Any of the tobacco defendants could have developed a less harmful cigarette by, among other things:

- Reducing the nitrosamines in cigarettes.
- Reducing the carbon monoxide in cigarettes.
- Reducing the radioactive material in cigarettes.
- Reducing the polyaromatic hydrocarbons in tobacco.
- Using better filters.
- Reducing the aldehydes in tobacco.
- Using less Burley tobacco in their products, shifting to "air-cured Bright" tobacco and generally publishing and supporting programs to make the tobacco used less hazardous as measured by internal biological testing.
- Removing ammonia.
- Lowering nicotine levels.

Some of the manufacturers have recently begun to claim that new products, such as Eclipse, Accord, and Omni (none of which necessarily fall within the accepted definition of a “cigarette”), reduce levels of some of these toxins delivered in cigarette smoke. However, the technologies to accomplish exactly these ends existed much earlier, but efforts to incorporate them successfully into marketed products were never seriously undertaken.

I was personally involved in development of one method for removing from smoke virtually all nitrosamines, generally recognized as one of the most carcinogenic agents, even in

"low tar" cigarettes, but never saw the result successfully marketed. Oxides of nitrogen can also be reduced dramatically simply by working with tobacco farmers to reduce the use of nitrate fertilizers in tobacco. Neither the industry nor any individual Defendant has ever set, or even suggested a standard for Tobacco Specific Nitrosamines in tobacco, or otherwise recommended or established standards which would prevent purchase or use of tobacco high in TSNAs. I was also involved in research to reduce the CO (carbon monoxide) levels of mainstream and side stream smoke, either by changes in the curing process, genetic manipulation or fertilizing.

There were a variety of other technologies available to cigarette manufacturers back in the 1970s which were not exploited by the defendants. Some examples include: removal of nicotine from tobacco; reduction or removal of radioactive materials such as polonium 210; and use of nicotine analogues. Charcoal filters are another example of available technology which was not developed for widespread commercial use in the U.S. market. Although, as early as 1964, the charcoal filter was an acknowledged physiological improvement, and is very effective at removing many toxic materials, defendants' agreement among themselves to avoid competing on health issues prevented them from reporting on or pursuing this benefit. Similarly, it is relatively simple to screen for the presence of excess radioactive materials. Aldehyde levels could be decreased through more careful selection of sugar additives and by carbon filters. These methods for reducing carcinogens were known to all of the defendants; I am not aware of any evidence that they were implemented to move toward a safer cigarette. Even in those instances where defendants used available technologies, they did not perform product testing necessary to

determine whether or not there was a reduction in hazard. I have not seen, nor am I aware of any evidence that the manufacturers are producing a safer product. The current products such as Premier, Eclipse and Accord are the first for which the manufacturers have provided extensive biological data, but they still have not been compared to high tar, “low tar,” and other cigarettes by brand. It is only through biological testing with brand identification that consumers can truly understand whether one cigarette or smoking article is safer than another.

Many potentially significant technologies were patented by the industry. These patents would, if utilized, result in a safer cigarette and may have spawned further advancement in design or delivery technology. As a further example, Philip Morris researcher Scott Osborne conceived of an “indirect cigarette” in the early 1970's which, had Philip Morris pursued it, would have provided the same central nervous system impact as the traditional cigarette but without all the harmful effects.

Additionally, in the area of gas phase delivery of toxic substances in cigarettes, the industry had technology available to reduce these gases and failed to use it. Although the industry claims reductions in FTC delivery numbers as evidence of "good faith" in reducing hazardous compounds, they have failed to:

- Investigate the levels to which the hazardous compounds must be reduced so that the reduction is meaningful;

- disclose the specific design changes that exacerbate differences between the measured FTC levels and the levels of these compounds that the smoker actually receives; and

- disclose that compounds that do not go into the mainstream smoke to the smoker end up in the side stream smoke to pose a risk to "passive smokers" and smokers sitting in the side stream fumes when dilution or ventilation is the means for reduction of tar delivery. Industry researchers estimate that smokers obtain 16 times more side stream exposure than passive smokers yet the additional load of carcinogens from side stream smoke is never mentioned to smokers.

Within Philip Morris, although much of the research was directed to development of promising technologies, including some of the methods described above, that could potentially produce a safer cigarette, none to my knowledge were ever pursued to the point of actually marketing a cigarette that one could prove as less harmful with even elementary toxicology data.

In addition, the industry could have reduced, and could still reduce, the adverse health effects of their products by:

· Performing and disclosing the results of biological activity tests on all of their

products, as branded and as sold in the same manner that products are tested for tar and nicotine. This would allow informed choice among products.

- Using well known brand names for products they deem to be safer.

- Admitting, much earlier than 1999, that there is a causative link between smoking and cancer, emphysema, and other diseases. Indeed, some companies have refused to publicly concede this causative link.

- Providing data on the chemical composition of the mainstream and sidestream smoke for all toxic or carcinogenic materials in smoke from conventional cigarettes, much as they have done for their novel products recently announced.

- Working with FDA or other appropriate regulatory agencies to develop guidelines for the testing and publication of data on the biological effects of cigarette smoke.

Only after extensive litigation was initiated against the tobacco industry did it respond with products like Premier, Eclipse, and Accord. These products, as well as Philip Morris' denicotinized product, Next, were and are marketed in such a manner that there is no credibility that they are, in fact, safer, and appear to be on the market solely to make a case for the continued sale of the established products.

G. The industry has facilitated failure of safer products by failing to use its available resources and through the agreed upon restrictions on competition among manufacturers

Research programs that showed promise were either shut down or never used. The general excuse used by the cigarette manufacturers was that these programs led to products that were not "consumer acceptable." The “low tar” boom of the 70s induced many smokers to keep on smoking and the technology involved in those products was the focus of advertising and sales campaigns. The industry asserts that all the other technology that they developed was a failure.

The industry has not made serious efforts to market and develop these products in a manner which facilitates their success. As I discussed above, the industry has available to it a vast knowledge of flavoring devices which could be employed to develop a successful or “acceptable” taste. Additionally, when a new brand is introduced, general acceptance is not the usual case. Advertising and marketing is usually performed until it is accepted if the attempt is serious.

The industry often defends its decision not to provide less hazardous products by contending that they are not "acceptable" to consumers. For example, Philip Morris provides this excuse for “Next,” a denicotinized cigarette that was virtually free of nitrosamines because the process that removed the nicotine also removed the nitrosamines. Philip Morris had the capability to improve the flavor of this product without adding nicotine, and so create a non-

addictive cigarette. It also had the technology to re-add nicotine -- but not nitrosamines -- after their removal, resulting in a product nearly free of carcinogenic nitrosamines which still had the nicotine “kick” some smokers desire. Philip Morris, however, did neither of these, and knew the product would “fail” due to the lack of nicotine or other flavors, especially since they never provided the public with toxicology information for the product that could have made it more attractive to consumers.

Products such as Eclipse, Next, Premier and Accord, as well as other potentially safer products which might be developed, could be commercially successful if properly supported and maintained. These products allegedly reduce harmful constituents, but defendants have claimed that these products were or are not “acceptable.” It is my opinion that this is the result of choices by defendants, not technological limitations. The technology existed to add nicotine such that the products had the same physiological impact without the carcinogens.

As another example, charcoal filters are recognized as very effective at reducing many of the toxic materials in smoke, but they are rarely used. Defendants generally claim this is because they result in an unacceptable taste. Defendants, however, have the ability and resources to create additional "flavor development" programs to differentiate the products. The additional cost of these programs is nominal; however, defendants’ agreement not to compete regarding issues regarding health or the relative harm of different cigarettes was a disincentive, as any reduction could not then be marketed as a point of distinction.

For a long time, the agreement among defendants not to compete regarding health issues prevented them from educating potential consumers about the reduction in carcinogens. The agreement also acted as a disincentive to add nicotine, because defendants' agreement prevented them from advising potential customers that the physiological effect they sought from more toxic cigarettes could be obtained from these alternatives.

Other defendants likewise possessed the technology to make safer products. Liggett developed product XA, which achieved reductions in PAH delivery. Although this was a safer cigarette, Liggett's emphasis on the lower carcinogen levels was considered a violation of the defendants' agreement not to compete based upon smoking and health issues. Confronted and threatened, Liggett ceased marketing this product.

H. Defendants' efforts to mislead and confuse

1. Tar and Nicotine Levels, Product Components, and Exposure Levels

With the dissolution of the Tobacco Institute and CTR, cigarette companies must now make their own scientific claims rather than rely on paid research which they selected to confuse the public and the scientific community. The industry continues to provide erroneous results to confuse the public.

The testimony of industry scientists is intended to confuse the scientific issues without

providing any useful information on steps taken by industry members to effectively and realistically produce a safer cigarette. In order to deal effectively with the problems caused by cigarettes, it is first necessary for the tobacco companies to understand those problems.

The cigarette industry argues it has been a leader in efforts to reduce or eliminate certain smoke constituents. However, industry representatives do not admit that these constituents actually damage smokers. They are essentially testifying that they have attempted to remove these constituents because other people think they damage smokers.

With only isolated exceptions, none of the defendants has provided any meaningful data on the relative amounts of the various carcinogens and toxic compounds in cigarettes over the years. For its new product Eclipse, Reynolds published a list of potent chemical toxins that were "reduced" compared to a typical “low tar” cigarette. Reynolds did not even identify the “low tar” cigarette to which the new product is compared. Further, Reynolds’s analysis indicates there is no meaningful distinction in mutagenic effects between “low tar” and full flavor cigarettes, despite decades of contrary suggestions by defendants. Philip Morris has developed the Accord, but has never released meaningful testing data on other brands. None of the defendants has ever provided comparable data evidencing reductions in carcinogens or other toxic compounds for other products over the years, or for products on the market now. Brown & Williamson has never offered a noncombustible alternative product, although their own documents state that such a design was believed feasible as early as 1963.

The claim of general reduction in tar appears to be another attempt to confuse the public. In the 1960s and into the 1970s the tobacco industry sought to produce “low tar” cigarettes, promoting the idea that reduction of tar as measured by the FTC produced a "safer" cigarette. The industry has not provided biological testing of the products against one another as a function of tar levels, smoking habits, or any other parameters.

Defendants claim that many of the constituents and additives in cigarettes have been found to be “generally accepted as safe” by FDA. However, FDA’s determination of safety is based on those substances being ingested, not burned and inhaled. None of the defendants has, to my knowledge, presented data on biologically safe inhalation levels for the constituents of cigarette smoke, nor have they advised smokers that exposure via inhalation is much more acute than exposure by ingestion. Rather, defendants have, for years, sought to convince the public that inhaled materials are to be judged by the same standards as materials you can eat or drink. This is not supported by science. Rather than providing truthful, accurate information, defendants and their representatives have chosen to ignore, distort or suppress the truth concerning pharmacology or physiology to allow them to provide values that seem small to the general public.

For example, industry scientists have long argued that smokers are exposed to only "small amounts of toxic materials." One microgram per cigarette collected in the FTC smoking regimen corresponds to 2.9 milligrams (mg) per cubic meter (m^3). The Threshold Limit Values for

workers exposed to many of these toxic chemicals for many of these compounds is 0.1 mg/m^3 and EPA safe air quality standards are many times lower than that. For carcinogens, safe levels are even lower and as little as 1 microgram/m^3 is considered unacceptable.

Defendants collectively report air pollution criteria and toxic measures for inhalation only in terms of nanograms per cigarette, rather than the concentration of nanograms/m^3 of the smoke being inhaled. For conventional cigarettes, the defendants do not say how many nanograms of any particular toxic substance is contained in a cigarette. Five nanograms per cigarette is equivalent to 14,300 nanograms/m^3 of inhaled smoke or 14.3 micrograms/m^3 for a compound known to cause cancer in the lungs. Obviously this is still far above a safe level.

The industry further claims a reduction in CO yields. Workers' exposure to CO is limited to 29 mg/m^3 and exposure limits for the general public is less than this. In an FTC smoking test this would correspond to 10 micrograms of CO per cigarette or less. Values of CO are always larger in realistic smoking tests than in the FTC test. Cigarettes are still so far above the safe exposure limit that the claimed reductions are meaningless.

2. Ammonia

Industry scientists also mislead concerning the use of ammonia and pH levels. While ammonia, as a base, raises the pH level, the pH is not as important as the way ammonia actually works. When ammonia is released during combustion it sweeps along the remaining tobacco,

which has been moistened by water of combustion replacing nicotine and causing the nicotine to be released in gas phase from the tobacco. FTC testing devices do not detect gas phase nicotine, a fact the industry has known for some time. Thus, reported nicotine levels will be lower than actual levels received by a smoker

Furthermore, studies on ammonia use do not accurately report the amount of ammonia present, as they do not also consider (and the researcher may not even know) the blend composition of the products or the additives used. These factors are important because the amount of ammonia reported as an ingredient does not include products that decompose to ammonia upon burning, such as diammonium phosphate and ammonium salts including urea, amino acids and polypeptides.

Ammonia use is significant because it increases nicotine delivery levels, which, as discussed above, are important to create, maintain and satisfy nicotine addiction. In fact, the need to precisely control nicotine levels is recognized in industry documents: "this process also permits us to partially or completely compensate for the variability in the nicotine content of tobacco from year to year, market to market, etc." One industry commentator notes that Philip Morris introduced the use of added ammonia in their cigarette products in 1965. "Philip Morris brands, especially Marlboro, began growing in sales very rapidly after introduction of added ammonia." The industry began studying ammonia technology as early as the 1950s when Claude Teague (RJR) investigated the ammoniation of tobacco. A comprehensive R&D effort in the

1970s reached the following conclusion (among others):

> Studies of the effect of ammonia in smoke composition showed . . . an increase in the levels of . . . minor alkaloids. Smoking panel results showed a decrease in smoke irritation and harshness and an increase in physiological satisfaction with increasing ammonia content.

Physiological satisfaction, impact, and satisfaction are words used by the industry to denote the satisfaction of the nicotine chemical addiction.

Research as early as 1975 showed that gas phase nicotine can account for 12% or more of the nicotine delivered to the mainstream in cigarettes. The use of ammonia to enhance nicotine production is spelled out in industry patents and research documents. An analysis of nicotine to tar ratios vs. total ammonia compounds in filler to tar ratios show a clear effect for increased nicotine. Although defendants have, in the past, cited the Surgeon General's report to support their claim that there is "virtually" no "free" nicotine in mainstream cigarette smoke, the test referred to only measured nicotine collected on the collection pad of the measuring device; it did not measure gas phase nicotine. Gas phase nicotine is virtually all in the "free" state.

Industry scientists suggest that pH has not increased over the years. Yet, the smoke pH of lower tar cigarettes, or cigarettes with higher nicotine to tar ratios, has increased. The pH of Now cigarette in one year shortly after its introduction was as high as 6.7. The use of pH enhancements was one of the tools used to increase nicotine impact in low tar cigarettes that began to be introduced in the late 60's and throughout the 70s. Indeed, the pH of cigarette smoke

has risen steadily since the late 1960s. The industry has produced a report written by Dr. G. Morie that clearly showed that pH at that time was an order of magnitude (about 1 pH unit) lower than the cigarettes tested by the Massachusetts Department of Health recently. In other words, before the tobacco industry started using additional ammonia in its products, the pH for tobacco was much lower. The pH increases were associated with the introduction of the new "lower tar, lower nicotine" brands.

