STATE OF VERMONT
CHITTENDEN COUNTY, SS.

CHITTENDEN SUPERIOR COURT
DOCKET NO. S1087-05 CnC

STATE OF VERMONT

v.

R. J. REYNOLDS TOBACCO CO.

FINDINGS OF FACT, CONCLUSIONS OF LAW, AND INTERIM DECISION ON LIABILITY

". . . . I'm so tired I'll have another cigarette, and curse Sir Walter Raleigh, he was such a stupid get!"[1]

In this action brought by the State of Vermont seeking to impose liability for allegedly deceptive advertising used by Defendant R. J. Reynolds Tobacco Co. ("RJRT" or "Reynolds") for its non-traditional Eclipse cigarette,[2] Reynolds has conceded the pharmacological basis for the insomniac smoker's lament: nicotine is a powerful addictive substance, and the cigarette is essentially a nicotine delivery device which the smoker uses to ingest the necessary amount of nicotine that the individual smoker craves. Indeed, that premise, which tobacco companies have known for decades,[3] was one of the principal reasons behind RJRT's development and marketing of the Eclipse cigarette. Because Reynolds knew that smokers are addicted to nicotine and attempts to quit smoking are difficult at best and rarely successful on the 1st (or 2nd or 3rd) try without medical aids and other support and assistance; and because it also knew, and now fully acknowledges that cigarettes are an inherently dangerous product — which, even when used properly and as directed, will result in unnecessary disease, bodily injury and harm, and even death — it sought to develop, and market a cigarette product for smokers who were concerned about their health but unable to quit, which could potentially result in a reduced risk to that smoker of contracting one (or more) of the most common tobacco-related diseases. Such a "potentially reduced exposure product," or "PREP," may well be the Holy Grail for cigarette

[1] J. Lennon, "I'm So Tired," *White Album* (Apple Records 1968).

[2] The Eclipse heats, but does not actually burn the tobacco inside its otherwise traditional looking shell. The heated vapor carries the tobacco "taste," and other chemical "smoke" components.

[3] In other cases, tobacco companies, including RJRT, have denied that nicotine is in fact highly addictive, beyond just a psychological habit, and have until recently resisted evidence showing they have known for years about nicotine's addictive properties. *See, e.g., United States v. Philip Morris USA, Inc., et al.,* 566 F.3d 1095, 1119, 1127-28 (D.C. Cir., May 22, 2009) (civil RICO judgments affirmed against RJRT (and others) for fraudulent statements regarding health effects of smoking). "As early as 1963, Brown & Williamson's [now owned by, and a subsidiary of RJRT] general counsel wrote a confidential memorandum stating: 'We are, then, in the business of selling nicotine, an addictive drug effective in the release of stress mechanisms'." *Id.* at 1127-28.

makers and tobacco sellers facing ever-increasing regulatory restrictions, and a business model in which the product being sold inevitably results in the death of a significant number of customers and an otherwise shrinking customer base.[4]

Although technologically feasible,[5] marketing such a product so that sufficient numbers of smokers would adopt it as their "usual brand" is, and was the much stiffer challenge for Reynolds, as it has (and had) been for other cigarette makers. Not only is nicotine maintenance an issue, but there are also "taste," "mouth feel," and "cigarette ritual" factors which must be considered and, at times, overcome to make the PREP acceptable to smokers who choose to keep smoking. To entice smokers to try Eclipse, RJRT decided that it would have to emphasize what it had concluded, after many years of testing and product development, were the potential health benefits of smoking Eclipse over traditional tobacco-burning cigarettes. Accordingly, in magazine ads, Eclipse packaging, and on-line websites devoted to Eclipse beginning in 2000 and expanded nationally in 2003, Reynolds essentially stated:

> The smoke from Eclipse contains far less of many of the components that have been linked to the risk of cancer and certain other smoking-related diseases. **SCIENTIFIC STUDIES SHOW THAT, COMPARED TO OTHER CIGARETTES, ECLIPSE:**
>
> > ● May present less risk of cancer, chronic bronchitis, and possibly emphysema . . . .
>
> THE BEST CHOICE FOR SMOKERS WHO WORRY ABOUT THEIR HEALTH IS TO QUIT. THE NEXT BEST CHOICE IS ECLIPSE.

Reynolds relied on a panel of scientists it had assembled to vet the tests, studies, and other evidence backing up these statements, although the panel itself did not formally approve or disapprove the ads or marketing statements.

The principal Reynolds print advertisement for the Eclipse at issue here, primarily used only in 2003-2004 and then withdrawn – the so-called "Scott ad" – is set forth below, and repeats the essential marketing message described above.[6]

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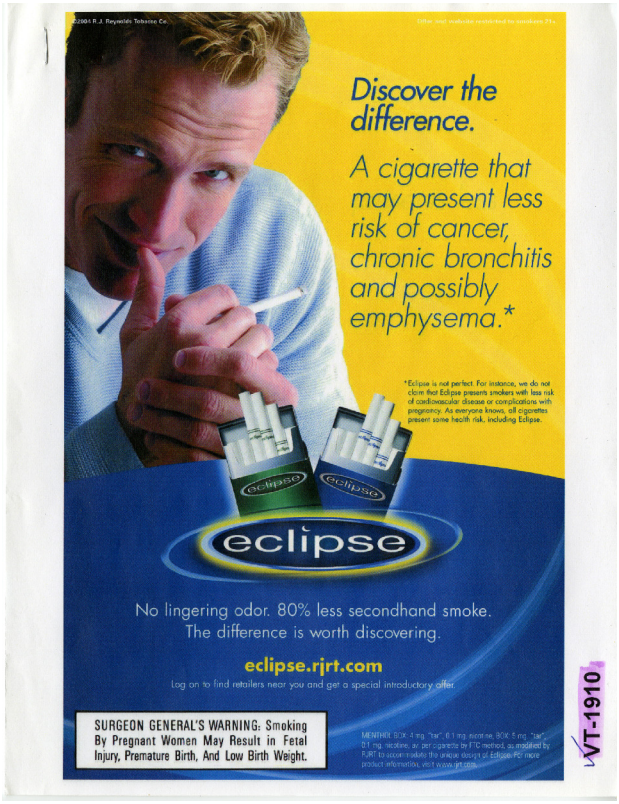
[4] At least domestically, in the U.S. market, where the absolute number of smokers continues a slow, but fairly steady decline (despite some reported recent bumps in teenage smoking, at least in Vermont). In foreign markets, however, cigarette sales are reported to be strongly increasing.

[5] Cigarettes are perhaps one of the most highly engineered, constantly tested, and precisely manufactured consumer products ever. There is very little that is still "natural" about the end product in packs and cartons in the locked cabinets at the supermarket and convenience store.

[6] The * note on the ad reads as follows: "Eclipse is not perfect. For instance, we do not claim that Eclipse presents smokers with less risk of cardiovascular disease or complications with pregnancy. As everyone knows, all cigarettes present some health risk, including Eclipse."



The controlling legal standard is clear. "[W]here advertising expressly or impliedly represents that it is based on scientific evidence, the advertiser must have that level of substantiation, and, in particular, must satisfy the relevant scientific community that the claim is true."[7] Thus, in order to establish that RJRT has made deceptive and misleading statements in violation of Vermont's Consumer Fraud Act, 9 V.S.A. § 2453(a),[8] the State was, and is required in this case "(1) to establish the particular evidence that would pass muster in the medical (or scientific) community for the types of claims made; and (2) demonstrate that the proffered substantiation failed to meet these standards."[9]

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[7] *In Re Removatron International Corp.,* 111 F.T.C. 206, 299 (1988) (cits. omitted).

[8] The State also contends that RJRT has violated the 1998 Master Settlement Agreement ("MSA") between Vermont (and other states) and Reynolds (and other settling tobacco companies), and the resulting Consent Decree entered by this court adopting the MSA, which prohibits Reynolds (and the other signatory tobacco companies) from making "any material misrepresentation of fact regarding the health consequences of using any Tobacco Product." MSA, § III(r), Decree, ¶ V(I).

[9] *Removatron, supra* fn. 6. Vermont law provides that application of the CFA, and what constitutes a deceptive or misleading statement, is to be "guided by the construction of similar terms" by the Federal Trade Commission and federal courts. 9 V.S.A. § 2453(b). Although the court later concludes that not necessarily all of the legal precepts announced by the FTC in its reported decisions are binding under the CFA as a matter of Vermont law, that essential standard

By a clear preponderance of the evidence in this case, stretching over 26 days of trial; 22 trial witnesses (all but one were MDs or PhDs, all with impressive resumes); numerous depositions of additional witnesses which have also been reviewed by the court; and thousands of pages of exhibits, the State has done so.

