NICOTINE DISCLOSURE

Eclipse: does it live up to its health claims?

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Objective: To examine the plausibility of health claims for Eclipse, a novel smoking article being marketed by the RJ Reynolds Tobacco Company (RJR) as potentially reducing the risk of cancer and other diseases compared to conventional cigarettes.
Data sources: A company product website (www.eclipse.rjrt.com) summarising scientific studies of various versions of Eclipse, and the published review of these studies by an expert panel convened by RJR, an independent study comparing the smoke yields of major carcinogens from Eclipse and two low yield "ultralight" brands (Now and Carlton), and an analysis of the levels of these compounds in Eclipse and Premier (its predecessor) over time.
Analysis: The overall doses and effects of toxins in the aerosol from Eclipse are smaller than those from most conventional cigarettes on a per mg basis. However, two tests that compared Eclipse on a per cigarette basis revealed that Eclipse was as or more toxic than an ultralight cigarette. Studies show that consumers smoke Eclipse (like they do cigarettes) at puff volumes and puff frequencies far higher than those used for the Federal Trade Commission (FTC) test. RJR's test results, which are based on aerosols generated under FTC conditions, may not reflect actual human dosing, since the operating temperature of Eclipse is highly dependent on these puffing parameters. Even under FTC/International Organization for Standardization (ISO) standard measures, Eclipse smoke carcinogen yields were higher than Now, but similar to Carlton. The yields of carcinogens from Premier and different versions of Eclipse have increased over time. Furthermore, the human studies reviewed by the RJR expert panel do not offer compelling evidence of reduced harm, as they have not been conducted in smokers who have adopted Eclipse.
Conclusion: There is as yet unsatisfactory evidence that Eclipse is less harmful than conventional cigarettes. Eclipse appears to be at least as toxic as some commercially available cigarette brands. Consumers may be misled by RJR's health claims into believing that Eclipse is a safer alternative to conventional cigarettes, underscoring the need for regulatory intervention.

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In 1996, the RJ Reynolds Tobacco Company (RJR) began test marketing Eclipse, a novel cigarette-like smoking article. Eclipse was the successor to Premier, a similar product that was introduced in 1988 but later withdrawn from test markets a few months later because of what the manufacturer described as poor consumer acceptance.[1] The withdrawal was associated with considerable opposition from the public health community, which had petitioned the Food and Drug Administration (FDA) to regulate Premier as a drug. Premier and Eclipse differ radically from conventional cigarettes in that they both purportedly heat rather than burn tobacco. This advanced design delivers a nicotine containing aerosol to the user, while ostensibly reducing the delivery of many smoke compounds that contribute to the risk of cancer and other illnesses.

Eclipse was test marketed in Chattanooga, Tennessee, and similar versions of the product were sold in Germany (HI.Q), Sweden (Inside), and Japan (Airs). While Eclipse fared better with consumers than Premier, its success was nonetheless limited.[2] In 1997, RJR introduced a new Eclipse in which the filter was replaced by a hollow mouthpiece.[3] This redesigned version was launched in the spring of 2000 in the Dallas/Fort Worth area through a website and toll-free ordering number, which were supplemented by retail sales in early 2001.[4] The national marketing campaign for the new Eclipse is distinguished by its explicit health claims. Remarking "There's no cigarette like Eclipse", RJR claims that, compared to other brands, Eclipse:

- may present less risk of cancer
- produces less inflammation in the respiratory system, which suggests a lower risk of chronic bronchitis and possibly even emphysema
- may pose less risk to smokers of developing cardiovascular disease.[5]

These claims rest on data compiled by the company from a wide range chemical, animal, and human studies conducted on several Eclipse prototypes, which are summarised on the website.[5] Some of these studies were performed in house, while others were conducted by contract laboratories or by university researchers working under company grants.

RJR also assembled a panel of paid consultants to conduct an independent review of the data. This panel included the editor-in-chief of *Inhalation Toxicology,* the journal in which the review was published (as a supplement supported entirely by RJR),[6] and one of the scientists who had received a grant from the company. The panel chair had also served as the independent pathologist reviewer of the tissue slides from the rodent inhalation studies. The editor had informed one of the authors of this paper that he was going to personally select the peer reviewers of the panel's manuscript (D Gardner, personal communication, February 2000). The panel's conclusions are consistent with RJR's health claims for Eclipse.