Another example of how the industry actively mislead smokers, regulators and the public generally was through their repeated insistence that nicotine levels are not manipulated. In testimony under oath before Congress in 1994, in concurrent newspaper advertisements, and in response to the FDA inquiry in 1996, the industry collectively denied changing nicotine to tar ratios deliberately. They indicated that the change in nicotine to tar ratios either did not occur or was accidental. Nevertheless, the manufacturers defend their use of ammonia, other additives and blending techniques to increase nicotine levels by claiming that these efforts "modify tar/nicotine ratios [were done] in response to the requests of the public health community," implicitly admitting that sustaining nicotine levels is a conscious objective of their manufacturing techniques.

3. Sidestream Smoke

Defendants have also long known that sidestream smoke, which is smoke not inhaled by the smoker (and is sometime referred to as environmental tobacco smoke or ETS) contained toxic

substances, just as inhaled smoke does. While I was employed at Philip Morris, Philip Morris had programs to study and measure the toxicity of sidestream smoke. Although defendants undertook studies to mask the smell or reduced the visibility of sidestream smoke, I am not aware of any effort by them to reduce the toxicity of sidestream smoke. Only recently has Philip Morris, in a report, acknowledged the adverse health effects of secondhand smoke. Previously, none of the defendants had acknowledged, let alone disclosed to smokers or non-smokers, the toxic effects of sidestream smoke. Defendants have generally argued that sidestream smoke is only an inconvenience and refuse to recognize the well established fact that sidestream smoke contains virtually all of the carcinogens found in mainstream smoke.

I charge $150/hour for expert-related work in this case, and $250/hour for testimony.

I reserve the right to supplement or amend this report to account for additional information.

Dated: _____ _____

William A. Farone, Ph.D.

Appendix Eight

The legal and scientific basis for FDA's assertion of jurisdiction over cigarettes and smokeless tobacco

D. Kessler, P. Barnett, A. Witt, M. Zeller, J. Mande, W. Schultz

The Legal and Scientific Basis for FDA's Assertion of Jurisdiction Over Cigarettes and Smokeless Tobacco

David A. Kessler, MD; Philip S. Barnett, JD; Ann Witt, JD; Mitchell R. Zeller, JD; Jerold R. Mande, MPH; William B. Schultz

On August 28, 1996, the US Food and Drug Administration (FDA) asserted jurisdiction over cigarettes and smokeless tobacco under the Federal Food, Drug, and Cosmetic Act. Under this Act, a product is a "drug" or "device" subject to FDA jurisdiction if it is "intended to affect the structure or any function of the body." The FDA determined that nicotine in cigarettes and smokeless tobacco does "affect the structure or any function of the body" because nicotine causes addiction and other pharmacological effects. The FDA then determined that these pharmacological effects are "intended" because (1) a scientific consensus has emerged that nicotine is addictive; (2) recent studies have shown that most consumers use cigarettes and smokeless tobacco for pharmacological purposes, including satisfying their addiction to nicotine; and (3) newly disclosed evidence from the tobacco manufacturers has revealed that the manufacturers know that nicotine causes pharmacological effects, including addiction, and design their products to provide pharmacologically active doses of nicotine. The FDA thus concluded that cigarettes and smokeless tobacco are subject to FDA jurisdiction because they contain a "drug," nicotine, and a "device" for delivering this drug to the body.

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ON AUGUST 28, 1996, President Clinton announced the final regulations of the US Food and Drug Administration (FDA) restricting the sale and promotion of cigarettes and smokeless tobacco.[1] The FDA's assertion of jurisdiction over tobacco products under the Federal Food, Drug, and Cosmetic Act (the Act) was the culmination of an exhaustive, 2½-year investigation of tobacco products. This article explains the legal and scientific basis for this assertion of jurisdiction.

In asserting jurisdiction over cigarettes and smokeless tobacco, FDA relied on its authority to regulate drugs and devices. Under the relevant portion of the Act, a product is a "drug" or "device" if it is an article (other than food) "intended to affect the structure or any function of the body."[2] When FDA last considered this issue, it declined to assert jurisdiction over cigarettes because it lacked evidence that cigarettes were intended to affect the structure or function of the body.[3] Since that time, however, substantial new evidence became available to FDA. This evidence included the emergence of a scientific consensus that the nicotine in cigarettes and smokeless tobacco causes and sustains addiction, as well as the disclosure of thousands of pages of internal tobacco company documents revealing that the tobacco manufacturers know that nicotine causes significant pharmacological effects, including addiction, and design their products to provide pharmacologically active doses of nicotine.

See also p 410.

This new evidence demonstrated to FDA that (1) nicotine in cigarettes and smokeless tobacco does "affect the structure or any function of the body" and (2) these effects on the structure and function of the body are "intended" by the manufacturers. These findings, which are explained below, provided the basis for the agency's determination that cigarettes and smokeless tobacco are subject to FDA jurisdiction as products that contain a "drug," nicotine, and a "device" for delivering this drug to the body.[4]

EFFECTS ON STRUCTURE AND FUNCTION

The scientific evidence before FDA established that the nicotine delivered by cigarettes and smokeless tobacco has significant pharmacological effects on the structure and function of the body. First, this evidence showed that nicotine in cigarettes and smokeless tobacco causes and sustains addiction. As the US Surgeon General has reported, nicotine exerts psychoactive (or mood-altering) effects on the brain that motivate repeated, compulsive use of the substance. These pharmacological effects create dependence in the user. The pharmacological processes that cause this addiction to nicotine are similar to those that cause addiction to heroin and cocaine.[5,6(pp7-8,270,284-335)]

Second, scientific studies showed that nicotine in cigarettes and smokeless tobacco produces other important pharmacological effects on the central nervous system. Under some circumstances and doses, for instance, the nicotine has a sedating or tranquilizing effect on mood and brain activity. Under other circumstances and doses, the nicotine has a stimulant or arousal-inducing effect on mood and brain activity.[7,8]

Third, as the US Surgeon General also documented, nicotine in cigarettes and smokeless tobacco affects body weight.[6(pp481-482)]

From the US Food and Drug Administration, US Department of Health and Human Services, Rockville, Md.

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The FDA found that these effects on the structure and function of the body are significant and quintessentially druglike. They are the same as the effects of other drugs that FDA has traditionally regulated, including stimulants, tranquilizers, appetite suppressants, and products, such as methadone, used in the maintenance of addiction. For these reasons, the agency concluded that cigarettes and smokeless tobacco "affect the structure or any function of the body" within the meaning of the Act.

THE ISSUE OF INTENT

Having established that nicotine in cigarettes and smokeless tobacco affects the structure and function of the body, the central question before FDA became whether these effects of nicotine on the structure or function of the body are "intended" by the manufacturers. To answer this question, FDA was required to evaluate objectively all the relevant evidence of intent before the agency.

This evidence fell principally into 3 categories: (1) evidence that the pharmacological effects and uses of cigarettes and smokeless tobacco are foreseeable to a reasonable manufacturer; (2) evidence that consumers actually use cigarettes and smokeless tobacco predominantly for pharmacological purposes; and (3) evidence of the statements, research, and actions of the manufacturers themselves. The agency determined that, whether considered independently or cumulatively, this evidence demonstrated that cigarettes and smokeless tobacco are in fact "intended" to be used for pharmacological purposes.

NICOTINE'S FORESEEABLE PHARMACOLOGICAL EFFECTS

Before 1980, when FDA last considered its jurisdiction over tobacco products, no major public health organization had determined that nicotine was an addictive drug. Today, however, all major public health organizations in the United States and abroad with expertise in tobacco or drug addiction recognize that the nicotine delivered by cigarettes and smokeless tobacco is addictive. Since the 1980s, nicotine in tobacco products has been recognized as addictive by the American Psychiatric Association (1980),[9] the US Surgeon General (1986 and 1988),[5(pp384-386)] the American Psychological Association (1988),[10] the Royal Society of Canada (1989),[11] the World Health Organization (1992),[12] the American Medical Association (1993),[13] and the Medical Research Council in the United Kingdom (1994).[14] This scientific consensus is based on a wealth of epidemiologic and laboratory data establishing that tobacco users display the clinical symptoms of addiction and that nicotine has the characteristics of other addictive drugs.[15-23]

It is also now well established that the nicotine in cigarettes and smokeless tobacco will cause, and be used for, other significant pharmacological effects, including its psychoactive or mood-altering effects in the brain.[7,8,24] In addition, it is widely recognized today that nicotine plays a role in weight regulation, with substantial evidence demonstrating that cigarette smoking leads to weight loss.[5(pp431-432)]

The FDA found that this new scientific consensus made it foreseeable to any reasonable manufacturer that cigarettes and smokeless tobacco would cause addiction to nicotine and be used by consumers for pharmacological purposes, including satisfying their addiction. In light of the overwhelming scientific data and consensus, FDA concluded that the tobacco industry's public assertions that nicotine is not addictive were simply not credible.

The agency's finding that cigarettes and smokeless tobacco have foreseeable pharmacological effects has important legal significance. When Congress expanded the current definition of "drug" in 1938 to include products "intended to affect the structure or any function of the body," it was well understood that "[t]he law presumes that every man intends the legitimate consequences of his own acts."[25] Consistent with this well-accepted legal principle, FDA's regulations provide that a product's intended pharmacological use may be established by evidence that the manufacturer "has knowledge of facts that would give him notice" that the product will be widely used for a pharmacological purpose, even if the product is not promoted for this purpose.[26] Thus, the agency concluded that the tobacco manufacturers must be held to "intend" the foreseeable pharmacological uses of their products.

CONSUMER USE OF TOBACCO PRODUCTS

A second and related basis for establishing that a product is intended to affect the structure or function of the body is evidence showing that consumers actually use the product for pharmacological purposes. In fact, courts have recognized that even in the absence of any evidence that the manufacturer has promoted the product for a pharmacological purpose, the product's intended use as a drug or device may be established solely by evidence showing that consumers use the product "predominantly" for pharmacological purposes.[3(pp239-240)]

In the case of cigarettes and smokeless tobacco, studies conducted since 1980 demonstrated to the agency that consumers do use these products "predominantly" for pharmacological purposes, including satisfying an addiction to nicotine. Major recent studies have concluded that 77% to 92% of smokers are addicted to nicotine in cigarettes.[27-30] Similarly, the US Department of Health and Human Services recently estimated that 75% of young regular users of smokeless tobacco are addicted to nicotine.[31] A recent survey by the Centers for Disease Control and Prevention also showed that the majority of young consumers who use cigarettes or smokeless tobacco daily do so for mood alteration.[32]

Thus, this evidence of actual consumer use provided an independent basis for FDA's conclusion that cigarettes and smokeless tobacco are intended to affect the structure and function of the body.

MANUFACTURER STATEMENTS, RESEARCH, AND ACTIONS

The third category of evidence considered by the agency was newly disclosed evidence showing that tobacco companies expect their products to be used by consumers for pharmacological purposes and have designed their products to be pharmacologically active. Although this evidence included 3 decades of tobacco industry statements, research, and actions, virtually all of it became available only recently as the result of FDA's investigation, congressional hearings, and other sources.

The evidence of the tobacco manufacturers' statements, research, and actions in the administrative record led FDA to make two central findings regarding the manufacturers' actual intent. First, FDA found that "[m]anufacturers of cigarettes and smokeless tobacco know that nicotine in their products causes pharmacological effects in consumers, including addiction to nicotine . . . , and that consumers use

their products primarily to obtain the pharmacological effects of nicotine.[33(pp44619,44630)]

This finding was based in part on evidence that showed that senior officials and researchers working for the tobacco manufacturers had for decades consistently described nicotine as a pharmacologically active drug. For instance, the record showed that in internal documents tobacco company officials and researchers called nicotine "a very remarkable beneficent drug" (1962),[34] "addictive" (1963),[35] "a potent drug with a variety of physiological effects . . . [and] a habit-forming alkaloid" (1972),[36] "a narcotic, tranquilizer, or sedative" (1976),[37] "pharmacologically active in the brain" (1976),[38] "the physiologically active component of smoke having the greatest consequence to the consumer" (1978),[39] "a powerful pharmacological agent with multiple sites of action" (1980),[40] "an extremely biologically active compound capable of eliciting a range of pharmacological, biochemical and physiological responses" (1980),[41] "a 'drug'" (1981),[42] and "a physiologically active . . . substance . . . [that] alters the state of the smoker by becoming a neurotransmitter and a stimulant" (approximately 1992).[43]

The agency's finding was also supported by repeated acknowledgments in the internal company documents that consumers use tobacco products to obtain the pharmacological effects of nicotine. These documents showed, for instance, that tobacco company researchers recognized that "the confirmed user of tobacco products is primarily seeking the physiological 'satisfaction' derived from nicotine"[36] and that "[w]ithout any question, the desire to smoke is based on the effect of nicotine on the body."[44] The documents also showed that the tobacco company researchers' knowledge of the importance of nicotine was communicated to the highest levels of the companies. Thus, as early as 1969, Philip Morris' vice president for research and development told the Philip Morris board of directors that "the ultimate explanation for the perpetuated cigaret habit resides in the pharmacological effect of smoke upon the body of the smoker."[45]

Second, FDA found that "[m]anufacturers of cigarettes and smokeless tobacco design their products to provide consumers with a pharmacologically active dose of nicotine."[33(p44630)] The FDA based this finding in part on industry documents that disclosed internal research to determine the dose of nicotine that must be delivered to provide "pharmacological satisfaction for the smoker,"[46] as well as estimates by industry scientists of the minimum and optimum doses of nicotine that tobacco products must deliver.[44,47,48] As one former senior official at Philip Morris put it, "a key objective of the cigarette industry over the last 20-30 years" was "maintaining an acceptable and pharmacologically active nicotine level" in low-tar cigarettes.[49]

The record before the agency showed that several methods of enhancing nicotine delivery are commonly used in the manufacture of commercial cigarettes. Tobacco blending to raise the nicotine concentration in low-tar cigarettes is common. According to the vice chairman and chief operating officer of Lorillard Tobacco Co, for instance, "the lowest 'tar' segment is composed of cigarettes utilizing a tobacco blend which is significantly higher in nicotine."[50] Another common technique for enhancing nicotine delivery in low-tar cigarettes is the use of filter and ventilation systems that by design remove a higher percentage of tar than nicotine.[33(pp44963-44969)] Yet a third type of nicotine manipulation is the addition of ammonia compounds that increase the delivery of "free" nicotine to smokers by raising the alkalinity or pH of tobacco smoke. These ammonia technologies are widely used within the industry.[33(pp44970-44975)]

In the case of smokeless tobacco, the evidence before the agency showed that nicotine manipulation is accomplished through the use of chemicals that alter the pH of the smokeless tobacco. The FDA found that moist snuff brands that are marketed as "starter" brands have a low pH and consequently deliver a low level of "free" nicotine to the user, limiting the absorption of nicotine in the mouth. The low nicotine deliveries allow the new user to develop a tolerance to nicotine without experiencing adverse reactions such as nausea and vomiting. In contrast, moist snuff brands that are marketed to experienced users have a high pH and consequently deliver a high level of "free" nicotine to the user, increasing the amount of nicotine available for absorption. The increased nicotine deliveries provide sufficient nicotine to sustain the user's addiction.[33(pp45110-45116)]

Consistent with this evidence, the internal company documents actually described tobacco products as vehicles for the delivery of nicotine. In these documents, for example, senior officials and researchers for the tobacco manufacturers expressly conceived of tobacco products as "a dispenser for a dose unit of nicotine,"[48] "[n]icotine delivery devices,"[43] "a vehicle for delivery of nicotine, designed to deliver the nicotine in a generally acceptable and attractive form,"[36] and "the means of providing nicotine dose in a metered fashion."[51]

Under the Act, these findings of the manufacturers' actual knowledge and product design provided a third independent basis for establishing that the manufacturers "intend" to affect the structure and function of the body. The plain meaning of "intend" includes "to have in mind" or "to design" for a particular use.[52] As the agency's investigation of the tobacco company documents revealed, the manufacturers did both (1) "have in mind" the use of cigarettes for the particular purpose of delivering the pharmacological effects of nicotine and (2) "design" their products to provide these effects.