The relevant, and larger scientific and medical community knowledgeable about tobacco-related diseases, including several of the same scientists who performed some of the underlying studies and/or sat on RJRT's expert panel, would require that Reynolds' affirmative health benefit statements about Eclipse be supported by long-term epidemiological studies which would (a) follow an adequate number of actual Eclipse smokers in real-world settings for a sufficiently lengthy exposure period under sufficiently controlled circumstances, and (b) establish to a statistically significant degree that smoking Eclipse instead of a traditional cigarette in fact reduces the likely incidence of, or risk of contracting "cancer, chronic bronchitis, and possibly emphysema" for all smokers (or any given smoker) who might choose to continue smoking but switch to Eclipse. Alternatively, at the very least the Eclipse ad claims would have to be measured against validated "biomarkers" for the identified diseases, but no such surrogates for disease incidence are generally agreed to.

Although the tests and studies cited and relied on by RJRT were consistently promising and indicated sometimes substantial reductions in toxic smoke components, observable laboratory impacts, or some of the harmful effects of smoking (e.g., lung inflammation), the State proved there is no present scientific consensus that these reductions were medically "linked to the risk of cancer and certain other smoking-related diseases" as claimed by Reynolds. Inasmuch as RJRT concedes there are no such epidemiological studies of Eclipse smokers – indeed, Reynolds argues that conducting such studies is an unreasonable, if not impossible requirement in this instance – its claim that a smoker switching to Eclipse will in fact face a lesser risk of contracting "cancer, chronic bronchitis, and possibly emphysema," which is the unqualified message actually communicated by RJRT's ads for and statements concerning Eclipse, is deceptive and misleading as a matter of law.

Reynolds also contends that under deceptive advertising law established in numerous FTC decisions, which is then a guidepost for application of Vermont law under the CFA, its actions here should be judged only on a multi-factor "reasonable basis" standard, of which its "good faith" in relying on the recommendations of its expert panel is key, and that this analysis should excuse it from liability. The court does not agree that FTC law actually is, or applies here as Reynolds contends, but in any event the court further concludes that any such FTC rule is not binding, and that Vermont law under our CFA does not, and would not recognize a "good faith" or "reasonable basis" defense.

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for assessing allegedly deceptive advertising involving scientific, health or medical claims is likely to be recognized, and is applied here.

However, the tests and studies which Reynolds did rely on were for the most part adequately, and properly performed to a reasonable scientific basis. All of the personnel primarily involved – both in-house RJRT employees involved in the actual testing and product development, and even the Eclipse marketing, as well as the expert panel and outside researchers – acted responsibly, with sincere consumer-protection motives (although at the same time they all wanted RJRT to be commercially successful in selling Eclipse), and in "good faith" to the extent that, although Reynolds did breach the 1998 MSA and corresponding provision of this court's 1998 Consent Decree, it should not be held in willful contempt for that violation because RJRT did make reasonable efforts to remain in compliance with the order of this court. At bottom, although Reynolds' marketing of the Eclipse cigarette was ultimately misleading and deceptive because the support relied on was scientifically and medically insufficient, there was no "bad intent"[10] and in fact a deliberate, indeed considerable effort to develop and sell a tobacco product which might potentially do some good for some smokers, and more likely than not do no additional, or different harm.[11]

Trial of this action has been bifurcated by the court, so that evidence was presented only on the merits of the CFA violation and other claims. Remedies, and any damages to be awarded, as well as the inevitably considerable issue of attorney's fees and litigation expenses, will now have to be addressed in additional proceedings. How, when, and to what extent[12] and in what order those remaining matters will be taken up, will be addressed and discussed at a status conference to be scheduled forthwith.[13]

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[10] Although the evidence also clearly established that Reynolds' motivation was not entirely altruistic, and that developing and successfully selling a tobacco PREP was viewed at the highest management levels to be important to the company's own long-term survival as a viable, indeed profitable company, those financial/economic concerns do not automatically translate into bad motive. Making and selling cigarettes is an entirely legal (although increasingly regulated) business, and RJRT is fully entitled to run its business in a profitable manner so long as it remains in compliance with all regulatory rules and legal requirements. It is only that latter, more discrete, and (hopefully) entirely objective issue that the court addresses here.

[11] The State's additional claim at the outset of the case, that RJRT engaged in additional "false and deceptive practices" because its Eclipse marketing induced smokers to delay or quit smoking altogether, or might even encourage some non-smokers to start, was abandoned, and no evidence was presented to establish those claims. Reynolds will be granted judgment on, and Count II of the Complaint will be dismissed.

[12] Given the enactment in 2009 of significant federal legislation providing the FDA with authority to regulate the very advertising and marketing claims at issue in this case, and in light of the substantial claims of pre-emption already asserted, the court anticipates that the issue of this court's power under the CFA, or to remedy any breach of the MSA, may well be substantially disputed to the extent that any forward-looking injunctive relief is still sought by the State. That issue has not, of course, been formally raised, or briefed, and it is certainly not decided here.

[13] Given the extensive delay in issuing this decision, the court readily acknowledges the irony in proclaiming that anything in this case will happen "forthwith."

FINDINGS OF FACT

I. Tobacco Generally and The Eclipse Cigarette

1. A conventional cigarette is a column of highly processed tobacco wrapped in paper, with or without a cellulose (or other) filter at the end inserted into the smoker's mouth, which is lit at the other end and then burned to create the smoke which the smoker inhales. Tobacco smoke is a highly complex mixture. There are now over 4000 identifiable compounds, or chemicals in the smoke generated by burning tobacco; slightly more than 100 were known in the 1950s, when tobacco research greatly intensified. Of those, at least 60 (if not more, possibly as many as 70-80+) chemicals, or compounds are identified as known, or suspected carcinogens in humans and/or animals. It is theorized that incomplete combustion of the tobacco is a principal, if not primary cause of the production of carcinogenic, and other disease-associated compounds and chemicals in tobacco smoke.

2. Cigarettes are not just psychologically, or emotionally addictive. One of the principal components of cigarette smoke is nicotine, a psycho-active drug which alters certain sensory receptors in the human brain, and causes severe physiological addition over a relatively short period of time. Once established, nicotine addiction is one of the most difficult chemically-induced addictions for any person to break, typically requiring extraordinary levels of perseverance, and often medical aids (e.g., counter-active drugs, or nicotine replacement therapies), psychological therapy, and emotional assistance and support from friends and family to overcome the physical withdrawal symptoms. The craving for cigarettes may last for years before it is completely gone, even after the former smoker has not actually smoked a cigarette during that entire period; just the smell of second-hand tobacco smoke on another person's clothing may trigger the urge to light up, or new withdrawal pangs.

3. Cigarettes are a known, and entirely avoidable cause of human disease, diseases which cause significant and substantial harm and bodily injury, and death. Cigarettes have been linked to, or statistically associated with more than 425,000 "excess" American deaths per year (as of 2001), primarily from cancer, heart disease, and lung disease. This linkage has been well-known for many years, to the American public since the epochal Surgeon General's report in 1964, and because of the subsequent restrictions on tobacco marketing and advertising; and to the tobacco companies, including RJRT, even before that, and certainly over the ensuing years as the association has become even more widely accepted and medically established. However, only 1 in 10 smokers (approximately) will actually develop lung cancer (by far, the primary killer of the tobacco-related diseases). The physical, or biological mechanism(s) through which some smokers contract lung cancer, although the vast majority do not, is still not medically, or scientifically understood even after almost 50 years of intensive study and testing of cigarettes since the first Surgeon General's report.

4. Conventional tobacco-burning cigarettes are a highly manufactured product which have been continually redesigned, re-engineered, and reformulated by tobacco companies, including RJRT, in response to consumer demand and/or marketing decisions, such as the creation of new brands, or even new categories or types of cigarettes. The "typical" cigarette consists of a mixture of "flue-cured" (about 50%) and "burley" (about 30%, more or less) tobaccos, plus other proprietary materials, including the wrapper (about 20%, or less). Although the exact chemical composition of the tobacco, and of the resulting tobacco smoke when burned, cannot be completely controlled, through the entire process of growing, selecting, and drying or curing the tobacco, and manufacturing the cigarette itself, RJRT and other tobacco cigarette sellers are able to essentially manipulate the chemical composition of cigarette smoke. For example, since the 1970s the industry has developed, and extensively marketed so-called "low tar" cigarettes on the premise that less "tar" in the inhaled smoke would present less risk of harmful disease.[14] However, the overall association of smoking tobacco-burning cigarettes with an increased risk of contracting the noted diseases cannot be eliminated, or even reduced to a negligible, non-statistically-significant level by presently available manufacturing techniques. Thus tobacco companies, including RJRT, knowingly produce, and sell to consumers an inherently dangerous product which, even when used precisely by the consumer as designed and intended, creates an increased risk of developing debilitating, if not deadly disease.

5. Knowing that they sell an inherently dangerous product which is physically addictive, thereby creating a captive market in which some will be injured if not killed by the product itself; and also recognizing the inevitability of ever-increasing tobacco regulation because of that essential fact (at least in the "Western" or industrialized nations), tobacco companies, including RJRT, have over the last 20-25 years sought – for both "product stewardship" reasons and genuine concern for their customers, and for industry viability and profit-making reasons as well – to develop alternative tobacco products which might potentially reduce a smoker's risk of developing one (or more) of the tobacco-related diseases, i.e., a "PREP," or potentially reduced exposure product.