Since these claims have not been subjected to an independent review by a regulatory agency, they warrant further investigation to determine whether they are truly justified. Objective analysis of scientific data used to back health claims in tobacco industry marketing is especially important with

Abbreviations: FTC, Federal Trade Commission; ISO, International Organization for Standardization; MDPH, Massachusetts Department of Public Health; PREPs, potential reduced exposure products; RJR, RJ Reynolds; SCE, sister chromatid exchange; TPM, total particulate matter

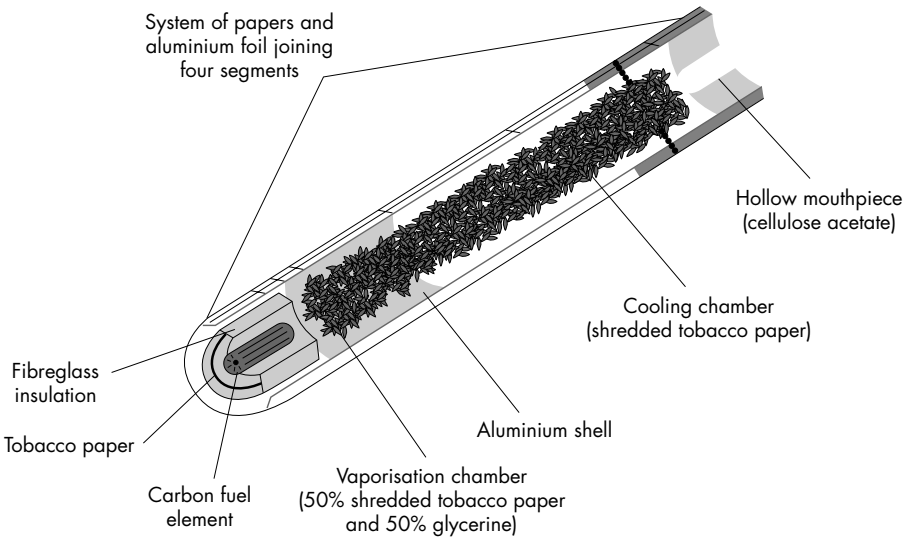

Figure 1 RJ Reynolds Eclipse nicotine delivery system. Source: Henningfield *et al*. Unpublished report available from the author.

regard to potential reduced exposure products (PREPs)[7] such as Eclipse, as smokers may be encouraged to use them as an alternative to quitting.

GENERAL DESCRIPTION OF ECLIPSE

Like its predecessor Premier, Eclipse superficially resembles a conventional filtered cigarette. However, instead of a single column of a tobacco blend capped by a filter, it contains a series of four functionally discrete sections that work together to generate a nicotine-containing aerosol[8] (fig 1).

At the distal end lies a carbon fuel element that is surrounded by a fibreglass insulator, or in some versions, by a piece of paper derived from tobacco. When lit, the fuel element provides the energy that vaporises the material in the adjacent aluminium lined chamber, which consists of a mixture of glycerin and shredded papers derived from tobacco in an approximately 50:50 ratio.[9] The operating temperature of this chamber increases the more vigorously the device is puffed, which increases the fraction of nicotine that is vaporised and transferred to the aerosol (fig 2).[8] Next is a cooling chamber filled with another formulation of shredded tobacco papers, where vapours condense to form the aerosol inhaled by the smoker. The final segment is a cellulose acetate mouthpiece, which acts as a filter in some versions but is hollow in the currently marketed product. Of the numerous Eclipse prototypes that have been developed, the RJR expert panel review considered testing performed on six of them.* Two of these were never test-marketed in the USA but they may be similar to the Airs version of Eclipse sold in Japan.

TESTS CONDUCTED BY RJR ON ECLIPSE

To determine whether Eclipse may present less risk for diseases associated with smoking, RJR conducted four main types of comparative tests:

- smoke composition tests
- in vitro studies using animal and human cells
- inhalation and skin tumour studies in rodents
- studies with smokers who switched to Eclipse from their usual brand of tobacco burning cigarettes.[5 6]

RJR contends the results of these tests indicate that the aerosol from Eclipse generally produces "demonstrably less biological activity" than that of conventional tobacco burning cigarettes.[5] It is on this basis that the company justifies its marketing health claims for Eclipse.