TOBACCO PRODUCTS ARE COMBINATION PRODUCTS

Under the Act, products such as cigarettes and smokeless tobacco that are intended to affect the structure and function of the body can be either a "drug" under section 201(g)(1)(C) or a "device" under section 201(h)(3).[5] The principal difference between a drug and a device is that a device "does not achieve its primary intended purposes through chemical action within or on the body . . . and . . . is not dependent upon being metabolized."[2] Since enactment of the Safe Medical Devices Act of 1990, products can also be regulated as "combinations" of a drug and a device.[53] Examples of combination products include drug delivery systems such as nebulizers used by persons with asthma and transdermal patches.[54]

Based on the agency's findings regarding the pharmacological effects and intended uses of nicotine in cigarettes and smokeless tobacco, FDA concluded that the nicotine in these products is a "drug" under the Act.

The FDA further found that cigarettes and smokeless tobacco are not simply packaged nicotine. The agency found that cigarettes are "a highly engineered product" with components such as the tobacco blend, the filter, and the ventilation system that "have been carefully designed to deliver controlled, pharmacologically active doses of nicotine to the smoker."[33(p45209)] Likewise, FDA found that the processed tobacco in smokeless tobacco functions "to deliver the nico-

tine to the cheek and gum tissue for absorption into the body.[1(p45218-45214)] The FDA determined that these components of cigarettes and smokeless tobacco meet the statutory definition of a "device." Thus, FDA concluded that cigarettes and smokeless tobacco products are "combination products" under the Act.

THE TOBACCO INDUSTRY'S ARGUMENTS

The tobacco industry made two principal arguments contesting FDA's assertion of jurisdiction. First, the industry asserted that the agency was barred from regulating tobacco products because FDA had previously taken the position that it did not have jurisdiction over tobacco products, causing Congress to enact alternative approaches to regulating these products, such as the Federal Cigarette Labeling and Advertising Act and the Comprehensive Smokeless Tobacco Health Education Act.

Historically, FDA has asserted jurisdiction over tobacco products when there is sufficient evidence before the agency to establish that the products in question are "intended" to affect the structure and function of the body. Over 30 years ago, for instance, FDA asserted jurisdiction over a brand of cigarettes that were intended to reduce body weight.[55] In that case, the weight-reduction claims made by the manufacturer were sufficient evidence to allow the court to conclude that the cigarettes at issue were "obviously an article intended to affect the structure and/or function of the body."[56(p851)] In the past, however, FDA did not regulate cigarettes and smokeless tobacco as a class of products, because in the absence of advertising promoting cigarettes and smokeless tobacco for weight loss or other pharmacological uses, FDA could not establish that these products were intended to affect the structure or function of the body.

The FDA's recent assertion of jurisdiction is consistent with this approach. The reason FDA is now regulating cigarettes and smokeless tobacco as a class of products is that for the first time the evidence before the agency is sufficient to show that these products are in fact "intended" to affect the structure or function of the body. None of the statutes cited by the tobacco industry bar FDA from regulating cigarettes or smokeless tobacco once this intent has been demonstrated. For example, the narrow preemption provision in the Federal Cigarette Labeling and Advertising Act only restricts federal agencies from requiring "statement[s] relating to smoking and health . . . on any cigarette package."[56]

Second, the tobacco industry argued that the intended use of a product must be determined exclusively on the basis of the promotional claims made by the manufacturer. Under the industry's legal theory, unless tobacco products are labeled and advertised for sustaining nicotine addiction, altering mood, or regulating weight, they are not "intended" as drugs or devices. Thus, the industry urged FDA to disregard the evidence from internal company documents, as well as the evidence of the foreseeable and actual consumer uses of cigarettes and smokeless tobacco.

The FDA rejected this interpretation of the Act for several reasons. First, the industry's position is contrary to the plain language of the Act. The Act does not provide that only products "promoted" to affect the structure or function of the body are drugs or devices. Rather, the Act provides that products "intended" to affect the structure or function of the body are drugs or devices. The ordinary meaning of "intend" permits a wide range of evidence to be considered in determining intent, including the types of evidence relied upon by FDA.

Second, consistent with the plain meaning of "intend," the courts have concluded that FDA is "free to pierce . . . a manufacturer's misleading . . . labels to find actual therapeutic intent on the basis of objective evidence."[57] The courts have thus recognized that FDA may consider many categories of evidence beyond the manufacturer's promotional claims, including evidence of the pharmacological effects of the product,[58] the purposes for which consumers actually use the product,[3(pp239-240)] the medical use of the product,[59] and how the product was formulated.[60]

Third, preserving FDA's authority to consider evidence of the pharmacological effects and uses of a product, as well as evidence of the manufacturer's knowledge and actions, is necessary for the protection of the public health. If promotional claims alone determined the intended use of a product, virtually any manufacturer of drugs or devices could avoid being required to demonstrate the safety and effectiveness of its product under the Act by simply refraining from making pharmacological claims for the product. For instance, under the tobacco industry's interpretation, a company could market a potent tranquilizer or an antidepressant for its "pleasurable" effect and thereby avoid FDA regulation. To protect the public from the unregulated distribution of products with pharmacologically active ingredients, the agency must be able to look beyond a manufacturer's promotional claims when determining whether to regulate such products.

CONCLUSION

For the reasons summarized above, FDA concluded that (1) the evidence before it demonstrated that cigarettes and smokeless tobacco are intended to sustain addiction and produce other pharmacological effects and (2) these products should therefore be regulated as "devices" intended to deliver the "drug" nicotine. This assertion of jurisdiction is the basis for one of the most important regulations in the agency's history: the Children's Tobacco Rule, a comprehensive approach to reducing cigarette and smokeless tobacco use by children by restricting their access to tobacco products and limiting the appeal of tobacco advertising to youth.[1]

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Appendix Nine

Statement on nicotine-containing cigarettes

D. Kessler, former US Food and Drug Administration Commissioner

Tobacco Control 1994; 3: 148–158

From the US Food and Drug Administration

Statement on nicotine-containing cigarettes

David A Kessler

On 25 March 1994 the Commissioner of the US Food and Drug Administration (FDA), Dr David Kessler, presented testimony to the Subcommittee on Health and the Environment, Committee on Energy and Commerce, US House of Representatives. In his statement Dr Kessler commented on the addictive nature of cigarette smoking. He also presented evidence which, in his view, suggests that the cigarette industry has manipulated the level of nicotine in cigarettes with the intent to create and sustain addiction in smokers. We consider this testimony, because of both its content and the position of the person who gave it, to be an historic event in the history of tobacco control. Therefore, despite its length, we are reproducing the statement below.

We have used bold type to highlight some of the more noteworthy statements made by Dr Kessler. Eight figures have been omitted (such omissions are noted in brackets), and some of the references have been modified to conform to the journal's style. Otherwise, the testimony is reproduced in its original form.

An editorial by Dr John Slade commenting on this testimony appears on page 99. A cover essay by Dr Edythe London, which addresses nicotine action in the brain, appears on page 101. – ED

Mr Chairman, the cigarette industry has attempted to frame the debate on smoking as the right of each American to choose. The question we must ask is whether smokers really have that choice.

Consider these facts:

- Two-thirds of adults who smoke say they wish they could quit.[1]
- Seventeen million try to quit each year, but fewer than one out of 10 succeed.[2] For every smoker who quits, nine try and fail.
- Three out of four adult smokers say that they are addicted.[1] By some estimates, as many as 74% to 90% are addicted.[3]
- Eight out of 10 smokers say they wish they had never started smoking.[1]

Accumulating evidence suggests that cigarette manufacturers may intend this result – that they may be controlling smokers' choice by controlling the levels of nicotine in their products in a manner that creates and sustains an addiction in the vast majority of smokers.

That is the issue I am here to address. Whether it is a choice by cigarette companies to maintain addictive levels of nicotine in their cigarettes, rather than a choice by consumers to continue smoking, that in the end is driving the demand for cigarettes in this country.

US Food and Drug Administration, 5600 Fishers Lane, Rockville, Maryland 20857, USA
DA Kessler

Although the FDA has long recognised that the nicotine in tobacco produces drug-like effects, we never stepped in to regulate most tobacco products as drugs. One of the obstacles has been a legal one. A product is subject to regulation as a drug based primarily on its intended use. Generally, there must be an intent that the product be used either in relation to a disease or to affect the structure or function of the body. With certain exceptions,[4,5] we have not had sufficient evidence of such intent with regard to nicotine in tobacco products. Most people assume that the nicotine in cigarettes is present solely because it is a natural and unavoidable component of tobacco.

Mr Chairman, we now have cause to reconsider this historical view. The question now before us all is whether nicotine-containing cigarettes should be regulated as drugs. We seek guidance from the Congress on the public health and social issues that arise once the question is posed. This question arises today because of an accumulation of information in recent months and years. In my testimony today, I will describe some of that information.

The first body of information concerns the highly addictive nature of nicotine. The second body of information I will be talking about – in some detail – concerns the apparent ability of cigarette companies to control nicotine levels in cigarettes. We have information strongly suggesting that the amount of nicotine in a cigarette is there by design. Cigarette companies must answer the question: what is the real intent of this design?

Nicotine is a highly addictive substance

Let me turn then to my first point about the addictive nature of nicotine. The nicotine delivered by tobacco products is highly addictive. This was carefully documented in the 1988 US Surgeon General's report. You can find nicotine's addictive properties described in numerous scientific papers.[6–12]

As with any addictive substance, some people can break their addiction to nicotine. But I doubt there is a person in this room who hasn't either gone to great pains to quit smoking, or watched a friend or relative struggle to extricate himself or herself from a dependence on cigarettes.

Remarkably, we see the grip of nicotine even among patients for whom the dangers of smoking could not be starker. After surgery for lung cancer, almost half of smokers resume

smoking.[13] Among smokers who suffer a heart attack, 38% resume smoking while they are still in the hospital.[14] Even when a smoker has his or her larynx removed, 40% try smoking again.[15]

When a smoker sleeps, blood levels of nicotine decrease significantly. But the smoker doesn't need to be an expert on the concept of nicotine blood levels to know full well what that means. More than one-third of smokers reach for their first cigarette within 10 minutes of awakening; nearly two-thirds smoke within the first half hour.[16] Experts in the field tell us that smoking the first cigarette of the day within 30 minutes of waking is a meaningful measure of addiction.[17]

I am struck especially by the statistics about our young people. A majority of adult smokers begin smoking as teenagers.[6] Unfortunately, 70% of young people aged 12–18 who smoke say that they believe that they are already dependent on cigarettes.[6] About 40% of high school seniors who smoke regularly have tried to quit and failed.[6]

It is fair to argue that the decision to start smoking may be a matter of choice. But once they have started smoking regularly, most smokers are in effect deprived of the choice to stop smoking. Recall one of the statistics I recited earlier. Seventeen million Americans try to quit smoking each year. But more than 15 million individuals are unable to exercise that choice because they cannot break their addiction to cigarettes. My concern is that the choice that they are making at a young age quickly becomes little or no choice at all and will be very difficult to undo for the rest of their lives.

Mr Chairman, nicotine is recognized as an addictive substance by such major medical organisations as the Office of the US Surgeon General,[18] the World Health Organisation,[19,20] the American Medical Association,[21] the American Psychiatric Association,[22] the American Psychological Association,[23] the American Society of Addiction Medicine,[24] and the Medical Research Council in the United Kingdom.[25] All of these organisations acknowledge tobacco use as a form of drug dependence or addiction with severe adverse health consequences.

Definitions of an addictive substance may vary slightly, but they all embody some key criteria: first, compulsive use, often despite knowing the substance is harmful; second, a psychoactive effect – that is, a direct chemical effect in the brain; third, what researchers call reinforcing behaviour that conditions continued use (figure 1).[18] In addition, withdrawal symptoms occur with many drugs and occur in many cigarette smokers who try to quit. These are hallmarks of an addictive substance and nicotine meets them all.

When a smoker inhales, once absorbed in the bloodstream, nicotine is carried to the brain in only 7–9 seconds,[26] setting off a biological chain reaction that is critical in establishing and reinforcing addiction.

Over the past few years, scientists have generated a tremendous amount of information

Criteria for drug dependence

Primary criteria
- highly controlled or compulsive use
- psychoactive effects
- drug-reinforced behaviour

Additional criteria

Addictive behaviour often involves:
- stereotypic patterns of use
- use despite harmul effects
- relapse following abstinence
- recurrent drug cravings

Dependence-producing drugs often produce:
- tolerance
- physical dependence
- pleasant (euphoric) effects

Figure 1 Source: US Surgeon General's report, 1988[18]

on the similarities among different addictive substances. Some crucial information has come from the fact that, in a laboratory setting, animals will self-administer addictive substances. This self-administration may involve the animal pushing a lever or engaging in other actions to get repeated doses of the addictive substance. With very few exceptions, animals will self-administer those drugs that are considered highly addictive in humans, including morphine and cocaine, and will not self-administer those drugs that are not considered addictive.[27,28]

Understanding that animals will self-administer addictive substances has fundamentally changed the way that scientists view addiction in humans.[27] It has turned attention away from the concept of an "addictive personality" to a realisation that addictive drugs share common chemical effects in the brain.[27]

Despite the wide chemical diversity among different addictive substances, a property that most of them share is the ability to affect the regulation of a chemical called dopamine in parts of the brain that are important to emotion and motivation.[29] It is now believed that it is the effect of addictive substances on dopamine that is responsible for driving animals to self-administer these substances and for causing humans to develop addictions.[27]

Regulation of dopamine rewards the activity, and causes the animal or person to repeat the activity that produced that reward.[27,29] The process by which the regulation of dopamine leads an animal or a human to repeat the behaviour is known as "reinforcement".[27] Drugs that have the ability to directly modify dopamine levels can produce powerfully ingrained addictive behaviour.[27]

One of the ways that researchers now test the addictive properties of drugs is to determine whether animals will self-administer that substance and then to determine whether the animals will stop self-administering if the chemical action of the substance is blocked by

the simultaneous administration of another drug that prevents the first substance from acting in the brain. Data gathered over the past 15 years have documented that laboratory animals will voluntarily self-administer nicotine;[18,28,29] that nicotine stimulates the release of dopamine;[30] and that laboratory animals will decrease self-administration of nicotine if the action of nicotine, or the release of dopamine, in the brain is blocked.[31,32]

A number of top tobacco industry officials have stated that they do not believe that tobacco is addictive.[33,34] They may tell you that smokers smoke for "pleasure", not to satisfy a nicotine craving. Experts tell us that their patients report that only a small minority of the cigarettes they smoke in a day are highly pleasurable.[35] Experts believe that the remainder are smoked primarily to sustain nicotine blood levels and to avoid withdrawal symptoms.[35]

The industry couches nicotine's effects in euphemisms such as "satisfaction" or "impact" or "strength". Listen to what they say in one company's patent:

> It also has been generally recognised that the smoker's perception of the "strength" of the cigarette is directly related to the amount of nicotine contained in the cigarette smoke during each puff.[36]

But these terms only sidestep the fact that the companies are marketing a powerfully addictive agent. **Despite the buzzwords used by industry, what smokers are addicted to is not "rich aroma" or "pleasure" or "satisfaction". What they are addicted to is nicotine, pure and simple, because of its psychoactive effects and its drug dependence qualities.**

To smokers who know that they are addicted, to those who have buried a loved one who was addicted, it is simply no longer credible to deny the highly addictive nature of nicotine.