6. One such product developed, and studied for years by RJRT beginning in the early 1980s, was the Premier cigarette. Premier was a "tobacco-heating" cigarette, in which a ceramic heat source at the end was ignited, but there was no actual tobacco inside the paper casing. Encapsulated "tobacco flavor beads" were then heated to produce "smoke" which was inhaled at the other end, through a filter. After considerable testing, Premier was launched as an available consumer tobacco product in 1988. The ads and marketing for Premier did not tout any

[14] That premise has only recently been called into question, on a medical and scientific basis, by further research which has become available since the late 1990s and early 2000s. The legal status of that premise is already under substantial scrutiny, if not fatal attack, *see, e.g., United States v. Philip Morris USA, Inc., et al.*, 566 F.3d 1095 (D.C. Cir., May 22, 2009). The concept of "tar" in cigarette smoke, itself a somewhat artificial definition, is discussed below.

health benefits from switching to Premier. There was almost no consumer acceptance of Premier, and RJRT withdrew it from the market in March 1989.

7. In the prior iteration of this lawsuit, which resulted in the aforementioned Consent Decree (entered December 14, 1998) arising out of the MSA, *see State v. Vermont v. Philip Morris, Inc., et al.,* Dkt. #s S744-97 CnC, S816-98 CnC[15], the State included as a very minor part of its overall allegations the assertion that RJRT had already developed a "safer" cigarette with "reduced physiological consequences," i.e., Premier, which the State claimed Reynolds "did not market … because of [an] intra-industry pact not to promote 'safer' cigarettes." Complaint, ¶ 220 (July 6, 1998). There were never any evidentiary proceedings with regard to those assertions by the State, and no judicial finding, one way or the other, as to any such "pact" or whether Premier was in fact a "safer" cigarette. Eclipse is not the same cigarette as the Premier.

8. Reynolds did not give up on development of a tobacco-heating cigarette as a viable PREP that could be designed, manufactured, and successfully marketed to consumers. Several of the RJRT employees who testified in this case were involved in (all, or parts of) the Premier campaign, and continued to push for a similar approach, or product. In 1991, upper echelon officials at Reynolds were persuaded to authorize, and grant substantial funding for development of a new tobacco-heating PREP, which came to be the Eclipse cigarette.

9. Eclipse is a somewhat similar, but simpler design and technology than the Premier. Eclipse has a very pure carbon tip, or heating element at the "business" end of the cigarette, which otherwise looks exactly like a regular cigarette; it is held by the smoker, and weighs and feels the same as a conventional tobacco-burning cigarette. The carbon tip is ignited,[16] and then heated glycerol vapor is created which travels through the inside column of shredded tobacco (all wrapped in white paper, like any other cigarette) until it passes out a hollow filter into the smoker's mouth and lungs.[17] Along the way the heated glycerol vapor picks up most, but not necessarily all of the same chemicals and compounds as conventional cigarette smoke, or in necessarily the same

[15] For administrative convenience, if not clarity, the State's claim for alleged violation of the Consent Decree entered in those two original cases is being prosecuted under this newer docket number, S1087-05 CnC, in which the related, and factually intertwined claims for breach of the MSA, and violation of the CFA, are asserted by the State.

[16] At some point during the Eclipse development, RJRT cigarette engineers decided to add some tobacco in that part of the paper wrapper around the carbon tip, so that on lighting up, the smoker would notice an initial taste sensation similar to a conventional cigarette. This was to overcome smoker resistance and initiation difficulties, one of the problems that negatively affected consumer acceptance of Premier.

[17] The resulting Eclipse "smoke "for the 5-104C/2005 prototype the court will focus on, *see* below, and depending on the machine-smoking protocol used to produce it, *see* below, is somewhere between 64% - 79% water and glycerol, and the rest (21%-36%) nicotine, particulates, and all the other chemicals and compounds identified in Table 4 below. *See* Table 8, VT-1105, Bates # 8116.

amount(s). The premise of the Eclipse is that the heated vapor ingested by the smoker will contain enough of the tobacco taste elements, and sufficient nicotine, to satisfy the smoker, but significantly fewer, or at least lesser amounts, of harmful smoke toxicants. At its most simplistic, Reynolds' thesis behind its marketing for Eclipse at issue here, is that reduced exposure to known harmful compounds reduces the risk of contracting the noted tobacco-related disease(s), i.e., "cancer, chronic bronchitis, and possibly emphysema."

10. Reynolds continued to develop and test the Eclipse in-house from 1991 through 1996, when it began limited "test launches" of the product in selected markets (the first usable prototype was available in 1993). In the 1996 and 1998 Eclipse ads in those limited markets, no health-related claims were made; the ads focused on the exterior cleanliness of the product, i.e., "no ashes" and "close to 90% less second-hand smoke." As the testing of various marketing approaches was conducted by RJRT, Eclipse itself went through numerous physical iterations, or prototypes, all of which were essentially similar and varied only in minutely measurably ways not pertinent here. By 2000, after review and a written report from its panel of appointed outside experts, *see infra,* Reynolds was prepared to, and did begin marketing Eclipse nationwide (including eventually Vermont) with the above-referenced health claims. As of mid-2006, after this action was filed, the "current market product" actually being sold by RJRT, in Vermont and elsewhere, was Eclipse prototype 5-014C/2005. This latest prototype had been slightly modified, including changes to the carbon tip heat source, to reduce the production of CO (carbon monoxide), which was suspected of contributing to slightly elevated levels of carboxy-hemoglobin observed in Eclipse testing subjects.[18]

11. Because it is the Eclipse prototype which was still in use and being marketed in Vermont closest to the time of trial in this case (which was late 2008 and early 2009) – the Eclipse cigarette was primarily sold in Vermont from 2003 (when Eclipse marketing "went national") until it was withdrawn in 2008, and RJRT no longer marketed or sold Eclipse in Vermont[19] – the court will primarily utilize the comparative "mainstream" smoke[20] chemistry results for prototype 5-

[18] The parties' continuing dispute, and jousting over the carboxy-hemoglobin issue was one of several areas where considerable time and resources were devoted to a topic which was only marginally relevant to the primary claims and evidence in the case, and predestined to be inconclusive either way. The latest Eclipse prototype also included a tobacco blend containing tobaccos lower in nitrosamines, a suspected (but not proven) carcinogen, as part of Reynolds' voluntary company-wide program to use such tobaccos in all of its products. (Reduction of nitrosamines was achieved, in part, by changes to the tobacco curing process.)

[19] During that period, approximately 420 cartons of Eclipse were sold at retail in Vermont, with another 30 or so cartons sold through a dedicated Eclipse website (*see* below). By comparison, Reynolds sold some 329,000 cartons of its most popular Camel brand in Vermont during the same time.

[20] Mainstream smoke is the burned tobacco gas (including visible particulates) that passes through the inside of the cigarette and out the end held in the smoker's mouth. "Sidestream" smoke is the smoke that comes off the burning tip of a conventional cigarette, often referred to as

014C/2005, as the primary departure point for discussion of all of the scientific analysis and testing. Significant smoke chemicals, and compounds identified in the vapor produced by "smoking" an Eclipse, as identified and studied by RJRT itself, are set forth in "Table 4" from Defendant's "Chemical and Toxicological Evaluation Eclipse Prototype … 5-014C/2005 …" (dated May 30, 2006) which is reproduced below, on the following page. *See* Exhibit VT-1105, Bates pg. # 8112. Of particular importance were some 14 chemicals or compounds which Reynolds indentified as being especially "toxic," and then chose to emphasize in its marketing for Eclipse, in particular on its special Eclipse website, *see* below.[21]

12. Tobacco smoke for laboratory and chemical analysis is produced by automatic smoking machines, with banks of up to 20 cigarettes at a time on each machine in either a rotary or straight-line configuration. Although these machines have been improved and have become more technically advanced since they were first widely used, and now come with computerized settings and controls, and are now quite expensive so that few independent cigarette investigators/researchers can afford them, the basic technology is still pretty much the same. Beginning in 1966, until just recently rescinded by the FTC, *see* 73 Fed. Reg. No. 236, at 74500 (Dec. 8, 2008), the FTC provided "guidance" that it would allow cigarette companies to "make factual statements of the tar and nicotine yields of cigarettes when … supported by testing conducted pursuant to the 'Cambridge Filter Method,'[22] also frequently referred to as 'the FTC method'." *Id*. The so-called "FTC method" stipulates a certain set of machine-smoking variables so that consistency can be achieved in comparing one cigarette to another for purposes of each cigarette's "smoke chemistry" and constituent compounds and chemicals.

13. The variables used in the FTC method are to have the machine smoke each cigarette at a rate of one puff per minute (i.e., 60 seconds), with each puff of

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"second-hand smoke." The design of the Eclipse produces little, if no sidestream smoke, as the early ads emphasized; the State does not dispute that marketing claim, and second-hand smoke is not a focus of scientific analysis here. Finally, use of the term "smoke" is understood as generic in this instance, since there is no actual tobacco combustion in the Eclipse, and the primary product passing through the tobacco column inside the cigarette is heated glycerine vapor.