The validity of smoke comparison tests with regard to claims of reduced health risks is questionable because they use the FTC method, which bears little resemblance to human smoking patterns. The results of 32 human smoking studies listed in the 1988 Surgeon General's report indicate that humans tend to take larger puff volumes than the Federal Trade Commission (FTC) smoking machine and puff at nearly twice the rate (table 1). The results of a recent laboratory study showed that smokers of low yield (≤ 0.8 mg FTC nicotine) and high yield (0.9–1.2 mg FTC nicotine) cigarette brands had significantly shorter interpuff intervals (about 20 seconds) than those of the FTC protocol.[10] Thus, smokers often take more than one puff per minute, thereby potentially increasing their intake over the FTC yields.

Furthermore, research conducted by RJR has shown that when smoking Eclipse prototypes, human smokers tended to take larger, more frequent puffs than when they smoked their usual brand of tobacco-burning cigarettes (see below).[5]

Greater attention should therefore be placed on biological studies.

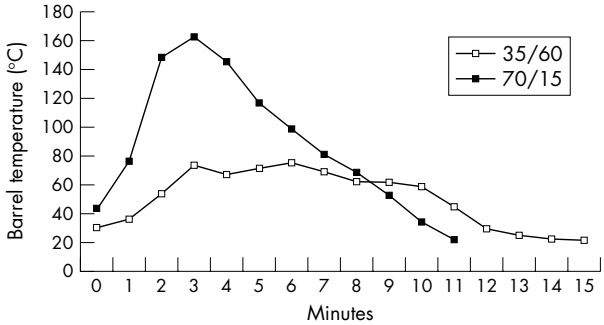

Figure 2 The operating temperature of Eclipse is a function of how vigorously the device is smoked. Eclipse version GTC 5-535. Barrel temperature is the external temperature at the midpoint of the aluminium chamber. In both smoking conditions, the puff duration was two seconds. Eclipse barrel temperature 35 ml/60" and 70 ml/15". Source: Slade.[8]

*GTC 4-098. GTC 5-014. GTC 5-535, GTC 7-026, GTC 7-067, and GTC 7-088. GTC is an RJR acronym for "great tasting cigarette".

Table 1 Average published values of common measures of smoking

	FTC method	Human
Puff duration (s)	2	1.8 (1–2.4)
Puff volume (ml)	35	43 (21–66)
Interpuff interval (s)	60	34 (18–64)
Number of puffs	–	11 (8–16)

Source: US Department of Health and Human Services 1988.

Table 2 Total particulate matter yields of Eclipse and three cigarettes, mg (%)*

Fraction	Eclipse	1R5F	Merit Ultralight	1R4F
Nicotine	0.2 (4)	0.1 (8)	0.5 (8)	0.8 (7)
Water	2.1 (35)	0.2 (10)	0.5 (8)	1.4 (12)
"Tar"†	3.6 (61)	1.5 (82)	5.2 (84)	9.3 (81)
"Soot"	1.2 (21)	1.1 (63)	4.8 (77)	8.3 (72)
Glycerin	2.3 (40)	0.3 (19)	0.4 (7)	1.0 (9)
TPM	5.9 (100)	1.8 (100)	6.2 (100)	11.5 (100)

*Selected fractions using FTC smoking parameters (one 35 ml, 2 second puff every 60 seconds). For Eclipse, the FTC protocol was modified, since the device does not shorten as it is consumed. Instead, 15 puffs were taken, which was sufficient to exhaust the fuel element under these testing conditions. It is unclear which version of Eclipse is represented in these data.
†By definition, "tar" is total particulate matter (TPM) minus both water and nicotine. Here, "tar" consists of "soot" plus glycerin. Hence, the five fractions are not additive.
Source: RJ Reynolds Tobacco Co.[14]

Eclipse smoke constituent yields

RJR compared the Eclipse total particulate matter (TPM) yield under FTC conditions to that of three different conventional cigarettes: a commercial higher-yield "Ultra Light" (Merit Ultralight) and two research cigarettes designated 1R4F and 1R5F, which are made to resemble a "low tar" and an "ultra low tar" marketed product, respectively.[5] The Eclipse website provides four pie charts that break down these yields into percentage nicotine, water, glycerin, and "other", the fraction that contains the major toxic constituents, or "soot".[5] Table 2 presents these data (including "tar") as both percentages and absolute amounts.