Controlling the level of nicotine in cigarettes

My second point today involves a growing body of information about the control of nicotine levels exercised by the tobacco industry. Mr Chairman, I do not have all the facts or all the answers today. The picture is still incomplete. But from a number of pieces of information, from a number of sources, a picture of tobacco company practices is beginning to emerge.

The public thinks of cigarettes as simply blended tobacco rolled in paper. But they are much more than that. **Some of today's cigarettes may, in fact, qualify as high technology nicotine delivery systems that deliver nicotine in precisely calculated quantities – quantities that are more than sufficient to create and to sustain addiction in the vast majority of individuals who smoke regularly.**

But you don't have to take it from me. Consider how people in the tobacco industry itself view cigarettes.

Just take a moment to look at the excerpts from an internal memorandum written by a supervisor of research that circulated in the Philip Morris Company in 1972:

> 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 for nicotine... Smoke is beyond question the most optimized vehicle of nicotine and the cigarette the most optimized dispenser of smoke.[37]

"Dispensers of smoke... [which is] a vehicle for delivering nicotine." This quote is a revealing self-portrait. Or listen to the words in one tobacco company patent:

> Medical research has established that nicotine is the active ingredient in tobacco. Small doses of nicotine provide the user with certain pleasurable effects resulting in the desire for additional doses.[38]

THE DESIGN OF CIGARETTES

How does this industry design cigarettes?

The history of the tobacco industry is a story of how a product that may at one time have been a simple agricultural commodity appears to have become a nicotine delivery system. Prior to the 1940s, the waste products from cigarettes – the stems, the scraps, and the dust – were discarded. The tobacco industry had identified no use for these materials in the cigarette manufacturing process.

Then, in the 1940s and '50s, the industry created reconstituted tobacco from the previously unusable tobacco stems, scraps, and dust. This gave cigarette makers the ability to reduce the cost of producing cigarettes by using fewer tobacco leaves and making up the difference by using reconstituted tobacco. While the motive appeared to be purely economic, the reconstitution process was nevertheless a critical development that started the industry down the path toward controlling and manipulating nicotine levels. The ability to control and manipulate nicotine levels becomes important in light of another key realization. Industry patents show that the industry recognized that nicotine is the active ingredient in tobacco smoke. It is what produces the psychoactive effects that lead smokers to crave cigarettes.

Numerous patents illustrate how the industry has been working to sustain the psychoactive effects of nicotine in cigarettes. These charts [omitted here] show samples from several categories of patents: eight patents to increase nicotine content by adding nicotine to the tobacco rod (patents 3,109,436; 4,215,706; 4,830,028; 4,836,224; 5,031,646; 3,861,400; 4,715,389; 4,595,024); five patents to increase nicotine content by adding nicotine to filters, wrappers and other parts of the cigarette (patents 3,280,823; 3,584,630; 5,105,834; 4,676,259; 4,236,532); three patents that use advanced technology to manipulate the levels of nicotine in tobacco (patents 0,280,817; 4,898,188; 5,018,540); eight patents on extraction of nicotine from tobacco (patents 3,046,997; 4,068,671; 4,557,280; 3,139,435;

4,150,677; 5,065,775; 4,967,771; 5,018,540); and nine patents to develop new chemical variants of nicotine (patents 5,138,062; 5,015,741; 4,590,278; 4,155,909; 4,321,387; 4,220,781; 4,442,292; 4,452,984; 4,332,945).

Patents not only describe a specific invention. They also speak to the industry's capabilities, to its research, and provide insight into what it may be attempting to achieve with its products.

It is prudent to keep in mind that patents do not necessarily tell us what processes are currently being used in manufacturing cigarettes. Nevertheless, the number and pattern of these patents leave little doubt that the cigarette industry has developed enormously sophisticated methods for manipulating nicotine levels in cigarettes. Today, a cigarette company can add or subtract nicotine from tobacco. It can set nicotine levels. In many cigarettes today, the amount of nicotine present is a result of choice, not chance.

Let me show you the language in some of these patents. This is in the industry's own words. Listen to what industry says it *wants* to be able to do with nicotine.

First, the industry wants precise *control* of the amount of nicotine in cigarettes to provide desired physiological effects:

> Maintaining the nicotine content at a sufficiently high level to provide the desired physiological activity, taste, and odor ... can thus be seen to be a significant problem in the tobacco art.[39]

Second, the industry wants to *increase* the amount of nicotine in some cigarettes.

> ... the perceived taste or strength of the cigarettes classified as having lower levels of "tar" and nicotine are progressively less than that of the cigarettes which are classified as approaching the characteristics of the "full flavor" cigarettes. It has been proposed to add nicotine and other flavorants to the cut filler of the lower "tar" cigarettes to enhance the taste, strength, and satisfaction of such cigarettes.[40]

> This invention ... concerns the problem of maintaining or increasing the nicotine content of the smoke whilst avoiding an undesirable level of particulate matter in the smoke ...[41]

Now listen to what the industry says it *can* do, right now, at least for patent purposes, with the nicotine in cigarettes. It can precisely *manipulate nicotine levels* in cigarettes:

> This invention permits the release into tobacco smoke, in controlled amounts, of desirable flavorants, as well as the release, in controlled amounts and when desired, of nicotine into tobacco smoke.[39]

> It is another object of the invention to provide an agent for the treatment of tobacco smoke whereby nicotine is easily released thereinto in controlled amounts.[42]

> [I]t can be seen that the process ... enables the manipulation of the nicotine content of tobacco material, such as cut leaf and reconstituted leaf, by removal of nicotine from a suitable nicotine tobacco source or by the addition of nicotine to a low nicotine tobacco material.[43]

> ... processed tobaccos can be manufactured under conditions suitable to provide products having various nicotine levels.[44]

> Examples of suitable tobacco materials include ... processed tobacco materials such as expanded tobaccos, processed tobacco stems, reconstituted tobacco materials or reconstituted tobacco materials having varying levels of endogenous and exogenous nicotine ...[44]

> ... the present invention ... is particularly useful for the maintenance of the proper amount of nicotine in tobacco smoke.

> ... previous efforts have been made to add nicotine to tobacco products wherein the nicotine level in the tobacco was undesirably low.[42]

It can precisely *manipulate the rate* at which the nicotine is delivered in the cigarette:

> It is a further object of this invention to provide a cigarette which delivers a larger amount of nicotine in the first few puffs of the cigarette than in the last few puffs.[36]

It can *transfer nicotine from one material to another* at will:

> Moreover, the process is useful for transferring naturally occurring nicotine from tobacco having a generally high nicotine content to a nicotine deficient tobacco, tobacco filler materials, or RL (reconstituted leaf) which are used in the production of cigarettes and other smoking products ... [A] low nicotine tobacco ... can also be used as the nicotine donor ...[43]

> It is another object of this invention to provide a process for the migration of nicotine from one tobacco substrate (leaf material or reconstituted leaf) to a second tobacco substrate (leaf material, reconstituted leaf material or tobacco stems) or to a non-tobacco substrate.[45]

It can *increase* the amount of nicotine in cigarettes:

> If desired, nicotine can be incorporated into the expansion solvents used to provide a volume expanded processed tobacco material having a high nicotine content.[44]

> The present invention provides a nicotine-enhanced smoking device with a high nicotine release efficiency ... Thus, the smoker is provided with more nicotine from the nicotine-enhanced device than from a similar smoking device which does not contain the nicotine solution or from a comparable cigarette.[38]

> The present invention is concerned with the application of additives, such as ... physiologically active agents such as nicotine components to the smoking rod, in order to improve or help to improve the satisfaction provided to the smoker.[46]

It can *add nicotine to any part* of the cigarette:

> The salts [nicotine levulinate] can be incorporated into the smoking article in a variety of places or sites. For example, the salt can be applied to the filler material, incorporated within some or all of the filler material, applied to the wrapper of the tobacco rod, applied within the glue line of the wrapper of the tobacco rod, applied within a region (eg, a cavity) ...[40]

It can use a variety of methods to add nicotine to tobacco:

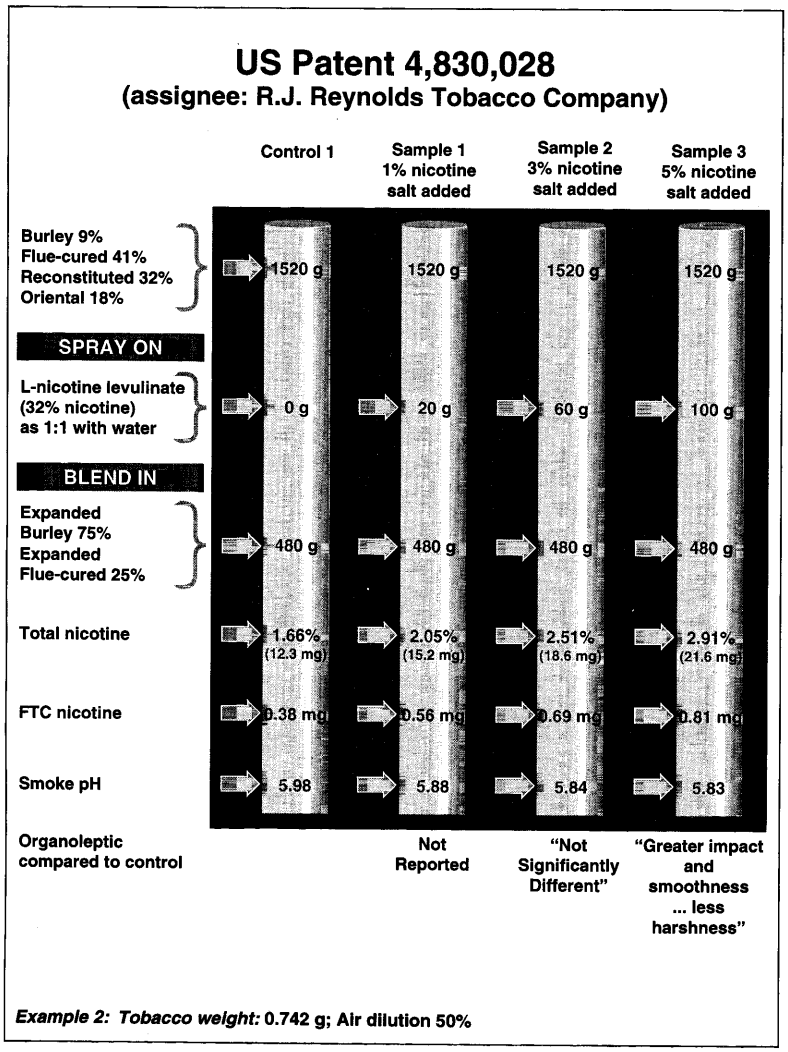


Figure 2

... [T]he additive [nicotine levulinate] can be applied using syringes or techniques such as spraying, electrostatic deposition, impregnation, garniture injection, spray drying, inclusion and encapsulation technologies, and the like.[40]

Let me describe in some detail how some of the technologies can be used to increase or control the nicotine level of tobacco.

The industry had to tackle a new problem beginning in the 1960s as public concern about the health consequences of smoking intensified. The industry began to market cigarettes it described as low yield. It faced a major challenge, however, because in the words of Patent No 4,830,028 (RJ Reynolds Tobacco Company), "the perceived taste or strength of the cigarettes classified as having lower levels of 'tar' and nicotine are progressively less than that of the cigarettes which are classified as approaching the characteristics of the 'full flavor' cigarettes."

The patent then describes a way to add nicotine to the "low-yield" cigarettes. If nicotine alone is sprayed on a blend of tobacco, the patent states that the smoke that results will be unacceptably harsh or irritating to the user. So, instead of just spraying nicotine on the tobacco blend, the patent combines nicotine with another compound, an organic acid called levulinic acid, to form a salt that masks the irritating qualities of nicotine (figure 2) [one figure omitted]. The patent demonstrates that different percentages of the nicotine salt can be added to blends of tobacco to produce different nicotine concentrations. The control cigarette, the one without any added nicotine, contains 1.66% nicotine. Adding 1% nicotine salt results in a cigarette with 2.05% nicotine. As one increases the amount of nicotine salt sprayed on the tobacco blend, the nicotine content of the tobacco increases.

In this process, great care is paid to the pH of the smoke because pH affects the bioavailability of nicotine – that is, how much the body absorbs. The patent demonstrates the technology to increase nicotine content in tobacco by up to 76%.

US Patent No 5,065,775 (Col 3: 55–63) (RJ Reynolds Tobacco Company) describes another technology that can control the nicotine content of tobacco filler (figure 3). This involves a process for "modifying the alkaloid content of a tobacco material and, in particular, for providing a processed tobacco material having a controlled nicotine content". In the words of the patent "[t]he process of the present invention provides a skilled artisan with an efficient and effective method for changing the character of a tobacco material (eg, rearranging components of a tobacco material or altering the chemical nature or composition of a tobacco material) in a controlled manner. That is, the process ... can be employed in a way such that changes in the chemical composition of tobacco can be monitored as to occur to a desired degree."

The patent allows for the removal of selected substances from tobacco, and incorporating controlled amounts of substances into tobacco. Example 4 within this patent shows how a tobacco blend that starts off with a 2.3% nicotine content can end up with a 5.2%

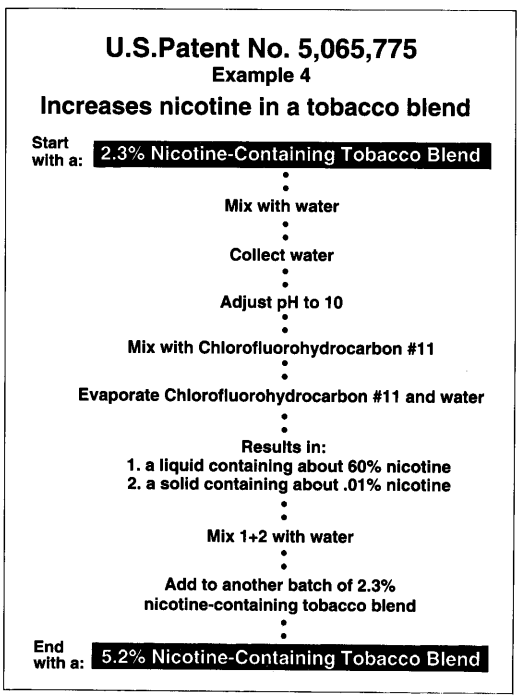


Figure 3

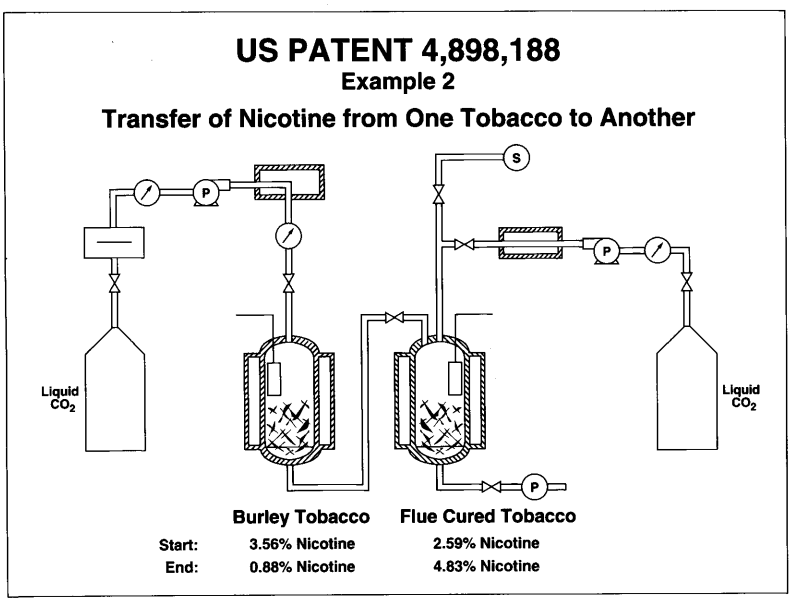


Figure 4

nicotine content. A highly concentrated nicotine solution is created by subjecting a tobacco blend to a series of chemical steps, including adding water, removing solids, increasing the pH, and mixing this substance with chlorofluorocarbon (CFC) 11 and then evaporating off that CFC 11. This concentrate is then added to water-washed tobacco to increase its nicotine content. This patent demonstrates the technology to increase the nicotine content in tobacco by more than 100%.