[21] Reynolds' Eclipse expert panel repeatedly concluded that all of the subsequent Eclipse prototypes were substantially equivalent in their resulting smoke chemistry to the earlier versions on which most, if not all of the lab testing was based. However, it must be noted that almost all of the in-house *in vitro* and *en vivo* testing done by Reynolds itself, discussed *infra*, was conducted using the 7-026 Eclipse prototype, which has not been the "current market product" since 2001.

[22] Apart from "whole smoke" which can be captured in containers by the automatic smoking machines for concentration and further use, or sometimes directed immediately to an adjacent device for use in laboratory experiments with lab animals, *see infra*, the smoke can also be directed to pass through "Cambridge filter" pads where the residue of the smoke ("total particulate matter," or TPM) can be collected and analyzed. That residue is the primary means of calculating a cigarette's "tar" production, *infra*. "Whole smoke" is typically 80% (or more) of vapor and gases (including the volatile chemicals and compounds), and only 5-10% TPM.

Table 4. Mainstream smoke yields of test cigarettes and comparisons to Eclipse prototype 5-014C/2005 at FTC puffing regimen♦

	CMP	5-014C/2005	MULT	K2R4F	K1R5F	% Change 5014C vs. CMP	% Change 5014C vs. MULT	% Change 5014C vs. K2R4F	% Change 5014C vs. K1R5F
Puffs/cig	15.00	15.00	7.96	8.98	7.10	ns	88%	67%	111%
TPM, mg/cig	6.08	5.20	6.36	10.80	1.76	-15%	-18%	-52%	196%
Nicotine, mg cig	0.17	0.17	0.53	0.83	0.16	ns	-69%	-80%	ns
Tar, mg/cig	4.22	3.64	5.38	9.02	1.42	-14%	-32%	-60%	156%
CO, mg/cig	7.74	2.80	6.38	11.64	2.62	-64%	-56%	-76%	ns
Ammonia, ug/cig	2.40	3.15	9.25	12.61	2.18	31%	-66%	-75%	44%
Hydrogen Cyanide, ug/cig	<10.00	10.00	64.17	130.00	17.50	ns	-84%	-92%	-43%
Nitric Oxide, ug/cig	33.53	36.60	131.82	205.97	106.85	ns	-72%	-82%	-66%
Formaldehyde, ug/cig	4.15	4.50	6.98	10.60	1.55	ns	-36%	-58%	190%
Acetaldehyde, ug/cig	104.92	136.63	329.38	603.90	155.82	30%	-59%	-77%	ns
Acetone, ug/cig	36.65	47.92	160.93	293.48	75.63	31%	-70%	-84%	-37%
Acrolein, ug/cig	18.33	30.60	33.45	58.78	11.10	67%	ns	-48%	176%
Hydroquinone, ug/cig	3.72	4.07	27.35	36.54	6.82	ns	-85%	-89%	-40%
Catechol, ug/cig	1.96	2.31	29.03	47.06	8.30	ns	-92%	-95%	-72%
Phenol, ug/cig	0.16	0.23	4.66	6.31	0.59	ns	-96%	-96%	ns
pm-cresol, ug cig	0.18	0.20	4.67	6.56	0.81	ns	-96%	-97%	-76%
1,3-Butadiene, ug/cig	3.89	6.72	29.20	41.15	13.17	ns	-77%	-84%	-49%
Isoprene, ug cig	17.22	34.88	254.97	337.88	118.58	ns	-86%	-90%	-71%
Acrylonitrile, ug/cig	1.29	1.86	5.54	7.46	2.12	44%	-67%	-75%	ns
Benzene, ug cig	4.77	6.44	24.92	36.29	13.36	ns	-74%	-82%	-52%
NNN, ng/cig	<18.00	<18.00	64.17	129.50	33.17	ns	-72%	-86%	-46%
NAT, ng/cig	<20.00	<20.00	64.33	115.50	34.67	ns	-69%	-83%	-42%
NNK, ng/cig	<18.00	<18.00	36.50	131.17	21.50	ns	-51%	-86%	ns
Pyridine, ug/cig	3.78	4.88	5.98	10.70	1.85	29%	-18%	-54%	164%
Quinoline, ng/cig	6.32	24.12	225.85	267.80	56.18	ns	-89%	-91%	-57%
1-aminonaphthalene, ng/cig	0.45	0.60	9.45	12.55	3.67	ns	-94%	-95%	-84%
2-aminonaphthalene, ng/cig	0.33	0.50	7.03	8.78	2.78	ns	-93%	-94%	-82%
3-aminobiphenyl, ng/cig	0.10	0.12	1.27	1.73	0.60	ns	-91%	-93%	-81%
4-aminobiphenyl, ng/cig	0.10	0.10	0.90	1.27	0.43	ns	-89%	-92%	-77%
Ethylene Oxide, ug/cig	1.70	2.66	6.49	12.67	3.83	ns	-59%	-79%	ns
Propylene Oxide, ng/cig	332.18	447.33	1116.70	760.67	182.57	35%	-60%	-41%	145%
Vinyl Chloride, ng/cig	5.33	6.80	25.02	40.84	13.14	ns	-73%	-83%	-48%
Acenaphthene, ng/cig	6.20	2.70	47.27	59.72	6.27	ns	-94%	-96%	ns
Acenaphthylene, ng/cig	3.03	18.17	31.78	52.55	14.90	499%	-43%	-65%	ns
Benzo(a)anthracene, ng/cig	2.00	3.84	12.42	20.33	1.93	92%	-69%	-81%	99%
Benzo(a)pyrene, ng/cig	1.74	1.88	4.50	7.01	1.17	ns	-58%	-73%	61%
Benzo(b)fluoranthene, ng/cig	1.22	2.30	1.61	3.70	0.96	89%	43%	-38%	140%
Benzo(k)fluoranthene, ng/cig	0.38	0.58	0.92	1.55	0.36	ns	-37%	-63%	62%
Dibenzo(a,h)anthracene, ng/cig	0.26	0.41	1.24	2.43	0.32	ns	-67%	-83%	ns
Fluorene, ng/cig	5.12	6.25	139.70	151.43	22.95	ns	-96%	-96%	-73%
Fluoranthene, ng/cig	1.82	5.27	23.95	42.78	5.22	190%	-78%	-88%	ns
Indeno(1,2,3-cd)pyrene, ng/cig	0.30	1.60	1.30	1.70	0.37	442%	ns	ns	332%
Naphthalene, ng/cig	24.32	21.60	190.48	284.13	85.62	ns	-89%	-92%	-75%
Arsenic, ng cig	1.45	4.60	7.49	9.86	2.87	217%	-39%	-53%	61%
Cadmium, ng/cig	7.35	11.85	100.90	168.66	59.73	61%	-88%	-93%	-80%
Chromium, ng/cig	<5.00	<5.00	<5.00	<5.00	<5.00	ns	ns	ns	ns
Nickel, ng/cig	9.83	7.33	<7.00	<7.00	<7.00	ns	ns	ns	ns
Particulate Spins/cig	7.7E+13	1.1E+14	2.1E+14	2.9E+14	5.8E+13	ns	-47%	-62%	ns
Vapor Phase Spins/cig	7.3E+14	1.5E+15	3.5E+15	5.8E+15	1.6E+15	ns	-57%	-74%	ns
% Carbon	27.83	29.11	61.33	60.60	63.24	5%	-53%	-52%	-54%
% Hydrogen	9.15	8.45	9.19	8.96	8.92	ns	ns	ns	ns
% Nitrogen	1.02	1.17	5.05	4.90	5.21	ns	-77%	-76%	-78%
Spectrophotometric Tar, mg/cig	1.06	1.61	6.45	9.96	1.85	52%	-75%	-84%	ns

Note that metals were tested using a 75/35/2 puffing regimen.
♦Percent values presented are statistically significantly different ($p < 0.05$) from Eclipse prototype 5-014C/2005.
ns - not statistically significantly different from Eclipse prototype 5-014C/2005.

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2 seconds duration, and drawing 35 ml by volume of smoke (plus ambient air or other gases), with the cigarette smoked until it burns down to a specified length

(which may be different for filter vs. non-filter cigarettes). *Id.,* 73 Fed. Reg. No. 236, at 74501 & fn. 1. Because the Eclipse does not burn, and there is no outwardly visible sign of when the cigarette has been completely "smoked," the Reynolds scientists had to assume their own modification to the FTC method, which was essentially to impose an overall time limit in terms of the number of puffs (typically 15 total) instead of an observed "burn down" length.