Glycerin, which is in itself unlikely to be toxic, makes up a large proportion (40%) of the Eclipse total particulate matter. The Eclipse percentage soot fraction is three to four times lower than the other three cigarettes. At the same time, however, one Eclipse cigarette produces the same amount of soot (1.2 mg) as the 1R5F (1.1 mg).

RJR also compared the FTC yields of 30 specific toxic constituents from these four cigarettes.[5 6] While Eclipse showed reductions in most compounds, the levels of four (ammonia, formaldehyde, NNK, and 4-aminobiphenyl) were statistically the same between Eclipse and 1R5F, and two (acrolein and furfural) were much higher in Eclipse. Carbon monoxide yields from Eclipse have also been high compared to conventional cigarettes.[8]

RJR also provided data on the FTC aerosol levels of 14 major carcinogens to support its claim that Eclipse has "80% less carcinogens" than a "typical" ultralight cigarette (Mert Ultralight).[5] Table 3 lists the levels of five of the most potent compounds analysed (italics), as well as tar, nicotine, and carbon monoxide. With the exception of acrolein, Eclipse produces 64–87% lower levels of these carcinogens than Merit.

An RJR study that examined delivery of smoke particulates using puff parameters similar to those taken by humans (that is, a 56 ml, 2 second puff every 26 seconds) showed lower yields of many smoke constituents other than water and glycerin, compared to cigarettes.[11] However, because the mean puff volume drawn on Eclipse by RJR's volunteer smokers was 67 ml and the interpuff interval was 19.7 seconds,[5] both of which are substantially less than maximal test parameters, these findings are not generalisable.

Table 4 Smoking machine testing parameters used in the Labstat study

Variable	"ISO/FTC"	"Increased"
Puff volume (ml)	35	50
Interval (s)	60	30
Duration (s)	2	2
Vents	"open"	"open"

Source: Labstat International Inc.[12]

MDPH study

To investigate the validity of this reduced carcinogens claim, the Massachusetts Department of Public Health (MDPH) commissioned an independent analysis of the Eclipse aerosol versus two brands in the ultralight category: Now King Size Hard Pack (RJR; FTC tar < 0.5 mg) and Carlton King Size Soft Pack (Brown & Williamson; FTC tar 1 mg).† The study was performed by Labstat International Inc of Canada, a certified cigarette testing laboratory that periodically conducts smoke constituent testing for RJR.[12] Two protocols were used: the International Organization for Standardization(ISO)/FTC method and a more intensive "increased" method developed by the MDPH (table 4). These are the same settings employed by RJR scientists in a 1996 report comparing Eclipse yields with those of conventional cigarettes.[13]

The Labstat data, shown in table 5, using the ISO/FTC methodology indicate that Eclipse does not appear to have 80% less cancer causing agents in its aerosol. Under "increased" smoking conditions, the yields from Now remained very low while those from Carlton and Eclipse

Table 3 Comparison of FTC levels of major smoke toxins (including five potent carcinogens) in Eclipse and Merit Ultralight

Toxin	Eclipse	Merit Ultralight	Difference
Tar (mg)	3.2	5.3	40% less
Nicotine (mg)	0.18	0.47	62% less
Carbon monoxide (mg)	7.5	6.5	15% more
Acetaldehyde (µg)	75	311	76% less
Acrolein (µg)	33	35	6% less*
Benzo(a)pyrene (BaP) (ng)	0.6	4.0	86% less
N′-nitrosonornicotine (NNN) (ng)	20	148	87% less
[4-(methylnitrosamino)-1-(3-pyridyl)-1-butanone] (NNK) (ng)	23	63	64% less