A third example of sophisticated technology involves the direct transfer of nicotine from one type of tobacco to another type of tobacco (figure 4). US Patent No 4,898,188 (RJ Reynolds Tobacco Company) utilizes supercritical fluid extraction. In example 2 in the patent, liquid carbon dioxide is used to transfer nicotine from Burley cut tobacco filler to flue-cured cut tobacco. The flue-cured cut filler starts off with a nicotine content of 2.59% and ends up with a nicotine content of 4.83%. The Burley cut filler starts off with a nicotine content of 3.56% and ends with a nicotine content of 0.88%. This patent demonstrates that nicotine can be transferred in significant amounts from one type of tobacco filler to another.

Additional information about the ability to set nicotine content at varying levels comes from the following advertisement, headlined "MORE OR LESS NICOTINE", which appeared in an international tobacco trade publication (figure 5):

Nicotine levels are becoming a growing concern to the designers of modern cigarettes, particularly those with lower "tar" deliveries. The Kimberly-Clark tobacco reconstitution process used by LTR Industries permits adjustments of nicotine to your exact requirements. These adjustments will not affect the other important properties of customized reconstituted tobacco produced at LTR Industries: low tar delivery, high filling power, high yield, and the flexibility to convey organoleptic modifications. We can help you control your tobacco.

In fact the process described in this advertisement can raise the level of nicotine beyond what is naturally found in tobacco materials, especially the stems and scraps. A 1985 tobacco [industry] journal article describing the LTR process states:

Though standard reconstituted tobacco products contain 0.7–1.0 percent nicotine, LTR Industries offers the possibility of increasing the nicotine content of the final sheet to a maximum of 3.5 percent...

A dramatic increase in tobacco taste and smoke body is noted in the nicotine-fortified reconstituted tobacco.[47]

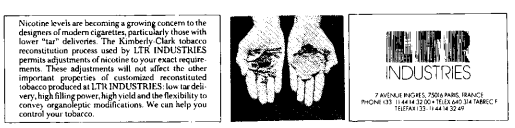
All of this apparent technology for manipulating nicotine in tobacco products raises the question of how the industry determines how much nicotine should be in various products. More importantly, **since the technology apparently exists to reduce nicotine in cigarettes to insignificant levels,[48,49] why, one is led to ask, does the industry keep nicotine in cigarettes at all?**

The tobacco industry would like you to believe that all it is doing is returning the nicotine that is removed during the process of producing reconstituted tobacco. It should be clear from what I have described thus far that the technology the industry may have available goes beyond such modest efforts.

The industry may also tell you that it is adjusting nicotine levels to be consistent with established "FTC yields" – these are the amounts of tar, nicotine, and carbon monoxide that are measured for each cigarette product by smoking machines, and disclosed under a voluntary agreement with the Federal Trade

A likeness of Jean Nicot, French diplomat, after whom "nicotine" and "Nicotiana Tabacum" were named

MORE OR LESS NICOTINE



Get more tobacco from all your tobacco

LTR INDUSTRIES, a subsidiary in France of
Kimberly-Clark Corporation

Figure 5

Commission (FTC). In fact, the control of nicotine levels in cigarettes, dating back at least to patents granted in 1966 for adjusting nicotine levels, preceded the first rules adopted by the FTC on disclosing tar and nicotine yields. Moreover, there is nothing about the FTC yields that would require tobacco companies to increase nicotine in low-tar cigarettes, as the industry patents suggest they do. There are no FTC restrictions on nicotine levels, and the FTC guidelines take into account crop variability by sampling completed cigarettes from 50 retail outlets across the country. Indeed, there is no FTC restriction that would prevent the industry from reducing nicotine below addicting levels or eliminating it altogether.

In fact, the technology reflected in the cigarette industry's patents appears to be intended to allow the industry to set the nicotine content of tobacco products at defined levels that have little to do with either the amount of nicotine that was removed during the processing of the tobacco, or with the simple goal of maintaining consistency with established FTC yields. **The technology may exist to allow the industry to set nicotine levels wherever it wants, or, in fact to remove nicotine entirely. With all the apparent advances in technology, why do the nicotine levels found in the vast majority of cigarettes remain at addictive levels?**

Nicotine levels may be dictated in part by marketing strategies and demographics. A blatant example comes from information on the marketing of smokeless tobacco. **There is evidence that smokeless tobacco products with lower amounts of nicotine are marketed as "starter" products for new users, and that advertising is used to encourage users to "graduate" to products with higher levels of nicotine** (figure 6). The evidence was developed in lawsuits brought against one manufacturer of smokeless tobacco.

The tobacco industry may tell you that nicotine is important in cigarettes solely for "flavour". There is a great deal of information that suggests otherwise. Some of the patents specifically distinguish nicotine from flavourants.[42] An RJ Reynolds book on flavouring tobacco, while listing around a thousand flavourants, fails to list nicotine as a flavouring agent.[50] Even research scientists from the same company acknowledge that the nicotine in cigarettes provides pharmacological and psychological effects in smokers in addition to any mere sensory effects.[33]

Moreover, the available information shows that the industry has gone to significant lengths to develop technologies to mask the flavour of increased levels in cigarettes. As I have already noted, the industry's own patents reveal that increasing nicotine in fact usually produces an unacceptably harsh and irritating product, and that the industry has had to take special steps to mask the flavour of increased nicotine in low-tar cigarettes.

This should not come as a surprise. The

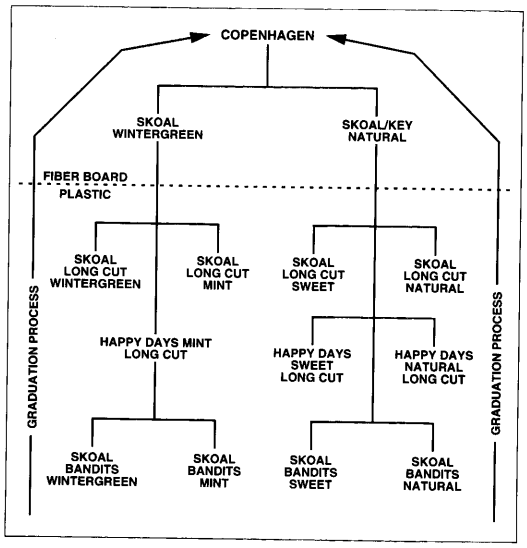


Figure 6 Source: Marsee *vs* US Tobacco Co, *plaintiff's exhibit 100 (provided by plaintiff's attorney)*

Merck Index, the authoritative encyclopaedia of chemicals, describes nicotine as having "an acrid, burning taste". *Webster's 7th New Collegiate Dictionary* defines acrid as "sharp and harsh or unpleasantly pungent in taste or odor; irritating, corrosive." In fact, US patent 4,620,554 uses the word "hazardous" to describe the taste of nicotine.

What appears to be true is that smokers become accustomed to the sensory impact of nicotine (burning in the throat) and associate it with the resulting psychoactive effects of nicotine, and thus look for those sensory signals in a cigarette; this is called "conditioned reinforcement".[51]

Moreover, **if nicotine is just another flavourant in tobacco, why not use a substitute ingredient with comparable flavour, but without the addictive potential?** For example, it has been repeatedly shown that substitute ingredients, such as hot pepper (capsaicin)[52] and citric acid,[53] have similar irritating sensory effects.

Similarities to the pharmaceutical industry

Mr Chairman, **this kind of sophistication in setting levels of a physiologically active substance suggests that what we are seeing in the cigarette industry more and more resembles the actions of a pharmaceutical manufacturer.** Besides controlling the amount of a physiologically active ingredient, there are a number of other similarities.

One similarity between the cigarette industry and the pharmaceutical industry is the focus on bioavailability. Bioavailability is the rate and extent that pharmacologically active substances get into the bloodstream. For example, the pH of tobacco smoke affects the bioavailability of nicotine.[54] The tobacco industry has conducted research on the pH of smoke[55] and has undertaken to control the pH in tobacco smoke. In patent examples,

chemicals have been added to tobacco to affect the pH of tobacco smoke.[40] The industry has even performed bioavailability and pharmacokinetic studies on conventional and novel cigarettes.[56]

The cigarette industry has undertaken research to look at the specific activity of added versus naturally occurring nicotine.[57] Additional research looked at the differences between spiking, spraying, and blending compounds into cigarettes.[58]

Development of an "express" cigarette, a shorter, faster burning cigarette with the same amount of tar and nicotine, has been reported in the lay press recently.[59,60] This is another example of how cigarette companies appear to be controlling the amounts of nicotine to deliver set levels.

The cigarette industry has also undertaken a significant amount of research looking at the potential "beneficial" effects of nicotine. It has studied the effects of nicotine on anxiety, heart rate, electroencephalograms, and behavioural performance tasks.[61–68] Such research on the physiological effects of an active ingredient is a common part of pharmaceutical drug development.

Psychotherapeutic Agents

(Patent 5,138,062)

Nicotine Analogues	Dose (IP) mg/kg	Sedation	Body Tone	Tranquilization (IVC) 50 ug
❶ R $-(CH_2)_2-N(CH_3)(CH_3)$	10	+	+	++++
	20	++	++	
❷ R $-(CH_2)_3-N(CH_3)(CH_3)$	5	+	+	++++
	10	++	+	
	20	+++	++	
❸ R $-(CH_2)_4-N(CH_3)(CH_3)$	10	+	+	+++
	20	+	+	
❹ R $-(CH_2)_5-N(CH_3)(CH_3)$	40	++	++	+++
❻ R $-(CH_2)_3-NH_2$	10	0	0	+++
	20	+	0	
❼ R $-(CH_2)_4-NH_2$	10	0	0	+++
	20	+	0	
❽ R $-(CH_2)_3-N$ (pyrrolidine)	10	+	0	+++
	20	++	++	
❾ R $-(CH_2)_3-N$ (piperidine)	10	0	0	++
	20	++	+	
❿ R $-(CH_2)_2-N$ (morpholine)	10	0	0	+
	20	+	+	
⓫ R $-(CH^2)-N$ (piperazine) $-N-CH_3$	20	++	+	++++
	40	+++	++	

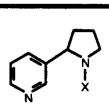
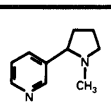
R =  NICOTINE =  (Data from rats)

Figure 7

Perhaps the most striking aspect of the research undertaken by the tobacco industry is its search for, and its patenting of, new nicotine-like chemicals that exhibit pharmacological properties which, in their own words, "are indicated for utility as potential psychotherapeutic agents".[69] One patent describes nicotine-like chemicals which

> exhibit tranquilizing and muscle-relaxing properties when administered to mammals. The nicotine analogs do not exhibit nicotine-like properties, such as tachycardia, hypertension, gastrointestinal effects, emesis in dogs, and the like.[69]

Example XXIX in the patent illustrates the pharmacological properties of nicotine analogues...

> The tranquilizing effects of invention nicotine compounds are measured after intraperitoneal (IP) and intraventricular (IVC) administration in the form of hydrochloride salts.
>
> Sedation is determined by measuring locomotion in an open field maze, and the response to noxious (air blast) stimuli. Body tone is estimated by handling rats and by the ability to hang from a rotating rod.
>
> Tranquilization after intraventricular (IVC) injection is estimated from muscle weakness in all four limbs, body tone and general activity.[69]

Figure 7 illustrates the results.

The problem of the low-yield cigarette

We at the FDA are concerned not only about the control over nicotine levels exercised by the cigarette industry, but also that the problems associated with nicotine are aggravated by significant limitations in the consumer's ability to reduce their exposure to nicotine by selecting "low"-nicotine cigarettes.

Most people who smoke low-yield or "light" cigarettes believe that they are getting less nicotine and tar by smoking these cigarettes. For the last 25 years the American public has relied on FTC ratings of tar and nicotine in advertising to tell them what they will be consuming. The "FTC method" utilizes a machine that tests cigarettes in a process involving a two-second, 35 ml puff each minute until a predetermined butt length is reached.[70]

Most people don't realise that low-yield cigarettes, as determined by the FTC method, do not usually result in proportionally less nicotine being absorbed when compared to high-yield cigarettes.[71,72] Furthermore, there is little correlation between low-yield FTC ratings and the total amount of nicotine in cigarettes.[71]

It is a myth that people who smoke low-nicotine cigarettes are necessarily going to get less nicotine than people who smoke high-nicotine cigarettes. There are several reasons for this. One reason is that there are differences between the smoking habits of a machine and a human. The way in which a cigarette is smoked is probably the most important determinant of how much tar and

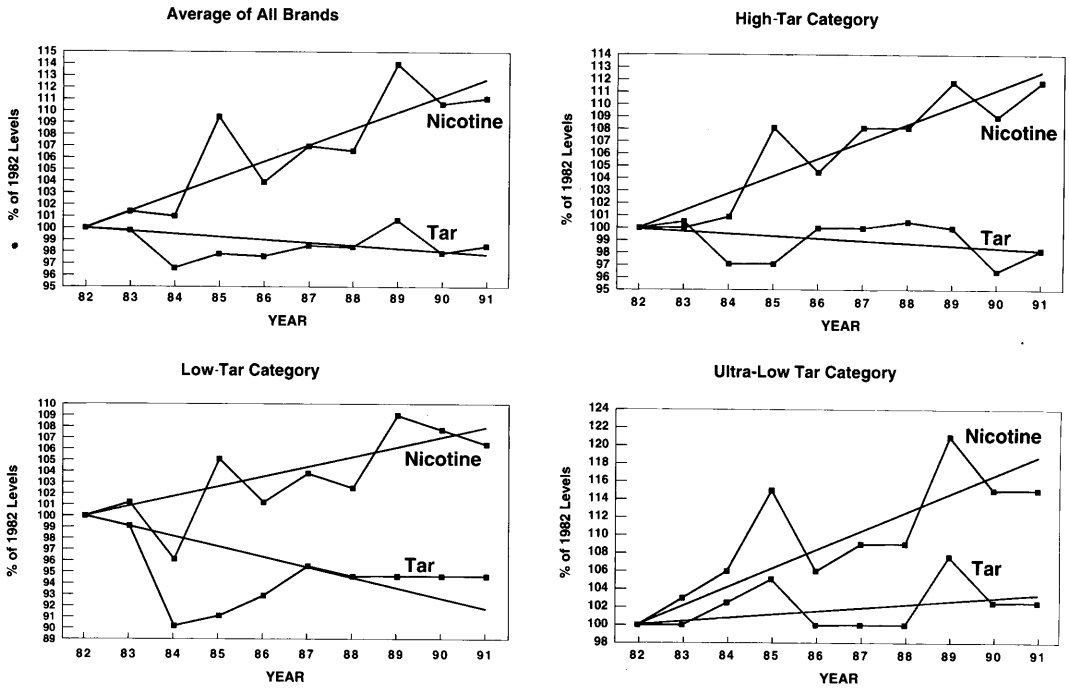


Figure 8 Sales-weighted nicotine and tar yields in smoke as a percentage of 1982 levels, for all brands and for specific tar categories. High tar: > 15 mg tar by the FTC method; low tar: 6–15 mg tar; ultra-low tar: < 6 mg tar. Source: FTC annual data

nicotine are inhaled. Humans can and do compensate when smoking low-yield cigarettes, by altering puff volume, puff duration, inhalation frequency, depth of inhalation, and the number of cigarettes smoked.[73–79] As a result of these compensatory mechanisms, a low-yield cigarette can actually result in a relatively high intake of nicotine.[72]

Beyond the human compensatory mechanisms, several other factors under manufacturers' control contribute to a lowering of machine ratings. These factors include the positioning of ventilation holes, how fast the cigarette paper burns, and the length of the filter paper overwrap.[80]

To understand how the position of ventilation holes in a cigarette can confound the FTC ratings, it is important to recognise that the main determinants of whether a cigarette has a high or low yield in machine testing are the cigarette's ventilation and burning characteristics.[71] Most low-yield cigarettes achieve their low ratings because of filter characteristics and also because the smoke is diluted with air. The air dilution is accomplished in part by placing ventilation holes in the filter. What scientists have demonstrated is that "although smoking machines which measure tar and nicotine do not occlude the perforations", 32 % to 69 % of low-tar smokers have blocked the holes with their fingers or lips, resulting in larger nicotine yields.[81] The ventilation holes are sometimes laser generated and can be hard for the smoker to see. Not all smokers are aware of the existence of these holes or that the smoker may be blocking them [figure omitted].