14. The FTC method of producing cigarette smoke by machine has never been formally recognized, or validated by any government agency, including the FTC, for purposes of conducting further analysis and testing as to the human health consequences, or effects of smoking. As noted, it had been recognized until September 2008 by the FTC itself, as a method of artificially producing cigarette smoke for purposes of simply comparing, and making unvarnished marketing statements about the measured nicotine and "tar" yields of a particular cigarette. In turn, those measured nicotine and "tar" levels became the basis in the industry, over many years, of designing, manufacturing, selling, and promoting so-called "light" and "low tar" cigarettes.[23] Reynolds, and senior executive scientists at RJRT who have worked for many years on Eclipse, essentially acknowledge – and the evidence at trial confirms – that "[n]o ... machine-smoking regimen can accurately reproduce human smokers' very complex smoking behavior . . . . In addition, no single machine regimen can accurately capture the range of exposures to smoke constituents in a [given, or single] smoker or between smokers." Nonetheless RJRT chose to use, and rely on machine-generated cigarette smoke in their various *in vitro* and *en vivo* laboratory studies, *see* discussion *infra*, out of scientific necessity to have sufficient, and consistent sample amounts of cigarette smoke and smoke condensate, and to primarily generate the smoke for that lab testing using the "FTC method" because it was the most well known and widely accepted protocol for machine-generated cigarette smoke.

15. Cigarette "tar" is to some extent an artificially defined concept, even though one might commonly think of, or visualize the brownish residue left on the filter pads as "tar." As used in the industry, and generally recognized, the term "tar" is the mathematical product of subtracting measured nicotine and water (or here, also glycerol vapor) from the total wet particulate matter ("TPM"), or smoke condensate, collected on the filter pad. Accordingly, for the Eclipse prototype marketed in 2006 and thereafter, as reported in Table 4 above (in column 2), the "tar" measurement was 3.64 mg per cigarette, and 0.17 mg of nicotine. For purposes of this case, these numbers have little absolute meaning

[23] This litigation does not directly implicate, or include the similar, but much larger controversy surrounding many years of industry marketing of "light" and "low tar" cigarettes; those issues are capably, and thoroughly covered elsewhere, *see, e.g., United Sates v. Philip Morris, supra,* and in any event jurisdiction over all such marketing claims will henceforward lie with the FDA under the 2009 federal legislation. That corner of the historic, and ongoing debate over cigarettes is tangentially relevant in this case only to the extent it frames certain statements made in earlier years by some of the State's witnesses here, which RJRT now contends should adversely impact their present credibility.

in and of themselves, inasmuch as comparison to other cigarettes smoked by consumers is key given the essential message of the Eclipse ads and marketing statements that switching to Eclipse "may represent less risk less risk of cancer, chronic bronchitis and possibly emphysema." *See* discussion *infra*. Within the industry, it is generally recognized that a so-called "full flavor" cigarette today produces in excess of 12-15 mg of "tar" per cigarette,[24] a "light" cigarette produces somewhere between 6-12 mg of "tar" per cigarette, and an "ultra-light" cigarette generally less than 6 mg "tar" per cigarette.

16. Table 4 thus includes smoke chemistry measurements of significant chemicals and compounds for other cigarettes, for comparison purposes. Reynolds consulted many sources inside, and outside the industry to select those chemicals and compounds they would primarily focus on, in terms of analyzing the basic smoke chemistry; they did not necessarily test for all known or suspected human carcinogens, and also included some not on that generally accepted "list." In particular, the smoke analysis was focused on carbonyls, hydrobenzenes, aromatic amines, unsaturated hydrocarbons, several inorganic compounds (including some metals), and tobacco-specific nitrosamines (NNN, NNK, and NAT). In column 1 are the results for the so-called "current market product" ("CMP"), that is the Eclipse prototype that was being manufactured and sold by Reynolds before 2006. In Table 3 are the results from testing a commercially available Marlboro Ultralight cigarette, and in columns 4 and 5 are the results from analysis of the machine-produced smoke from so-called "reference cigarettes" which are produced in quantity by the University of Kentucky just for the purpose of tobacco and cigarette testing, and used throughout the industry.[25] All of the results on Table 4 were produced by machine smoking of the identified cigarettes under the FTC method, except as noted for metals, which were extracted using a different machine protocol, or "75/35/2 puffing regimen."[26]

17. Even after decades of cigarette testing and studies, industry scientists, including those at Reynolds, still do not have a complete understanding of the physics of tobacco combustion. As noted, cigarette smoke is a "complex mixture"

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[24] For example, over many years, through many different design changes (e.g., simply shrinking the size of the cigarette, extractions from and treatment to the tobacco itself, and changes in the paper) Reynolds has reduced the "tar" production in its popular Winston brand from 38 mg, to now around 15 mg per cigarette. Across the entire industry, the average is now around 10 mg of "tar" and 1 mg of nicotine per cigarette.

[25] The "K2R4F" (column 4) was a so-called "light" cigarette (9.02 mg "tar" per cigarette), and "K1R5F" (column 5) an "ultra-light" cigarette (only 1.42 mg "tar" per cigarette).

[26] In this shorthand, the 1st number is the puffing interval (in seconds), the second the draw volume (in ml), and the third the puff duration (in seconds). As is discussed in somewhat more detail below, the effect, and propriety, of using different "puffing regimens" to produce the Eclipse "smoke" needed for certain tests and experiments on Eclipse was the subject of many, many hours of testimony and debate.

in which there are thousands of constituent elements and compounds, each of which may play a different, and unknown dynamic role in the overall composition of (and the human health consequences of inhaling) the resulting "whole smoke." Even when consistently smoked by machine under a standard protocol, the measurable results, as to individually identified chemicals or compounds, is not predictable, and varies unexpectedly given minute changes in tobacco composition and/or cigarette design and construction. Comparison among the 5 different cigarettes all depicted on Table 4 indicates that measured amounts of various substances will vary widely. For example, for ammonia, formaldehyde and arsenic,[27] the measured levels ranged from 2.18 ug (i.e., microgram) per cigarette (the K1R5F) to 12.61 ug/cigarette (the K2R4F)[28], while formaldehyde ranged from 1.55 ug/cigarette to 10.6 ug/cigarette (again, the two Kentucky reference cigarettes), and arsenic from 1.45 ng (nanogram) per cigarette (the prior Eclipse prototype) to 9.86 ng/cigarette (the K2R4F "light"). For all three of those measured compounds, the amount per cigarette produced by the Eclipse prototype Reynolds chose to begin marketing in 2006, was somewhat greater than the measured levels for the pre-2006 Eclipse (i.e., the "CMP").[29] There is no scientific or medical evidence, however, that conclusively links any particular chemical or compound on Table 4, including ammonia, formaldehyde and arsenic, with any specifically quantifiable increase in the incidence of, or number of deaths from any particular human disease.

18. When cigarette smoke is produced according to other machine-smoking protocols, the resulting measurable levels of the same chemicals and compounds again varies widely, and unpredictably. For example, when each of the 5 selected cigarettes was subjected to a "45/40/2 puffing regimen" with a greater puff frequency and larger puff volume,[30] the measured "tar" for the 5-014C prototype increased from 3.64 mg/cigarette (per the FTC method) to 10.18 mg/cigarette, an increase of 2.79 times the amount of "tar." *Compare* Table 4, above, *with* Table 5, Bates pg. # 8113 (VT Exhibit 1105). Other identified chemicals and compounds also increased compared to Eclipse "smoke" from the FTC method, again not in a straight-line or predictable fashion. *Id.* However, for all of the chemicals and compounds indentified on Table 4, using the FTC

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[27] Without drawing any inference that is determinative in this case, one might wonder if smokers' attention to the health consequences of smoking might be even further heightened if the required warning label made clear that in smoking each cigarette the smoker was inhaling measurable doses of ammonia, formaldehyde and arsenic.

[28] For a number of identified chemicals or compounds on Table 4, the Kentucky reference "light" cigarette had the highest reported levels. *See* fn. 25, above.

[29] The 5-014C/2005 prototype did substantially reduce the measured levels of CO, from 7.74 mg/cigarette to 2.8 mg/cigarette, thereby addressing the carboxy-hemoglobin concern, *see* fn. 18 above.

[30] The designated number of total puffs per cigarette also necessarily increased, to 20, because the intervals between puffs was shorter.

method the "smoke" from Eclipse contained lesser amounts (sometimes significantly) of those substances than either the commercially available Marlboro Ultralight, or the Kentucky reference "light" cigarette (K2R4F).[31]

19. A third iteration of smoke chemistry analysis using a machine-smoking "60/30/2 puffing regimen"[32] – sometimes known as, or at least similar to the "Canadian intense method" because it is often used by Canadian regulatory agencies – showed an increase in measured "tar" to 25.52 mg/cigarette for the 5-014C prototype, compared to the FTC method, an increase of more than 7 times the amount of "tar." *Compare* Table 4, above, *with* Table 6, Bates pg. # 8114 (VT Exhibit 1105). Under this machine-smoking protocol, the level of "tar" from the 5-014C Eclipse also substantially exceeded the "tar" level for the commercially available Marlboro Ultralight, by 63% as reported in the RJRT data itself. *Id.* Measured amounts of other compounds or chemicals also increased substantially, such as ammonia (to 62.50 ug/cigarette), formaldehyde (to 44.0 ug/cigarette), and benzene (from 6.44 ug/cigarette to 23.73 ug/cigarette). *Id.* Again, however, none of the measured increases, or variations in tested "whole smoke" chemical components occurred in a straight-line or predictable fashion; the changes are not consistently, or directly proportional to the overall 25.7% increase in total volume of cigarette smoke and other vapor captured at the end of the machine-smoking exercise. *See* fn. 30 below.