*No statistical difference ($p \leq 0.05$).
Source: RJ Reynolds Tobacco Co.[14]

Table 5 ISO/FTC yields of major smoke carcinogens in Eclipse versus Carlton and Now

	Eclipse	Carlton	% Difference	Now	% Difference
Acetaldehyde (µg)	84.2	99.8	16% less	10.1	734% more
Acrolein (µg)	11.5	10.4	15% more	2.0	475% more
(BaP) (ng)	1.2	1.3	8% less	NQ	Level too low to quantify
(NNN) (ng)	26	34.0	24% less	NQ	Level too low to quantify
(NNK) (ng)	31.8	NQ	Level too low to quantify	BDL	Level too low to quantify

NQ, not quantifiable; BDL, below detection limit.
Source: Labstat International Inc.[12]

Table 6 Major smoke carcinogens in Premier, Eclipse I, and Eclipse II

	Premier (1988)	Eclipse I (1996)	% Change *v* Premier	Eclipse II (2000)	% Change *v* Eclipse I	% Change *v* Premier
Acetaldehyde (µg)	41	54	+32%	84	+56%	+105%
BaP (ng)	0.08	0.70	+775%	1.20	+71%	+1400%
NNN (ng)	8.5	10.0	+18%	26.0	+160%	+206%
NNK (ng)	2.4	12.0	+400%	32.0	+167%	+1233%

Source: RJ Reynolds Tobacco Co[14]; Borgerding et al[13]; Labstat International Inc.[12]

increased notably, with greater increases for Eclipse for all compounds except acetaldehyde (data not shown).

Comparison of major carcinogen yields from Premier, Eclipse I, and Eclipse II

Additional data strongly suggest that the levels of certain carcinogens may have increased from Premier to Eclipse I, and again in Eclipse II.

Table 6 presents the yields of four carcinogens for the 1988 Premier, the 1996 Eclipse, and the current Eclipse, launched in 2000. These data were collected from a variety of sources, including a monograph that RJR published on its testing of Premier,[14] the company's 1996 report on Eclipse,[13] and the recent Labstat study.[12] Similar testing conditions were employed in each of the studies.

Levels of BaP increased 775% from Premier to Eclipse I, and Eclipse II levels were 71% greater than Eclipse I. Similar increases were observed for NNN and NNK (160% and 167% from Eclipse I to II, respectively). The differences between Eclipse I and II may be caused by the introduction of a hollow filter in the current product, which may have reduced filtration and resulted in increased yields of toxic constituents.

IN VITRO STUDIES

RJR conducted a range of genetic toxicology and cytotoxicity assays‡ comparing the smoke condensates from various Eclipse prototypes with those from the 1R4F and 1R5F cigarettes.[5 6] In each of these tests, the performance of the condensates—that is, the particulate matter, but not the vapour phase—was compared on a mg by mg basis.

These tests showed that the Eclipse condensate was less toxic, usually by a large amount, than that from either research cigarette. Condensate from the 1R5F generally had similar or even somewhat higher toxicity scores than the 1R4F condensate. Moreover, in a separate study of seven commercial cigarette brands with nominal tar yields between 1.0–5.5 mg, the most mutagenic condensates (mg by mg) were those from the two lowest yielding brands.[6]

Table 7 Neutral red and sister chromatid exchange (SCE) assay of whole smoke from Eclipse prototypes, 1R4F, and 1R5F*

Cigarette	Neutral red assay (EC50 value)	SCE assay
1R4F	5.9	0.31
1R5F	30.3	0.06
GTC 4-098	31.4	0.06
GTC 5-014	34.7	0.05
GTC 5-535	13.8	0.09
GTC 7-026	21.7	0.06

*Neutral red values: concentration of mainstream smoke (cigarettes per cubic meter of air) to cause 50% reduction in growth of cell population. A higher concentration of smoke condensate being required to reduce the cell population by 50% is indicative of lower cytoxicity.
SCE values: slope value, a measure of the increase in the number of sister chromatid exchanges per unit of smoke concentration (cigarettes per cubic meter of air). A lower slope value is indicative of lower mutagenic potential.
Source: Eclipse Expert Panel.[6]

However, the data from two separate neutral red and sister chromatid exchange (SCE) assays performed on whole smoke from four Eclipse prototypes and the two research cigarettes stand in notable contrast to the results obtained with condensate. These data are presented here in table 7, which is presented as table 8 in the expert panel report.[6]

The two versions of Eclipse that performed worse than the 1R5F in the neutral red assay were the two that were put into test markets in the USA. The performance of the other two was about the same as the 1R5F. In the SCE, the 1996 product (GTC 5-535) did somewhat better than the 1R5F, while the current version (GTC 7-026) was indistinguishable from the 1R5F.