Two other factors that are under manufacturers' control can also confound the usefulness of the FTC ratings. The FTC method smokes a cigarette down to within 3 mm of the tipping paper overwrap. According to one study, "between 1967 and 1978, 18 brands of filter cigarettes underwent increases in overwrap width that reduced the amount of tobacco smoked in the cigarettes on the machine, even though the remaining tobacco is still smokeable" [figure omitted].[80] Another way that the FTC numbers can be confounded is by "increasing the rate at which cigarettes burn." A faster burning cigarette lowers the puff count. Manufacturers can increase the rate at which a cigarette burns by controlling the porosity of the cigarette paper. The machine takes a puff every minute, but humans can adjust their smoking rate*.[80]

Because of all these confounding factors we are concerned that consumers may assume that low-yield cigarettes in fact deliver low tar and nicotine when in reality they do not.

ACTUAL NICOTINE LEVELS IN CIGARETTES

To assess the levels of nicotine in cigarettes, we did two things. First, FDA laboratories measured the amount of nicotine actually in several types of cigarettes. We analysed three varieties of one brand family of cigarettes; one regular, one low tar, and one ultra low tar. What surprised us was that the variety advertised as having the lowest yield in fact had the highest concentration of nicotine in the cigarette (table).

Second, we formally requested from our colleagues at the FTC summary information derived from their data base on the levels of

* According to data reviewed in the 1988 Surgeon General's report (pp 156–7),[18] smokers take a puff on average every 34 seconds. — ED

Table % Nicotine in one brand family

Variety	% Nicotine (mg/g)
Regular 100s	1.46
Low tar 100s	1.67
Ultra low tar 100s	1.99

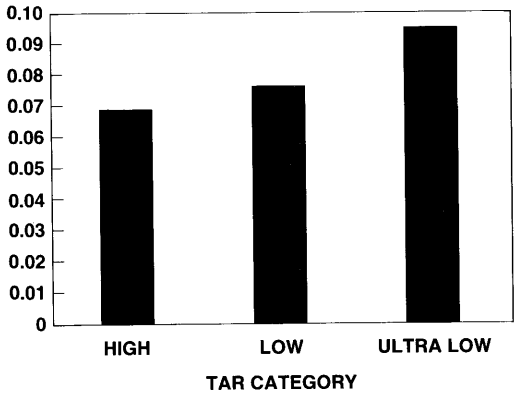


Figure 9 Sales-weighted nicotine: tar ratios, 10-year average 1982–91. Source: FTC annual data weighted by sales

nicotine in cigarettes. What we found was that since 1982 (the earliest year for which the computer data base is available), the sales-weighted levels of FTC nicotine in cigarettes appear to increase (figure 8). What was equally striking was that when we segmented sales into high-tar, low-tar, and ultra-low-tar cigarettes, the nicotine: tar ratio was higher in the ultra-low-tar group (figure 9). We would not have expected to see these differences because high tar has usually been associated with high nicotine, and low tar with low nicotine. It has often been said that tar and nicotine travel together in the cigarette smoke. The disparities in the nicotine: tar ratios among these varieties raise the question as to how this can occur.

FDA regulation of nicotine in cigarettes

The next task facing the FDA is to determine whether nicotine-containing cigarettes are "drugs" within the meaning of the Federal Food, Drug, and Cosmetic Act.

Our inquiry is necessarily shaped by the definition of "drug" in the Act. It is a definition that focuses on "vendor intent". More specifically, it focuses primarily on whether the vendor intends the product to "affect the structure or any function of the body".

Mr Chairman, the evidence we have presented today suggests that cigarette manufacturers may intend that most smokers buy cigarettes to satisfy their nicotine addiction.

We do not yet have all the evidence necessary to establish cigarette manufacturers' intent. It should be clear, however, that in determining intent, what cigarette manufacturers say can be less important than what they do. The fact that the technology may be available to reduce the nicotine to less than addictive levels is relevant in determining manufacturer intent.

It is important to note that the possibility of FDA exerting jurisdiction over cigarettes raises many broader public health and social issues for Congress to contemplate. There is the possibility that regulation of the nicotine in cigarettes as drugs would result in the removal of nicotine-containing cigarettes from the market, limiting the amount of nicotine in cigarettes to levels that are not addictive, or otherwise restricting access to them, unless the industry could show that nicotine-containing cigarettes are safe and effective. If nicotine were removed, the nation would face a host of issues involving the withdrawal from addiction that would be experienced by millions of Americans who smoke.

There is, of course, the issue of black market cigarettes. With nicotine, as with other powerfully addicting substances, a black market could develop.

In these issues, we seek guidance from Congress.

The one thing that I think is certain is that it is time for all of us – for the FDA, for the Congress, for the American public – to learn more about the way cigarettes are designed today and the results of the tobacco industry's own research on the addictive properties of nicotine.

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Appendix Ten

The control and manipulation of nicotine in cigarettes

D. Kessler, former
US Food and Drug Administration Commissioner

Tobacco Control 1994; **3**: 362–369

From the US Food and Drug Administration

The control and manipulation of nicotine in cigarettes

David A Kessler

On 25 March 1994 the Commissioner of the US Food and Drug Administration (FDA), Dr David Kessler, presented testimony to the Subcommittee on Health and the Environment, US House of Representatives, on the addictive nature of cigarette smoking and possible tobacco industry manipulation of nicotine levels in cigarettes. That testimony was reproduced in the Summer 1994 issue of Tobacco Control *(1994; 3:148–58).*

On 21 June 1994 Dr Kessler reappeared before the same subcommittee, and presented testimony on genetic and chemical manipulation of nicotine content. This statement is reproduced below. Twenty-two charts, which for the most part duplicated material in the text, have been omitted. Also, some of the references have been modified to conform to the journal's style. Otherwise, the testimony is reproduced in its original form. – ED

In my last appearance before this subcommittee on 25 March 1994, I raised the question of whether the FDA should regulate nicotine-containing cigarettes as drugs under the Federal Food, Drug, and Cosmetic Act.[1] A product is a drug if its manufacturer intends it to be used to affect the structure or function of the body.[2] Because of the enormous social consequences of such a decision, we have asked Congress for guidance as we try to answer this question.

Mr Chairman, the American public owes a huge debt of gratitude to this subcommittee for its tireless efforts to focus attention on this most important public health matter.

Let me begin by summarising the information that I presented at that hearing. I reviewed the evidence that supports the scientific consensus that nicotine is addictive. I also reviewed the evidence we had at that time on the ability of the tobacco industry to control nicotine levels, including numerous industry patents for technologies to manipulate and control nicotine content. I described activities of the cigarette industry that resemble those of pharmaceutical manufacturers. I presented information that raised the question of whether tobaccos were blended to manipulate and control nicotine levels. And I provided data showing that over the last decade, nicotine levels have not dropped in parallel with tar levels – in fact, they have risen.

Since March 25th we have continued to focus our analysis and investigation on the physiological and pharmacological effects of nicotine and on the degree to which cigarette companies manipulate and control the level of nicotine in their products.

The information that I presented about industry control and manipulation of nicotine the last time I testified before you was suggestive. Today I am going to provide you with actual instances of control and manipulation of nicotine by some in the tobacco industry that have been uncovered through painstaking investigational work over the last three months.

We have discovered that manipulation of nicotine has been carried out by some even before tobacco seeds were planted in the fields. We have discovered other forms of manipulation that occur later, in the design and manufacture of cigarettes.

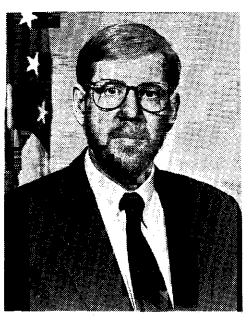
Today I want to discuss two examples of nicotine manipulation in some detail. First, we have discovered the deliberate *genetic* manipulation of the nicotine content in a tobacco plant. It is the story of how an American tobacco company spent more than a decade quietly developing a high-nicotine tobacco plant, growing it in Central and South America, and using it in American cigarettes. Second, I will discuss how chemical compounds are added to cigarettes to manipulate nicotine delivery.

Genetic manipulation of nicotine content

The project I am going to tell you about led to development of a tobacco plant code-named "Y-1". It has been an enormous task to piece together the picture of Y-1. Confidentiality agreements have made getting the facts very difficult.

The story begins in Portuguese with our discovery of a Brazilian patent for a new variety of a flue-cured tobacco plant (figure 1).[3] One sentence of its English translation caught our eye. "The nicotine content of the leaf of this variety is usually higher than approximately 6% by weight... which is significantly higher than any normal variety of tobacco grown commercially."[4]

Prior to our discovery of the patent, an industry executive had told us that "flue-cured tobacco naturally contains 2.5 to 3.5 percent nicotine."[5] Thus, this new specially bred plant would contain approximately twice the nicotine that occurs naturally in flue-cured tobacco.



US Food and Drug Administration, 5600 Fishers Lane, Rockville, Maryland 20857, USA
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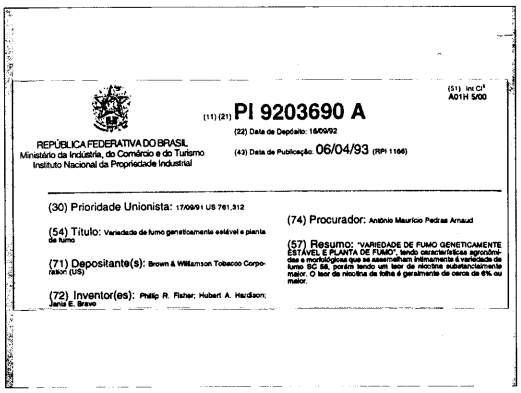

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REPÚBLICA FEDERATIVA DO BRASIL
Ministério da Indústria, do Comércio e do Turismo
Instituto Nacional da Propriedade Industrial

(30) Prioridade Unionista: 17/09/91 US 761,312

(54) Título: Variedade de fumo geneticamente estável e planta de fumo

(74) Procurador: Antônio Mauricio Pedras Arnaud

(57) Resumo: "VARIEDADE DE FUMO GENETICAMENTE ESTÁVEL E PLANTA DE FUMO", tendo caracteristicas agronômicas e morfológicas que se assemelham intimamente à variedade de fumo SC 58, porém tendo um teor de nicotina substancialmente maior. O teor de nicotina da folha é geralmente de cerca de 6% ou maior.

(71) Depositante(s): Brown & Williamson Tobacco Corporation (US)

(72) Inventor(es): Philip R. Fisher; Hubert A. Hardison; Jana E. Bravo

Figure 1

The holder of the Brazilian Y-1 patent was Brown & Williamson Tobacco Corporation, maker of such cigarettes as Kool, Viceroy, Richland, Barclay, and Raleigh.

Let me tell you why this discovery interested us. Industry representatives have repeatedly stated for the public record that they do not manipulate nicotine levels in cigarettes. The plant described in this patent represents a dramatic attempt to manipulate nicotine.

Moreover, when we asked company officials whether plants were bred specifically for higher nicotine content, we were told that this was not feasible. We were told that tobacco growers and cigarette manufacturers have an agreement that the nicotine level of new varieties of tobacco grown in the US can vary only slightly from the levels of standard varieties. Under this agreement, a new high-nicotine tobacco plant that varied more than slightly from the standard variety could not be commercially grown by farmers in the US.

Nevertheless, we learned that interest in developing a high-nicotine tobacco plant dates back to at least the mid-1970s. In 1977, Dr James F Chaplin, then of both the US Department of Agriculture (USDA) and North Carolina State University, stated:

"manufacturers have means of reducing tars but most of the methods reduce nicotine and other constituents at the same time. Therefore it may be desirable to develop levels constant or to develop lines higher in nicotine so that when the tar and nicotine are reduced there will still be enough nicotine left to satisfy the smoker."[6]

In fact, Dr Chaplin had been working on genetically breeding tobacco plants with varying nicotine levels. In a 1977 paper, Dr Chaplin indicated that tobacco could be bred to increase nicotine levels, specifically by cross breeding commercial varieties of tobacco with *Nicotiana rustica*. *N rustica* is a wild variety, very high in nicotine, but not used commercially in cigarettes because it is considered too harsh.[7]

Dr Chaplin has told us that his specially bred plants were not commercially viable because they did not grow well and literally did not stand up in the field. Furthermore, he was surprised that he could not get the nicotine levels as high as he anticipated. In fact, in his 1977 paper, the highest nicotine level he reported in these specially bred lines was 3.4% total nicotine, within the normal range for flue-cured tobacco.

At the same time, international efforts focused on controlling and manipulating nicotine by alternative methods. For example, the use of reconstituted tobacco:

"... [LTR, a maker of reconstituted tobacco] which homogenises tobacco for various European cigarette houses cannot only reduce the tar in the sheet it sends back to clients; it is able to work into client's scrap and waste new tobacco of the *rustica* type, rich in nicotine, in order to change the relationship of nicotine and tar in the sheet. It is able to do the same by the alternative method of adding salts of pure nicotine into the slurry that eventually becomes tobacco sheet. This is an operation parallel to, though more exact than, that on which US geneticists are engaged, in seeking to develop types of tobacco that are low in tar but fairly rich in nicotine."[8]

Over the next several years Dr Chaplin continued his efforts to breed a tobacco plant with a higher nicotine level. During that time, an employee of a Brown & Williamson-affiliated company asked Dr Chaplin for some of his seeds. Some of Dr Chaplin's original plant varieties were used as a basis for Brown & Williamson's work. From what we can gather, there was no formal release of this high-nicotine tobacco variety for private use. In the early 1980s, Brown & Williamson grew a number of different plant lines on its experimental farm in Wilson, North Carolina, selecting those that had the best agronomic characteristics.