20. Actual human smoking of cigarettes introduces still more unpredictability. No two smokers will smoke a given cigarette in precisely the same manner, or frequency. Even a single smoker will not consistently smoke the same cigarette in an always consistent fashion; variations occur based on time of day, emotional mood, and other circumstances, none of which can be accounted for by machine-smoking protocols.

21. Because of the different design of the Eclipse, and the fact that it does not actually burn, or combust the tobacco column inside the cigarette, a typical smoker used to smoking a conventional cigarette will "smoke" an Eclipse in a different manner as well. As RJRT researchers learned throughout the long development and testing process for the Eclipse (which is discussed in more detail below), conventional cigarette smokers had to "learn" how to "smoke" the

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[31] For just a few compounds, there were measurable increases in the Eclipse "smoke" compared to the Kentucky "ultra-light" cigarette (K1R5F) even within the same FTC protocol, e.g., total "tar" (156% increase), formaldehyde (190% increase) and acrolein (176% increase). Using other "puffing regimens," *see infra*, some of the increases were even more dramatic vs. the K1R5F (e.g., 252% increase in "tar") (Table 6, ¶ 19 below). There was no evidence, however, that any commercially available cigarette substantially similar to the K1R5F was used by any significant number of smokers in the general population.

[32] The designated number of total puffs per cigarette also increased, to 22. Why that is so, given the specified puffing frequency remained constant at every 60 seconds, and the puffing volume decreased from the FTC method (from 35 ml to 30 ml), was not explained, and is not apparent. Nonetheless, the total volume of smoke and vapor produced is significantly higher under the 60/30/2 regimen, as applied here (660 ml vs. 525 ml under FTC conditions).

Eclipse in a manner that would replicate the reasons why they were smoking, including taste and mouth feel. The principal controlling variable, however, would be the smoker's need to achieve the desired level of nicotine ingestion, in order to meet the addictive nicotine craving which had become psychotropically, and physiologically established by that person's particular smoking history.

22. The Eclipse (both the "CMP" and the 5-014C prototype) produced significantly lesser amounts of nicotine under any, and all of the puffing regimens studied, and reported by RJRT scientists, as well as generally reduced levels of "tar." While the measured nicotine levels for the commercially available Marlboro Ultralight cigarette ranged from 0.53 mg/cigarette to 0.88 mg/cigarette to 1.26 mg/cigarette as the machine-smoking regimen became more "intense," *compare* Tables 4, 5, and 6, Bates pg. #s 8112-14 (Exhibit VT-1105), the nicotine levels for the Eclipse ranged from 0.17 mg/cigarette to 0.40 mg/cigarette to 1.10 mg/cigarette. In order to ingest a comparable amount of nicotine, a typical smoker used to her or his "usual brand" would have to smoke an Eclipse more intensely to achieve the desired nicotine dosage, either from each cigarette, or over the course of a day (or other reasonably designated timeframe).[33] In turn, and generally, more intense smoking, and "more strenuous puffing" of Eclipse would, and did in the machine-smoking tests result in greater yields, or amounts of most, if not all of the smoke chemicals and compounds indentified in Tables 4-6 referenced herein. However, when testing data and lab results derived from using the "whole smoke" generated by the FTC method were presented to Reynolds' Eclipse expert panel, although the raw data from at least 3 different protocols was obviously included, the "compensatory smoking" phenomenon was not specifically referenced, and there was apparently no extended discussion among the panel members of whether, or how that phenomenon might affect reliance on those lab results. Moreover, RJRT did not prepare, or present to the expert panel any detailed cross-regimen smoke chemistry results, such as the illustrative calculations set forth in ¶ 19 above.

23. Reynolds did not present – either at trial, or years earlier to its Eclipse expert panel – any comparative data measuring, or reporting nicotine levels for

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[33] The "smoker compensation" phenomenon, although well-known inside the industry for years, has only more recently become widely known, and accepted within the larger regulatory and scientific community. This was one of the principal reasons for the FTC's recent rescission of its 42-year-old "guidance" approving the so-called "FTC method" of measuring "tar" and nicotine yields of a particular cigarette.

> Despite dramatic decreases in machine-measured tar and nicotine yields since [1966], the Commission has been concerned for some time that the current test method maybe misleading to individual consumers who rely on the ratings it produces to as indicators of the amount of tar and nicotine they actually will get from their cigarettes, or who use this information as a basis for choosing which cigarettes they smoke. In fact, the current yields tend to be relatively poor predictors of tar and nicotine exposure. This is primarily due to smoker compensation – *i.e.,* the tendency of smokers of lower-rated cigarettes to to take bigger, deeper, or more frequent puffs, or to otherwise alter their smoking behavior in order to obtain the dosage of nicotine they need.

73 Fed. Reg. No. 236, at 74501 (12/8/08). *See also, e.g., United Sates v. Philip Morris, supra.*

so-called "full flavor" cigarettes, or other types of cigarettes (e.g., non-filtered) which can deliver even higher levels of nicotine. The inference is clear, however, that in general a "heavy" smoker – usually defined as someone smoking 2 or more packs (i.e., 40+ cigarettes) per day – addicted to the levels of nicotine produced by such conventional cigarettes would, after switching to Eclipse, have to "smoke" the Eclipse in an even more sustained, or intense manner to replicate comparable pre-Eclipse nicotine levels.[34]

24. Reynolds was aware from its own in-house studies of actual human smoking behavior involving Eclipse, that smokers who did switch to Eclipse at least initially, and typically engaged in significant "compensatory smoking" behavior by "smoking" the Eclipse more intensely, that is, by taking longer, more frequent, and/or deeper puffs than a conventional tobacco-burning cigarette. Again, because RJRT has not completed any long-term studies of any substantial number of actual Eclipse smokers, there is no data on how, or if any smokers who may have chosen to continue using Eclipse beyond an initial introductory phase might moderate their smoking behavior over time such that it became less intense, and at least theoretically more like the variables used in the FTC machine-smoking protocol. However, one can infer from the fact that Eclipse has also not been commercially successful, much like Premier before it, that insubstantial numbers of actual consumers who have elected to try Eclipse have continued to use it as their "usual brand" of cigarette, in order to develop such data. Ultimately, no matter what machine-smoking regimen is utilized, the Eclipse does result in lower (if not the lowest) amounts, in absolute terms, of several (but not all) of the "most important" chemicals and compounds depicted on Table 4 above, and generally 50% less for total weight of TPM and carbon-based elements.[35]

II. Medical & Scientific Testing of Eclipse "Smoke"

25. Chemical testing and analysis of the "smoke" produced by the Eclipse cigarette could, and did take place over many years on several different levels,

[34] The actual studies conducted by Reynolds, and/or outside investigators selected and funded by Reynolds, which attempted to study actual human smoking behavior after switching to Eclipse – discussed in more detail *infra* – are inconclusive with respect to the actual details, or level of more intense smoking needed to achieve nicotine compensation. One of the principal criticisms of the State and its experts is that because no long-term studies of any kind have yet been completed by RJRT, it is unknown whether a PREP like Eclipse might be useful as a sort of "nicotine replacement" and/or "step down" device in that, over time, a smoker might become accustomed to the lower levels of nicotine, eventually stop smoking the Eclipse more intensely, and then theoretically benefit (or at least suffer no additional harm) from the reduction in constituent chemicals and compounds suggested by the data measured under FTC machine-smoking conditions.

[35] By gas chromatograph analysis, the Eclipse also generally demonstrated fewer, or less intense "peaks" for many, if not most of the volatile chemicals of particular concern. Although still a "complex mixture," Eclipse "smoke" was generally "simpler" overall than smoke from tobacco-burning cigarettes, with a somewhat reduced number of multi-chemical compounds.

after further research and development was approved by Reynolds in 1991. At the first level would be the basic "smoke chemistry" analysis already discussed, in which the principal components and constituent elements of the resulting "smoke" (again, primarily using the FTC method) were identified. This was all done by in-house RJRT scientists, using sophisticated, state-of-the-art laboratory equipment (e.g., gas spectrometers, and spin centrifuges) and recognized lab techniques and protocols. There is no evidence, or even suggestion otherwise, and the court finds that at this initial level the basic smoke chemistry analysis conducted in-house by RJRT scientists was unbiased, objective, competent, and reliable.