Furthermore, the comparisons in these whole smoke assays were based not on the weight of the aerosols, but rather on the number of cigarettes needed to generate them for measurement of the end points. While the mg by mg comparisons in the condensate tests work to the advantage of Eclipse (because the "soot" in its TPM is diluted by water and glycerin), Eclipse does not enjoy this artificial advantage in the measure used to score the whole smoke assays. In the latter, the 1R4F exhibits the greatest toxicity, the current Eclipse is intermediate, and the 1R5F is the least toxic.

†There are no regulatory standards by which products may be characterised as "ultralight". The industry uses FTC tar yields over the range of about 0–5 mg per cigarette to identify this class. The version of Merit that RJR compared with Eclipse is in the upper part of this range, while Now and Carlton version tested for the MDPH are in the lower part of this range.
‡Ames test, sister chromatid exchange, chromosome aberrations, neutral red assay, lactate dehydrogenase release.

Table 8 Mouse skin painting results for GTC 7-026 and 1R4F

Condensate dose	Total tumours		Tumor bearing animals	
	GTC 7-026	1R4F	GTC 7-026	1R4F
10 mg	1	11	1	6
20 mg	11	184	2	28
40 mg	31	242	12	36

Source: Eclipse Expert Panel.[6]

IN VIVO STUDIES

RJR conducted inhalation testing with four Eclipse prototypes in Sprague-Dawley rats and with one prototype (GTC 5-014, one of the non-marketed versions) in Syrian golden hamsters.§[5 6] Comparison of specific mg for mg doses (0.16, 0.32, and 0.64 mg TPM/litre for one hour daily, five days a week for 13 weeks) showed that the aerosol from the Eclipse devices produced less histological damage than the smoke from 1R4F cigarettes.

Mouse skin painting studies on four versions of Eclipse were performed using Sencar mice. Condensate was administered three times per week for 29 weeks in doses of 10, 20, or 40 mg per application. While the tests uniformly showed lower tumour production for Eclipse condensate on a mg by mg basis versus the 1R4F cigarette, there were pronounced differences among the various prototypes tested. The current product (GTC 7-026) was associated with the highest level of tumour production. However, the results for this version suggest that it performed better than the 1R4F merely because the tumorigenic material in the Eclipse condensate was about threefold less potent. This is shown here in table 8, which is derived from table 11 of the expert panel report.[6]

When compared within doses, Eclipse produced fewer tumours and fewer tumour bearing mice than the 1R4F. However, the number of tumours on the mice exposed to Eclipse condensate at 40 mg is intermediate between that of the 1R4F condensate exposed mice at 10 and 20 mg. This relationship also holds for the number of animals in each subgroup that developed tumours.

HUMAN SMOKING STUDIES

RJR conducted several studies in human volunteers, including assays of nicotine and carbon monoxide absorption from various versions of Eclipse, and urine mutagenicity tests comparing Eclipse with the subjects' usual cigarette brands.[5 6] In addition, a number of comparative assessments of pathological respiratory changes associated with tobacco use were measured in humans by university based researchers working under company grants.

The volunteers smoked Eclipse more aggressively than the FTC parameters. While ranges and standard deviations have not been reported, the mean puff volume was 67 ml, and the interpuff interval was 19.7 seconds.[5] The mean total puff volume was 1371 ml, compared to 640 ml for the subjects' usual brands, and only 525 ml by the FTC method.