In 1983, Brown & Williamson contracted with DNA Plant Technology to work on tobacco breeding. Much of the developmental work on Y-1 took place in the laboratories, greenhouses, and fields owned by DNA Plant Technology. After he retired from USDA, in 1986, Brown & Williamson also hired Dr Chaplin as a consultant to work on Y-1 and other projects.

The high-nicotine tobacco variety Y-1 was developed by a combination of conventional and advanced genetic breeding techniques (figure 2). These include traditional crosses and back crosses between different plant varieties and more sophisticated state-of-the-art breeding techniques including anther culture (figure 3), tissue culture (figure 4), hybrid sorting, and protoplast fusion (figure 5) that resulted in cytoplasmic male sterility. The

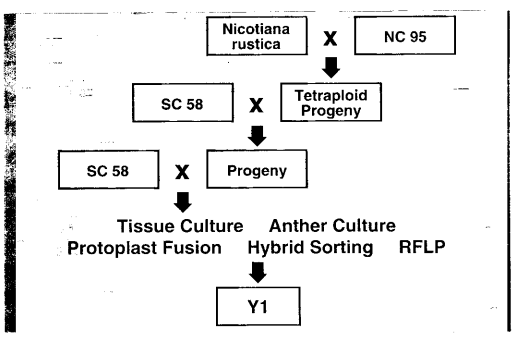

Figure 2 The breeding of Y-1. Sources: Brazilian Patent PI 9203690A and DNA Plant Technology Corporation

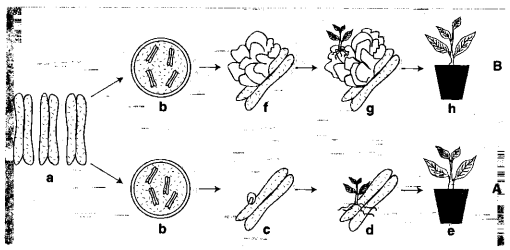

Figure 3 Anther culture. Source: Breeding field crops *3rd edn, J M Poehlman*

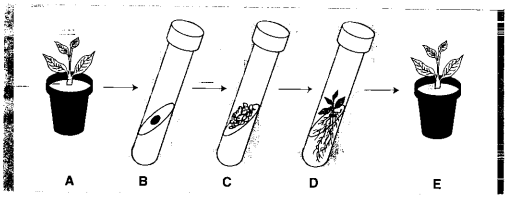

Figure 4 Tissue culture. Source: (as figure 3)

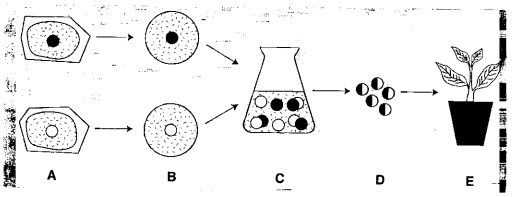

Figure 5 Protoplast fusion. Source: (as figure 3)

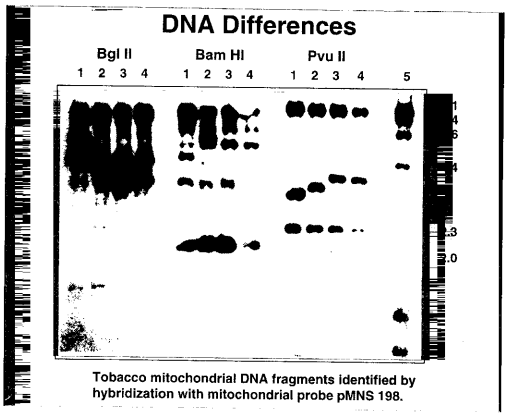

Figure 6 Y-1 restriction fragment length polymorphism. Tobacco mitochondrial DNA fragments identified by hybridization with mitochondrial probe pMNS 198. Source: US Patent application no 761,312

genetic makeup of Y-1 was verified by using genetic engineering techniques involving Restriction Fragment Length Polymorphism (RFLP) (figure 6).[9] The value of Y-1 to Brown & Williamson is reflected in the fact that Brown & Williamson had DNA Plant Technology make Y-1 into a male sterile plant. This procedure ensures that when a plant is grown it will not produce seeds that can be appropriated by others.

Brown & Williamson characterised its achievement in a patent filing as follows:

"By the present invention or discovery, applicants have succeeded in developing a tobacco plant that is agronomically and morphologically suitable for commercial tobacco production, ie, it closely

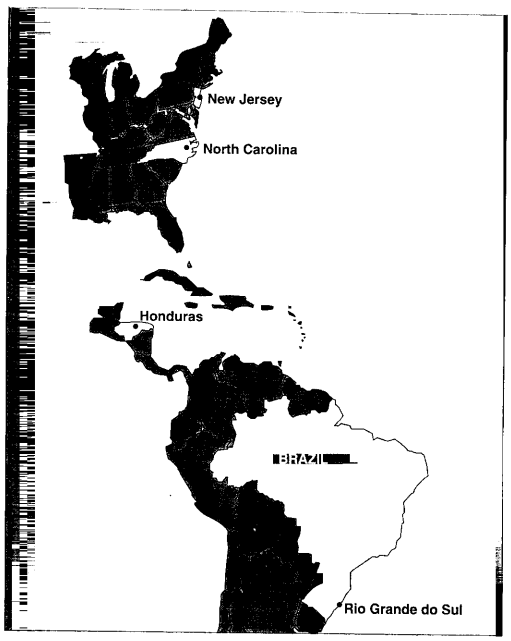

Figure 7 Where Y-1 was developed and grown

resembles SC 58, and provides a pleasant taste and aroma when included in smoking tobacco products, *yet it is possessed of the N rustica high-nicotine attribute.* So far as we know, this has not been accomplished before..."[10] [emphasis in original]

What was accomplished was the development of a tobacco plant with a high nicotine content – about 6 % – that grew well and could be used commercially.

The story of this high-nicotine plant continues in Rio Grande do Sul, Brazil (figure 7). DNA Plant Technology and Dr Chaplin both told us they saw Y-1 growing in Brazil in the 1980s. These farms were under contract to Souza Cruz Overseas, a sister company of Brown & Williamson.

We do not yet have all the details of how Y-1 came to be growing in Brazil. Until 13 December 1991, export of tobacco seeds or live tobacco plants was prohibited under Federal law unless a Tobacco Seed Plant Export Permit (Form TB-37) was granted by the USDA.[11] Such a permit could be granted only after satisfactory proof was offered that the seeds or plants were to be used solely for experimental purposes and then only in amounts of a half a gram or less.[12]

Brown & Williamson and DNA Plant Technology have each informed FDA that they believe the other may have been responsible for the shipment of Y-1 seed outside the US. We have asked both companies to furnish copies of any Tobacco Seed Plant Export Permits for Y-1.[13]

In reading the Brazilian Y-1 patent, we discovered that two related applications for the Y-1 variety of a tobacco plant were filed in the United States. Brown & Williamson filed a US patent application and a Plant Variety Protection Certificate Application in 1991.[14,15] The company also deposited samples of seeds from this plant with the National Seed Storage Laboratory in Fort Collins, Colorado.

When we attempted to obtain the Plant Variety Protection Certificate Application

- **Feb 21, 1991:** Brown & Williamson (B&W) files application for Plant Variety Protection Certificate
- **Sept 17, 1991:** B & W files U.S. Patent Application # 761, 312
- **Sept 16, 1992:** B & W files Brazilian Patent P1 9203690A
- **Feb 28, 1994:** B & W appeals rejection of U.S. Patent Application # 761, 312
- **March 14, 1994:** B & W withdraws application for Plant Variety Protection Certificate
- **March 16, 1994:** B & W abandons U.S. Patent Application # 761, 312

Figure 8 Chronology of significant events

from the USDA, we learned that the application was withdrawn about three months ago, on 14 March 1994. We were told that Brown & Williamson also withdrew all seed samples for this variety from the Seed Storage Laboratory.

We learned that the US patent application had been rejected by the patent examiner,[16] but that Brown & Williamson had filed an appeal on 28 February 1994.[17] However, two weeks later, on 16 March 1994, before receiving a response to their appeal, Brown & Williamson expressly abandoned the patent (figure 8).[18]

On Friday, 10 June 1994, DNA Plant Technology told us that it had been authorized by Brown & Williamson to tell FDA that Y-1 was never commercialised.

Mr Chairman, I wish to submit for the record two invoices filed with the US Customs Service in 1992 (figure 9). The invoices are addressed to Brown & Williamson Tobacco Corporation, Louisville, Kentucky from Souza Cruz Overseas. They refer to "Your Order Project Y-1" and reveal that more than half a million pounds of Y-1 tobacco were shipped to Brown & Williamson on 21 September 1992.[19]

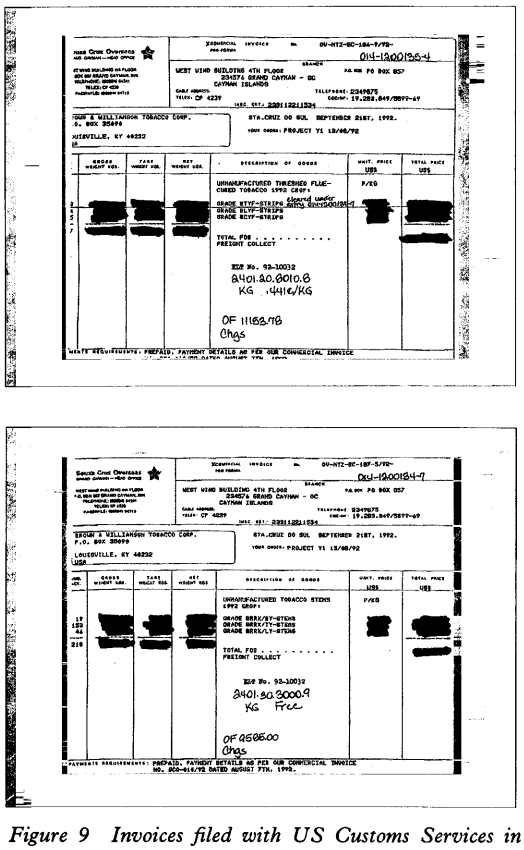

Figure 9 Invoices filed with US Customs Services in 1992

Four days ago, on Friday 17 June, after our questioning of DNA Plant Technology, and following our letter to Brown & Williamson indicating that Brown and Williamson had not been cooperative with our investigation, Brown & Williamson told FDA that, in fact, three and a half to four million pounds of Y-1 tobacco are currently being stored in company warehouses in the United States. More significantly, Brown & Williamson revealed that Y-1 had, in fact, been commercialised.

Mr Chairman, these brands of cigarettes – Viceroy King Size, Viceroy Lights King Size, Richland King Size, Richland Lights King Size, and Raleigh Lights King Size – were manufactured and distributed nationally in 1993 with a tobacco blend that contains approximately 10% of this genetically bred high-nicotine tobacco called Y-1.*

When we asked company officials why they were originally interested in developing a high-nicotine variety of tobacco, they told FDA that they wanted to be able to reduce tar, while maintaining nicotine levels.

The chemical manipulation of nicotine

Let me now move on to the second area. In April, the six major American cigarette companies released a list of 599 ingredients added to tobacco. Nicotine is not one of the additives listed. But, Mr Chairman, a number of chemicals on that list increase the amount of nicotine that is delivered to the smoker.

Around the time the list was made public, a great deal of interest was directed toward substances on the list that sounded particularly toxic. Among those frequently mentioned was ammonia. Many people may have wondered why the cigarette industry would add ammonia to tobacco. In fact, there are many uses of ammonia.[20] Our investigations have revealed an important one.

Let me refer to a major American tobacco company's 1991 handbook on leaf blending and product development. The handbook describes two ways that ammonia can be used in cigarette manufacture. One way is to interact with sugars in the tobacco. But it is the second way, the effect of ammonia and related compounds on the delivery of nicotine to the smoker, that is most striking. Let me quote from that handbook:

"[The ammonia in the cigarette smoke] can liberate free nicotine from the blend, which is associated with increases in impact and 'satisfaction' reported by smokers."

The handbook goes on to describe ammonia as an "impact booster":

"Ammonia, when added to a tobacco blend, reacts with the indigenous nicotine salts and liberates free nicotine. As a result of such change, the ratio of extractable nicotine to bound nicotine in the smoke

* See photograph published in the Autumn 1994 issue of *Tobacco Control* (1994; **3**: 203). – ED

may be altered in favor of extractable nicotine. As we know, extractable nicotine contributes to impact in cigarette smoke and this is how ammonia can act as an impact booster."

The important role that ammonia plays in the liberation of free nicotine is also emphasized in other parts of the handbook.

"This means that at the same blend alkaloid content, a cigarette incorporating [ammonia technology] will deliver more flavor compounds, including nicotine into smoke than one without it."

It is important to emphasize here that most of the nicotine in the average American cigarette is in the bound form. By that I mean it is not going to readily make its way to the smoker. Mr Chairman, I am not going to go into the details of acid-base, and vapor-phase chemistry, or the bioavailability of nicotine in the protonated versus the unprotonated form. Suffice it to say that only a fraction of the nicotine in the tobacco gets inhaled by the smoker. The handbook indicates that this ammonia technology enables more nicotine to be delivered to the smoker than if the ammonia technology is not employed.

What are the ammonia compounds used in this technology? The company handbook lists a number of different chemical compounds that can act as "impact boosters". Ammonia compounds known to be used include diammonium phosphate (DAP), ammonium hydroxide, and urea. In those countries, such as Germany, that do not allow DAP, other proprietary formulations are used.

To what are these compounds added? One of the most common places the ammonia and ammonia-like compounds are applied is to reconstituted tobacco.[21] When the cigarette is burned, the reconstituted tobacco serves as a source of ammonia in smoke. The amount of reconstituted tobacco can be as high as 25 % of the tobacco in the cigarette. And we've seen ammonia compound levels as high as 10 % in the reconstituted tobacco. Thus, as the company handbook goes on to state, the benefits of the reconstituted tobacco:

"come from being an ammonia source, as well as incorporating sugar-ammonia reactions. As a low alkaloid blend component, it also absorbs nicotine from higher alkaloid-containing components. [It thus becomes] ... a positive blend contributor rather than merely a filler."

The handbook also says that ammonia can be applied directly to the tobacco that goes into cigarettes.

How much additional nicotine does this technology impart? It is our understanding, based on smoke analysis described in the company handbook, that an experimental cigarette made of reconstituted tobacco treated with ammonia has almost double the nicotine transfer efficiency of tobacco.

How widespread is ammonia use in the industry? The company handbook states that many US tobacco companies use ammonia technologies. Until we have access to similar documents from other companies, we will not know whether other companies use it directly to affect nicotine levels.

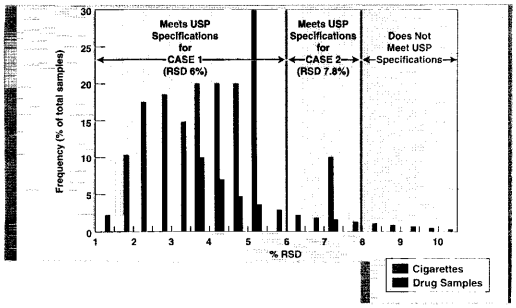

Figure 10 Comparison of the uniformity of drug samples and nicotine in 10 brands of cigarettes (11639 drug samples). RSD = relative standard deviation, being a measurement of content uniformity.