26. The next level of testing and analysis would be so-called *in vitro* tests, in which both smoke condensate and "whole smoke" from Eclipse and other reference cigarettes would be used in established chemical and/or bio-assays at a microscopic level, to screen for, and report possible adverse effects, or, in some instances, perceived reductions in adverse impacts. After that, a further level of testing and analysis conducted in-house by RJRT scientists would be the *en vivo* tests, in which either "whole smoke" and/or smoke condensate (again, machine-derived) would be used on or with laboratory animals, again under controlled conditions and using recognized testing protocols. Finally, there were limited tests using actual human volunteers smoking Eclipse under "real world" conditions to assess for possible indicators of adverse health impacts, or any potential reductions thereof; all of these latter research projects, which necessarily could not be unduly invasive or actually compromise any volunteer's health, were conducted by outside university researchers selected and funded, but not ultimately directed or controlled by Reynolds.[36]

27. Because Eclipse is different than a conventional tobacco-burning cigarette; because most of its constituent chemicals and compounds are released during the so-called "vapor" or "gas phase" (because the tobacco is only heated, not burned) rather than the "particulate phase" (particulate matter is primarily the result of combustion) which is principally captured by the filter pads and turned into condensate; because certain identified elements (e.g., aldehydes, or acrolein) would more likely be produced during the gas or vapor phase and thus included only in the "whole smoke" from Eclipse; and because the "whole smoke" was thus likely to be more cytotoxic (i.e., damaging at the cellular, or molecular level), it was, and is important to test *en vivo*, to the extent possible, both the "whole smoke" and smoke condensate from Eclipse. The RJRT scientists recognized this, and performed both types of lab tests.

[36] The "human smoking behavior" studies already alluded to were used not only to assess potential health impacts, but also the manner in which Eclipse was used by real smokers (although those details were also present to some degree in some of the university studies); the former were conducted mostly by and with RJRT employees, and to the extent necessary are discussed in more detail below. Other small-scale "clinical" tests by outside researchers also resulted in some "human smoking behavior" observations.

A. *In Vitro* Tests

28. There were three types of lab analyses principally performed by, and relied on by Reynolds to demonstrate that Eclipse is, in fact, a tobacco PREP. Different variations on the "Ames assay," a long-established and recognized lab test method to assess mutagenicity,[37] were conducted by RJRT scientists using primarily smoke condensate, which was derived from Eclipse "smoke" and the reference cigarettes as generated by machine using the so-called "FTC method." Two other types of standard lab tests, the "neutral red uptake" or cytotoxicity assay, and the "sister chromatid exchange" assay, both using harvested Chinese hamster ovary cells, were also conducted by RJRT scientists using both smoke condensate and "whole smoke" from Eclipse and the reference cigarettes. These basic tests on the comparative effects began in the early 1990s, after development of Eclipse was approved, and the early prototypes were developed. These initial test results on Eclipse were, in the view of the Reynolds' team, so promising, and favorable in terms observed reductions in potentially harmful effect, that continued development of Eclipse was approved. As early as 1996, at a major conference at Duke University, RJRT scientists first began to make public these initial lab test results, at around the same time as Reynolds' first introduction of Eclipse into a single test market (in Chattanooga, TN, *see* below).

29. Other types of *in vitro* assays were also secondarily conducted by RJRT scientists, and are relied on by Reynolds to support its marketing statements about Eclipse, including tests to measure "chromosome aberration" (i.e., formation, or reduction of DNA adducts); "gap junction intercellular communication" studies; "lactate dehydrogenase release" measurements; and "ciliary function" studies. Except for the last test, which primarily relates to lung function and thus the ad claims regarding bronchitis and emphysema, most of the in-house Reynolds' lab tests were focused on assessment of pre-clinical,[38] and microscopic measures of potential impacts on genetic and/or cellular performance. This focus was logical, because (A) cancer is generally, and grossly considered in the larger scientific and medical community, although not yet fully proven, to be primarily a disease strongly associated with, if not primarily caused by genetic and/or cellular disruption, defects, or injury; and (B) cancer represents by far the single largest category of tobacco-related diseases resulting in death.[39]

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[37] Mutagenicity is the relative propensity of a genetic component of a biological cell to mutate, or change. As noted, genetic or cellular change is thought to be associated with cancer.

[38] In this context, "clinical" is generally understood to refer to tests or analysis using live human subjects, and "pre-clinical" to *in vitro* assays and *en vivo* tests (i.e., with lab animals). A substance, or compound is "genotoxic" if it tends to result in observable damage to DNA (sometimes RNA), or the gene; it is "cytotoxic" if it tends to result in cell damage, or disruption of cell growth or cell functions.

[39] That is, cancer (lung, throat, esophageal, lip, tongue, and "other") was identified as the primary cause in 37% of the 428,000 deaths in 2001 attributed to cigarette smoking. Heart disease and stroke were next, at 24.35%, and "chronic lung disease" (undifferentiated) at 19.8%.

30. However, as discussed further below, although there is general scientific and medical consensus as to the genetic and/or cellular disruption theory of cancer genesis (or growth and promotion, once initiated), even after decades of research and study (at a societal cost of many billions of dollars) the precise etiology of any particular cancer, including lung cancer which is the single biggest cause of tobacco-induced death, is still not fully known or agreed upon. Therefore, the pre-cancerous effect of a particular chemical or compound, or measurable genetic and/or cellular condition, cannot be effectively, or ultimately correlated with onset, or progression of the disease itself.

31. The Ames assay tests for the effect of the subject compound (or chemical) on different identified strains of the salmonella bacteria,[40] which have been genetically altered in advance – the bacteria are propagated to omit an essential amino acid – to cause the bacteria to revert back to the bacteria's original state.[41] Thus, a greater number of "revertants" over a designated time period (e.g., 24 hours) indicates a greater level of mutagenicity associated with the subject compound; a lower number of revertants would indicate a lesser propensity to induce genetic changes. The Ames assay has been in use for years (since around 1977), and is generally recognized in the scientific community as a standard measure of mutagenicity, even though the lack of definitive correlation between salmonella bacteria and actual human cells (which generally cannot be kept alive in a test tube) is acknowledged . The test can be conducted with, or without a metabolic agent (S-9) that increases the intensity of the reaction;[42] RJRT scientists performed both, and did so using accepted lab techniques.[43]

32. Using smoke condensate from Eclipse, the two Kentucky reference cigarettes, and the Marlboro Ultralight, the Ames assay produced statistically significant[44] results indicating decreases in the number of revertants for Eclipse compared to the other cigarettes, at least in three salmonella strains using the S-9 agent, and in one strain (TA98) without metabolic activation. For example, at 5% S-9 activation and using a "per cigarette" basis of comparison, the 5-104C prototype produced 2673 revertants, compared to 5410 for the K1R5F (the

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[40] These bacteria strains (e.g., TA98, TA1535, etc.) are standardized and commercially available.

[41] Using sophisticated electron microscopy, and other techniques and equipment now common for DNA testing, specifically identified genes in the salmonella bacteria can be tested and compared at designated locii, to determine if the exact same gene sequence is present (or not).

[42] The S-9 agent is an extract from pulverized rat livers.

[43] The number of revertants in each sample are counted by an automated, computerized high-power microscope, with attached camera to record the results.

[44] "Statistically significant" is generally understood to mean any statistical analysis where the reported "confidence level" is greater than 95%, i.e., $P<0.05$. *See* .

Kentucky reference ultralight), 11,351 for the K2R4F (the Kentucky light cigarette), and 14,036 for the Marlboro Ultralight in the TA98 strain.[45] Accordingly, the Ames assay using Eclipse smoke condensate indicated that machine-generated Eclipse "smoke" under the FTC method was potentially likely to be less mutagenic than similar smoke condensate from the comparison cigarettes.

33. As noted, however, whether that preliminary conclusion about potentially lower mutagenicity can be extended to any statement about cancer incidence or progression in humans, is not generally accepted in the larger, and relevant medical and scientific community. For example, in a study involving 363 compounds or chemicals known, or thought to be either mutagenic in salmonella, or carcinogenic in animals (largely lab rats or mice), only 54% of the known animal carcinogens were found to foster greater mutagenicity in salmonella using the Ames assay, while conversely 43% of compounds (or chemicals) which were not mutagenic in salmonella, are known (or suspected) animal carcinogens. Add in the further complication that there is not 100% correlation even between animal and human carcinogens, and the predictive value of the Ames assay results with respect to the actual incidence of human cancer is further diminished.

34. The "neutral red uptake" assay measured the cytotoxic effect of the smoke condensate from the Eclipse and comparative cigarettes on Chinese hamster ovary ("CHO") cells.[46] This is another standardized lab test, and the necessary materials, including the CHO cells, are commercially available. The CHO cells are treated with the smoke condensate mixture, and then placed in a "bath" including the neutral red dye. The test then measures the absorption rate, or "uptake" of the red dye, using a powerful spectrophotometer. The accepted premise is that the more damage to the cell, or even cell death, the less dye that will be absorbed, and therefore the initially applied compound that results in lesser dye amounts being absorbed, or a lower rate of absorption, is considered to have induced more cell damage and thus has a higher level of cytotoxicity. Again,

[45] The results were also statistically significant, but less dramatic in absolute numbers, using a different basis of comparison, i.e., revertants/mg TPM ("total particulate matter"). Interestingly, however, in almost all the tests (except one, using the TA1537 strain and measuring revertants/mg TPM) the "current market product" ("CMP"), or version of Eclipse actually being sold prior to 2006, consistently had the lowest number of revertants, especially on a "per cigarette" basis. *See* Tables 13 & 14, VT-1105, Bates # 8123. Thus, to the extent that Reynolds relies heavily on the mutagenicity studies to support its claim of less cancer risk, its own decision to substitute and begin selling the 5-014C version – in effect, making any existing Eclipse smokers involuntarily "switch" to a cigarette that indicated greater potential mutagenicity (although not by much, in absolute terms) – would seem to run counter to the basic Mies van der Rohe premise behind its ad claims here, i.e., less is always more, or better.