Nicotine absorption from Eclipse was similar to that from the subjects' usual brands. This may be because the operating temperature of Eclipse is highly user dependent (fig 2) and increases with more vigorous puffing. Nicotine delivery on a per litre basis increases greatly at higher temperatures.[8] This pattern is distinctly different from the effect of changing puffing parameters for conventional cigarettes, for which deliveries per litre remain similar from one condition to another.[15] This phenomenon may also result in increases in toxic constituent yields at higher puff volumes and rates (and hence, at higher operating temperatures) from Eclipse than would be predicted from a simple increase in total puff volume.

Carbon monoxide absorption varied among the Eclipse prototypes. The 1996 version (GTC 5-535) had an average carboxyhaemoglobin (COHb) boost of 17–21%, while that of the current product (GTC 7-026) was 6–8% over that of the subjects' usual brands. An apparent tradeoff for this improvement is the higher delivery of other toxins in this version (table 6) and its poorer performance in toxicity testing (whole smoke and mouse skin painting assays).

Urine testing showed a reduction of at least 70% in mutagenicity versus the usual brands for all versions of Eclipse tested. However, because the study does not identify the subjects' usual brands, it is not known if they were smoking full flavour, low tar, or ultra low tar cigarettes before switching to Eclipse. Nor does it reveal how many of these cigarettes they had been smoking per day. This information is relevant to the interpretation of the testing results in light of the health claims being made for Eclipse, since it is essentially engineered as an ultralight-like product. Smokers of ultralight cigarettes, who would therefore be most likely to switch to Eclipse, make up only a small percentage of the smoker market.[16] Furthermore, although many consumers tried Eclipse in test marketing, very few actually switched (J Donald deBethizy, personal communication to J Slade). It may have been that those who did switch had been smoking lower yielding brands or were light smokers to begin with, but there is nevertheless no indication that the study subjects selected were likely adopters of Eclipse.

The expert panel report also summarises the results to date of five sets of university based studies designed to determine the physiological and biochemical effects of switching from tobacco burning cigarettes to Eclipse. Three of these studies were performed with the original market product (GTC 5-535), while two used the currently marketed version (GTC 7-026). The subjects in these studies also do not appear to have been selected based on whether they were likely adopters of Eclipse. Moreover, the one study that was presented at a scientific meeting was limited to subjects who smoked more than 40 cigarettes per day,[17] and it is unclear what proportion of such heavy smokers, who are also in the minority among US smokers,[18] might actually switch to Eclipse. This study involved bronchoscopic examination and lavage of subjects while smoking their usual brands and again after smoking Eclipse for two months. Significant reductions in a range of markers of bronchial inflammation were observed with Eclipse, compared to the usual brands. However, because the study subjects were heavy smokers, they had a significantly greater degree of bronchial inflammation at baseline compared to the non-smoking controls.

DISCUSSION

To substantiate its claims of health reduction for Eclipse, RJR relies on data from several studies, which have been reviewed by a panel of experts that concurred with the results. These studies demonstrate that, mg for mg, the total particulate matter, or condensate, from Eclipse under FTC conditions is less toxic than that from conventional tobacco burning cigarettes. However, on a unit for unit basis, Eclipse appears to be as toxic as the 1R5F cigarette, a result predicted by the relative yields of Eclipse as compared with Carlton and Now. In the mouse skin painting studies, Eclipse condensate had about one third the activity of the 1R4F condensate. But compared to a cigarette like the 1R5F, Eclipse has about three times the amount of total particulate matter under FTC conditions (table 1). It is also noteworthy that the inhalation

§RJR has only reported inhalation studies using one rodent species for the products that have actually been marketed in the USA.

studies, unlike the smoke chemistry and in vitro assays, did not compare Eclipse to the 1R5F cigarette but to their usual smoking brands (that were not specified). This raises the question of whether the 1R5F might have performed as well as or better than Eclipse, as it actually did in the neutral red assay of whole smoke.

Taken together, these considerations indicate that Eclipse is likely more toxic than Now, and about as toxic as Carlton and the 1R5F cigarette. Thus, RJR's marketing claim that Eclipse primarily heats tobacco (which actually consists of tobacco derivatives) has no apparent advantage over burning it when brands having similar yields of "soot" are compared. It is not clear whether with Eclipse, the soot which is diluted by glycerin and water, is analogous to the dilution of tar by air in ventilated cigarettes.[19] While manipulations such as this can affect the outcome of carefully selected tests, they do not necessarily result in important reductions in delivered doses of toxins, or in the incidence of illness or death, in actual smokers.