To determine how well nicotine content is controlled in cigarettes, FDA laboratories compared the content uniformity of drugs in either tablets or capsules to the content uniformity of nicotine in cigarettes. What is striking is how little the nicotine content varies from cigarette to cigarette, suggesting tight and precise control of the amount of nicotine in cigarettes.[22] In fact, as figure 10 shows, the nicotine content uniformity of the cigarettes tested meets drug content uniformity standards set by the US Pharmacopeia.

Mr Chairman, I have presented information on the control and manipulation of nicotine because I believe it raises certain important questions – questions that are even more important in light of the repeated assertions of the cigarette industry that it does not control or manipulate nicotine. Why spend a decade developing through genetic breeding a high-nicotine tobacco and adding that tobacco to cigarettes if you are not interested in controlling and manipulating nicotine? Why focus on the enhanced delivery of free nicotine to the smoker by chemical manipulation if you are not interested in controlling and manipulating nicotine?

The goals of control and manipulation

Why is there such interest in controlling and manipulating nicotine in cigarettes? Senior industry officials are aware that nicotine is the critical ingredient in cigarettes. Some in the industry have identified target levels of nicotine necessary to satisfy smokers' desire for nicotine. And the industry has undertaken research into nicotine's physiologic and pharmacologic effects.

TARGET RANGES

Let me give you one example of how a company has identified specific levels of nicotine necessary to satisfy smokers and has focused on how to achieve those levels. A company document describesconsumerpreferencetestingon"impact ", which according to the company correlates with nicotine. The document states that impact is a "high priority" attribute of cigarettes and is:

"... controllable to relatively fine tolerances by product development/product intervention... (by manipulating nicotine in blend/smoke...)."

This document goes on to describe an elaborate model for establishing the minimum and maximum nicotine levels tolerated by consumers. It states that the model provides "a median ideal point level for mg nicotine in smoke" for the population tested and a range of tolerable nicotine levels around this ideal point. After applying the testing method to a group of European smokers, for example, the document concludes:

"It is clear that consumers are less tolerant of decreases than they are of increases in nicotine delivery. By the time nicotine level falls to approximately 0.35 mg, 50% of consumers will be saying that the level of impact is so low they would reject the product. To reach the equivalent stage of 50% of consumers rejecting the product as having too high an impact level, a nicotine level of approximately 5.0 mg would be required. Again, it is important to note that there is a clear *upper* as well as lower rejection limit for nicotine in smoke."

It is thus clear that at least one major cigarette manufacturer is aware of the need to target nicotine delivery to levels necessary to satisfy smokers. In fact, as one tobacco flavour specialist has written, one of the most important goals of cigarette design is to "ensure high satisfaction from an adequate level of nicotine per puff", and that even cigarettes with reduced levels of nicotine and tar must have this property.[23]

Physiologic and pharmacologic effects of nicotine

Publicly available information, including recently released documents, reveals much about the industry's knowledge of the drug-like effects of nicotine.

I will begin by describing several studies commissioned by the tobacco industry. As I go through them, Mr Chairman and members of the Subcommittee, ask yourselves: Are these the kinds of studies that would be conducted by an industry interested only in the flavour or taste of nicotine?

On 16 May 1994, Brown & Williamson made available previously unreleased results of research that had been conducted more than 30 years ago. A review of this research, known as the Project Hippo studies, documents that the industry was interested in the physiologic and pharmacologic effects of nicotine as early as 1961.

The first report, known as Project Hippo I, contained an extensive discussion of the effects of nicotine in the body.[24] This included, for example, the effects of nicotine on the central nervous system.

Project Hippo II is an interesting study of what was, in the early 1960s, the newly evolving field of tranquilizers.[25] Let me quote from the opening paragraph of the summary of the Final Report on Project Hippo II:

"The aim of the whole research "HIPPO" was to understand some of the activities of nicotine – those activities that could explain why cigarette smokers are so fond of their habit. It was also our purpose to compare these effects with those of the new drugs called "tranquilizers", which might supersede tobacco habits in the near future."

Figure 11 Tobacco advertisement from the 1940s.

The comparison of the drug-like effects of nicotine and tranquilizers was not exactly a well-kept secret. Even in the 1940s you could pick up a magazine and see an advertisement like the one shown in figure 11. What seems to be new about the Hippo study was that it represented a serious commitment by a tobacco company to a scientific examination of this pharmacologic property.

Another report released with Hippo and conducted in the 1960s is called "*The fate of nicotine in the body*".[26] It reviews the state of knowledge about the distribution of nicotine in the body and presents the results of studies on nicotine metabolism in a group of smokers. The report states:

"The numerous effects of nicotine in the body may, at first, be conveniently measured by various physiological and pharmacological experiments."

The studies involved the use of radiolabelled nicotine in both humans and animals, which provided very sophisticated knowledge of the absorption and distribution of nicotine in the body. This included a knowledge of how much nicotine is present in the blood of smokers; how this nicotine is distributed; how it is excreted; and what variables affect the duration of a nicotine blood level.

It is clear that such research would be of interest to the industry only if the industry were concerned with the physiological and pharmacological effects of nicotine. Certainly, this is not consistent with the industry's representation that nicotine is of interest to it only because of flavour and taste.

Mr Chairman, we believe that the studies released by Brown & Williamson are relevant to the determination of whether nicotine-containing cigarettes are drugs for purposes of the Federal Food, Drug, and Cosmetic Act. And Brown & Williamson is not the only company that apparently has been involved in research on nicotine's physiologic and pharma-

cologic effects. Thanks to this Subcommittee's work, we now know that Philip Morris was conducting nicotine addiction research. We are also aware of research utilising electroencephalographic measurements to monitor the biological effects of nicotine on brain function at both RJ Reynolds[27–30] and Philip Morris.[31]

Major projects undertaken by at least two companies to develop cigarette alternatives also demonstrate that the industry understands that nicotine is the critical ingredient they are delivering to smokers.

It is widely known that in the late 1980s RJ Reynolds Corporation developed and test-marketed a cigarette alternative called Premier. It was smokeless and virtually tobacco free. It was essentially a nicotine delivery system. To make sure that Premier would be an acceptable alternative to smokers, RJ Reynolds conducted human studies to determine whether the nicotine from Premier and from a standard cigarette was absorbed into the blood of research subjects, metabolised, and excreted at the same rate.[32]

Recent reports in the media reveal that Brown & Williamson, too, launched an effort to develop a cigarette alternative. It was referred to as "Ariel". Brown & Williamson's own documents reportedly refer to Ariel as "a nicotine delivery device". One of the applicants for the patent for Ariel was Charles Ellis of British American Tobacco (BAT), Brown & Williamson's corporate parent. Ariel was composed of two parts: a source of nicotine and aerosol, and a heating material such as tobacco that served to heat the nicotine and cause the release of the nicotine and the aerosol.[33]

Mr Chairman, we further believe that recent reports in the media also may be relevant to the determination of whether nicotine-containing cigarettes are drugs.

Let me quote some of the recently reported statements of officials from one company that reveal a recognition of nicotine's drug-like effects:

"Nicotine is not only a very fine drug, but the techniques of administration by smoking has (sic) considerable psychological advantages."[34]
"... nicotine is a very remarkable, beneficent drug that both helps the body to resist external stress and also can, as a result, show a pronounced tranquilizing effect."[35]

These statements were apparently made by Sir Charles Ellis, a member of the Royal Society of London, who served as science advisor to the BAT Company board. He was responsible for advising the establishment of the company's research and development centre in Southampton, England. He was also responsible for advising on the research operations of BAT's associate companies.[36] Two of his recently reported statements are particularly striking. One statement was made in 1962:

"Smoking is a habit of addiction."[35]

But perhaps the most striking statement attributed to him is one from a meeting of company scientists in 1967:

"Sir Charles Ellis states that BATCO is in the nicotine rather than the tobacco industry."[37]

These statements are echoed by those made in an internal company document by another senior scientist at a British tobacco company:

"There is now no doubt that nicotine plays a large part in the action of smoking for many smokers. It may be useful, therefore, to look at the tobacco industry as if for a large part its business is the administration of nicotine (in the clinical sense)."

These statements are consistent with the quotes from William L Dunn, an official of Philip Morris, that I cited for you in my testimony last March.

"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 for nicotine."
"Smoke is beyond question the most optimized vehicle of nicotine..."

Other scientists are quoted in a 30 May 1963 paper that is reported to have been produced for Brown & Williamson's sister company, the BAT Company, and labelled "*Confidential. A tentative hypothesis on nicotine addiction.*"[38] As reported, it contains a number of statements regarding the powerful effect of nicotine on the body:

"Chronic intake of nicotine tends to restore the normal physiological functioning of the endocrine system, so that ever-increasing dose levels of nicotine are necessary to maintain the desired action. Unlike other dopings, such as morphine, the demand for increasing dose levels is relatively slow for nicotine."

Other statements reportedly made in this paper speak directly to the addictive nature of nicotine. The report goes on to describe what happens when a chronic smoker is denied nicotine:

"A body left in this unbalanced state craves for renewed drug intake in order to restore the physiological equilibrium. This unconscious desire explains the addiction of the individual to nicotine."

Conclusion

The information that we have presented today has been the result of painstaking investigation. We now know that a tobacco company commercially developed a tobacco plant with twice the nicotine content of standard tobacco, that several million pounds of this high-nicotine tobacco are currently stored in warehouses, and that this tobacco was put into cigarettes that have been sold nationwide. We now know that several tobacco companies add ammonia compounds to cigarettes, and that one company's documents confirm that one of the intended purposes of this practice is to manipulate nicotine delivery to the smoker. And we now know that some in the industry have identified target ranges of nicotine delivery. These findings lay to rest any notion that there is no manipulation and control of nicotine undertaken in the tobacco industry.

It is equally important to lay to rest, once and for all, the industry's assertion that nicotine is not addictive. Up until very recently, the tobacco industry was able to claim that it did not believe that nicotine was addictive. The release of company documents, and the testimony of company scientists before this Subcommittee, have opened a window on what some senior tobacco officials knew about nicotine's physiological and addictive properties, as much as 30 years ago.

One important thing that every teenager in this country needs to know before deciding to smoke his or her first cigarette is how one cigarette industry official viewed the business of selling cigarettes:

"We are, then, in the business of selling nicotine, an addictive drug..."[39]

1 Kessler DA. Statement on nicotine-containing cigarettes. Testimony before House Subcommittee on Health and the Environment, 25 March 1994 (see *Tobacco Control* 1994; **3**: 148–58).
2 21 USC § 321(g)(1).
3 Republican Federativa do Brasil, Institute Nacionel da Propriedade Industrial, PI 9203690A, "Variendade de fumo geneticanente estavel e planta de fumo", issued to Brown & Williamson Tobacco Corporation, 4 June 1993.
4 Brazilian Patent No PI 9203690A. US Department of State, official English translation.
5 Letter of JW Johnson, Chief Executive Officer, RJ Reynolds Tobacco Company, to DA Kessler, Commissioner, US Food and Drug Administration. RJ Reynolds Tobacco Company, Winston-Salem, North Carolina; 28 February 1994.
6 Chaplin JF. Tailoring tobacco plants to meet future demands. *World Tobacco* October 1978; **62**: 145–9.
7 Chaplin JF. Breeding for varying levels of nicotine in tobacco. *Proceedings from a symposium on recent advances in the chemical composition of tobacco and tobacco smoke.* Raleigh, North Carolina, 1977: 328–39.
8 [Anon]. Evolving techniques of making cigarettes milder. *World Tobacco* April 1979; 93–101.
9 US patent no 761,312, "Filing of utility patent application," Figure 1.
10 US patent no 761,312, "Appellant's brief on appeal," p 6.
11 7 USC §516. (Tobacco Seed and Plant Exportation Act, repealed on 13 December 1991)
12 7 CFR 34.4(b).
13 DNA Plant Technology did provide a copy of a Phytosanitary Certificate. This document, which certifies that exported plants or seeds conform with phytosanitary regulations of the importing country, was issued to DNA Plant Technology by US Department of Agriculture, Plant Protection and Quarantine, to facilitate importation of 20 g of tobacco pollen into Brazil. 20 March 1990.
14 US patent no 761,312, filed 17 September 1991.
15 Plant Variety Protection Certificate Application, PV No 9100119, filed 21 February 1991, US Department of Agriculture. (Referenced in US patent no 761,312, "Filing of utility patent application," on p 1 – unable to obtain copy of application from USDA).
16 US patent no 761,312, "Rejection of claims", 10 July 1992.
17 US patent no 761,312, "Appellant's brief on appeal", filed 28 February 1994.
18 US patent no 761,312, "Express abandonment of patent application", filed 16 March 1994.
19 Redacted copies of US Customs Service Invoices for Brown & Williamson, dated 21 September 1992.
20 For example, ammonia has been used in efforts to denicotinize cigarettes (US patent no 4,215,706) and, in reconstituted tobacco, for its adhesive properties (US patent no 5,159,942).
21 Reconstituted tobacco can be made (one of several methods) by mixing tobacco stems, dust, and other scraps, adding a liquid solvent to form a "slurry", and then extracting the liquid and pressing the remaining mixture into a flat sheet. Almost all US cigarettes contain some reconstituted tobacco. (Vogues E. Tobacco Encyclopedia, published by *Tobacco Journal International* 1984: 389–90.)
22 US Food and Drug Administration, Center for Drug Evaluation and Research, Division of Drug Analysis. Report on analysis of packages of cigarettes. 4 April 1994.
23 Hertz AN. The flavourist's role in the cigarette design team. *World Tobacco* March 1985: 97–104.
24 Herach J, Libert O, Rogg-Effront C. *Final report on Project Hippo I.* Batelle Memorial Institute, Geneva, for the British American Tobacco Co Ltd, January 1962 (released by Brown & Williamson Tobacco Corp, 16 May 1994).
25 Haselbach CH, Libert O. *Final report on Project Hippo II.* Batelle Memorial Institute, Geneva, for the British American Tobacco Co Ltd, March 1963 (released by Brown & Williamson Tobacco Corp, 16 May 1994).
26 Geissbuhler H, Haselbach C. *The fate of nicotine in the body.* Batelle Memorial Institute, Geneva, for the British American Tobacco Co Ltd, May 1963 (released by Brown & Williamson Tobacco Corp, 16 May 1994).
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32 RJ Reynolds Tobacco Company. *New cigarette prototypes that heat instead of burn tobacco.* Winston-Salem, North Carolina: RJ Reynolds Tobacco Company, 1988: 457–9.
33 US patent no 3,356,094, Col 1: 8–10.
34 Sir Charles Ellis, Scientific Advisor to the Board of British-American Tobacco Co, July 1962 (as reported by Hilts PJ, in the *New York Times*, 16 June 1994).
35 Sir Charles Ellis, Scientific Advisor to the Board of British American Tobacco Co, July 1962 (as reported by Harris R, for National Public Radio, 14 June 1994).
36 Hutchison K, Gray JA, Massey H (chapter authors). Biographical memoirs of fellows of the Royal Society of London: Chapter on Charles Drummond Ellis. London: Royal Society 1981; **27**: 199–233.
37 Excerpt from a British American Tobacco Company research chronology from June of 1967 (as reported by Hilts PJ, in the *New York Times*, 17 June 1994).
38 Excerpt from a 30 May 1993 British American Tobacco Company internal document entitled "Confidential: a tentative hypothesis on nicotine addiction" (as reported by Hilts PJ, in the *New York Times*, 17 June 1994).
39 Excerpt from a July 1963 Brown & Williamson Tobacco Corporation internal document, authored by its General Counsel Addison Yeaman, analysing whether the company should acknowledge the hazards of cigarettes or remain quiet (as reported by Hilts PJ, in the *New York Times*, 7 May 1994).