More importantly, there are no human studies reported by RJR involving subjects who are likely to adopt Eclipse. Those that have been conducted to date compare Eclipse with an unselected array of brands, and the evaluations of bronchial inflammation involved only very heavy smokers, who are unlikely to be typical of Eclipse adopters. Data supporting claims of reduced harm for a novel tobacco product as compared to conventional products must, in the final analysis, be relevant to the conditions under which the product will be used by consumers. The human studies conducted in support of RJR's claims for Eclipse do not pass this test.

For the most part, smokers get practically the same dose of nicotine and other toxins from their cigarettes, regardless of differences in nominal yields between brands.[10 19] The exception is the delivered doses from the lowest yielding "ultra low" tar brands, such as Now and Carlton. While the actual deliveries of these cigarettes are higher than those predicted from the nominal ISO/FTC yields, they are still substantially lower than those of other brands.[19 20] Eclipse appears to have FTC yields that are similar to the ultra low brands, but under actual human smoking conditions it delivers nicotine levels that are similar to the subjects' usual brands. The higher operating temperature of the device under actual conditions of use may explain this,[8] and may also increase the yields of toxic constituents.

The Institute of Medicine has recently published a thoughtful analysis of how a regulatory agency should approach the evaluation of a potential reduced exposure product such as Eclipse.[7] The Institute of Medicine panel determined that there was insufficient evidence to conclude that any currently marketed product, including Eclipse, actually delivered on the promise of reduced exposure, much less on that of reduced harm. Our analysis of Eclipse strongly supports this conclusion and also indicates that the current version of this product may be even more toxic than its predecessors. Furthermore, it underscores the need for regulatory oversight, since the tobacco industry continues to introduce new PREPs with promises of reduced health risks.

In this brief review, we have not explored whether RJR's choice of assays and substrates was optimal, nor have we examined in detail issues such as the fact that a second rodent inhalation study was done only with an early, pre-market prototype. Nonetheless, the data analysed permit us to conclude that the studies conducted to date on Eclipse do not yet adequately demonstrate this device to be less toxic than other cigarettes. Indeed, the evidence suggests that Eclipse is as toxic or more toxic than a number of conventional products that have long been on the market.

Is there really "no cigarette like Eclipse", as RJR claims? It appears that, in terms of likely toxicity, there are at least several of them.

What this paper adds

There have been many attempts by tobacco companies to develop and market low nicotine and ultralight cigarettes. In 1996, the RJ Reynolds Tobacco Company (RJR) began test marketing Eclipse, a novel cigarette-like smoking article that delivers a nicotine containing aerosol to the user. RJR claimed that Eclipse, by heating rather than burning tobacco, reduces the risk of cancer and other diseases compared to conventional cigarettes. Analyses of this claim had not been conducted. This paper analyses this claim by examining several data sources and scientific studies.

We found that Eclipse appears to be at least as toxic as some commercially available cigarette brands and that the data do not support the health claims made about the product. Consumers may be misled by RJR's health claims into believing that Eclipse is a safer alternative to conventional cigarettes, underscoring the need for regulatory intervention. The analyses reported in this paper have prompted the Massachusetts Department of Public Health to request that the Federal Trade Commission carefully review RJR's advertising and marketing practices for Eclipse and/or seek a temporary injunction banning its sale under the FTC Act.

Conclusions

While RJR's test results indicate that Eclipse may offer potential health benefits to smokers, our analysis of these indicates that they do not support the product health claims, and that consumers may be misled by the company's marketing materials.

The analyses reported here have prompted the MDPH to request that the FTC carefully review RJR's advertising and marketing practices for Eclipse and/or seek a temporary injunction banning its sale under the FTC Act. The department has also urged the Food and Drug Administration to assert its jurisdiction under the Food, Drug and Cosmetic Act to regulate the sale, marketing, and distribution of Eclipse. Finally, the department has petitioned the National Association of Attorneys General to investigate whether RJR is in violation of the Master Settlement Agreement because of the way in which the company is marketing Eclipse.

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