[46] The CHO cells are commercially propagated from actual hamster ovary cells first harvested in 1955; they are not actual reproductive cells, but "fibroblast" cells from the ovary lining.

RJRT scientists generally performed these assays using accepted lab techniques and procedures.

35. To measure, and report the effects of the "neutral red uptake" assay, the RJRT scientists calculated the concentration of Eclipse (and reference cigarette) smoke condensate that would be required to produce a measurable 50% reduction in cell growth (and/or increase in cell death), that is, a 50% reduction in observed rate of absorption of the neutral red dye. Thus, in the ultimate reported measurements for this assay, a higher number, or concentration indicates potentially less cytotoxicity, i.e., because it takes more to produce the observed toxic effect. Both the "current market product" (i.e., the Eclipse version being sold before 2006), and the 5-014C prototype (sold in, and after 2006)[47] resulted in less cytotoxic effect than the two Kentucky reference cigarettes, and the Marlboro UltraLight, to a statistically significant degree. The CMP needed a concentration of 95.4 micrograms/ml of TPM ("total particulate matter") to cause a 50% reduction; the 5-014C prototype needed 150.4 ug/ml of TPM; and the comparison cigarettes required concentrations ranging from 43.6 ug/ml TPM to 49.9 ug/ml TPM. In other words, the Eclipse prototype at issue here required approximately 3 times as much smoke condensate (machine-produced by the FTC method) to achieve the observed cytotoxic effect, as did the three tobacco-burning cigarettes. This lab test further indicated that Eclipse could be a promising PREP.

36. Reynolds also performed in-house "neutral red uptake" studies using "whole smoke" from Eclipse and the reference cigarettes; instead of condensate, the smoke (or, for the Eclipse, the tobacco-infused vapor) produced by the automatic smoking machines (again, under the FTC method) would be immediately directed at the *in vitro* CHO cell samples, without any further manipulation or enhancement. Because there is less control built into this test, the results are also less reliable. For example, the amount of "whole smoke" being directed at the CHO cells can only be stated in a range, and even then the range is different for Eclipse than for the conventional tobacco-burning cigarettes. For the Eclipse, the CHO cells were exposed to 0.08-0.30 mg/liter of "wet total particulate matter" within the "whole smoke," while the three comparison cigarettes produced 0.03-0.12 mg WTPM/liter for purposes of the same test. Exhibit VT-1105, Bates pg. # 8126. When the results were then assessed on a "per mg/WTPM" basis, there was again a statistically significant decrease in the predicted cytotoxicity of the Eclipse vs. the other cigarettes, that is, more "whole smoke" was required to produce the 50% reduction in red dye uptake.

37. However, when compared on a "per cigarette" basis, Eclipse was observed to be less cytotoxic than the Marlboro UltraLight and the "light"

[47] As noted, Reynolds changed to selling the 5-014C prototype to address the issue with increased levels of carboxy-hemoglobin in some Eclipse smokers' blood samples, even though the levels observed were not themselves toxic, and the carboxy-hemoglobin dispute has no relation to the disease, or health effects implicated by the ad claims contested here.

Kentucky reference cigarette,[48] but not the ultra-light Kentucky cigarette (20.49 (plus or minus 1.13) cigarette equivalents/cubic meter for the 5-014C, and 34.20 (plus or minus 1.99) for the K1R5F). *Id.* Since, as discussed below, almost all of the human smoking studies involving Eclipse showed that, generally, smokers who switched to Eclipse smoked a greater number of Eclipse cigarettes (primarily for nicotine compensation purposes), analysis on a "per cigarette" basis would seem to be more compelling. Also, as noted above, even the RJRT scientists recognized that studies using "whole smoke" instead of just condensate were important, because a number of the compounds and chemicals of concern would be produced only during the "vapor phase," and would not be present in the particulate phase. Thus, although a minor piece of the overall extensive testing conducted by Reynolds, the results of this particular "neutral red uptake" assay using "whole smoke" was inconclusive at best, and in one respect pointed in the opposite direction as other lab testing vs. the Kentucky ultra-light reference cigarette. Accordingly, the report on this assay ultimately concluded only that the results were "consistent with historical data relative to the tobacco-burning cigarettes." *Id.*

38. RJRT scientists also performed in-house lab tests on Eclipse for potential chromosome aberration, or genotoxicity. One such additional *in vitro* study was the so-called "sister chromatid exchange" ("SCE"), which could be, and was conducted using both smoke condensate and "whole smoke" (again, in all instances, machine-produced under the FTC method) on CHO cells. Using a powerful electron microscope, the rearrangement (i.e., "exchange") of related gene markers (i.e., "sister chromatids") on a single chromosome can be observed. This assay thus measures the potential of the introduced agent to result in that exchange, and thus to affect chromosome structure. The observed number of SCE is apparently accomplished by human counting with the microscope, and not automatically or by computer. The ultimate measurement is a calculated number that is the product of the amount of condensate, or "whole smoke," divided by the observed number of SCE; a lower number is indicative of less genotoxicity, because lesser amounts of the introduced agent are needed to produce the observed effect.

39. Using smoke condensate from both Eclipse and the comparison cigarettes, the SCE assay indicated a calculated (or "slope") value[49] of 0.008 (plus

[48] Because all of the lab and other testing occurred over many years, almost a decade, there were sometimes changes in the availability of the Kentucky reference cigarettes, and whether the University of Kentucky would continue to produce the same exact cigarette in sufficient quantities for the testing Reynolds (and other tobacco companies) needed. At some point the Kentucky "light" cigarette appears to have gone from the designation 1R4F (used in the earliest *in vitro* tests) to 2R4F (as used in the latest smoke chemistry tests, *see* Table 4 above). There was no evidence, however, that the cigarette composition was substantially different or would have affected any comparative test results. The court thus refers to either, or both, generically.

[49] Further refinements in the calculation formula stipulated that the "slope values" were actually the product of "regression lines" using the noted smoke concentrations vs. the "square root of SCE counts." Exhibit VT-1105, Bates pg. # 8125, Table 17. There was no persuasive evidence that these

or minus 0.0026) for the 5-104C prototype, compared to a range of 0.0273-0.0283 (plus or minus 0.0025-0.0029) for the two Kentucky cigarettes and the Marlboro UltraLight. Exhibit VT-1105, Bates pg. # 8125. That difference was clearly statistically significant, and indicated lower potential genotoxicity for Eclipse. Using "whole smoke" (again, the same mechanical procedure as for the "neutral red" assay described above), the results were essentially the same as the "whole smoke" testing for the "neutral red uptake" assay: On a "per mg TPM/liter" basis, Eclipse would appear to be significantly less genotoxic than all of the conventional cigarettes, but on a "cigarette equivalent" basis, the Eclipse (both the CMP and the post-2006 product) did less well than the Kentucky "ultra-light" (0.0543 (plus or minus 0.0018) for the CMP, and 0.0536 (plus or minus 0.0016) for the 5-014C prototype, vs. 0.0428 (plus or minus 0.0014) for the K1R5F). Exhibit VT-1105, Bates pg. # 8127.[50] The same caveats noted in ¶ 37 above are pertinent here as well, and Reynolds reported the same general conclusion about "consistency" with "historical data." *Id*.

40. Another genotoxicity test performed in-house at Reynolds was an *in vitro* "chromosome aberration" analysis using smoke condensate (generated by the FTC method) on the salmonella bacteria, both with and without the S-9 activation agent. Under microscopic observation, the gene is examined to determine the proclivity for the introduced substance to result in a break in, or missing DNA sequence, or so-called "DNA adducts," on either or both strands of the designated chromosome. Although less sensitive than the SCE assay, and one step removed because it does not involved mammalian cells or DNA, under all comparative modes of analysis the Eclipse condensate produce less indication of chromosomal aberration than the reference tobacco-burning cigarettes. This was another *in vitro* test that suggests the Eclipse may be less genotoxic, and a viable tobacco PREP.

41. A further cytotoxicity assay performed by Reynolds was the so-called "gap junction intercellular communication" study. In this study "millions" of biological cells, including rat liver cells and 4 types of human cells (including bronchial epithelial cells, *see* below), are grouped in trio formations, and all cells are then dyed with a fluorescent dye, treated with the smoke condensate from both Eclipse and the comparison cigarettes, and then the "middle" cell of the trio is "photo-bleached" with a computerized laser. The same computerized machine then reads the "leakage" of the fluorescent dye from the two adjacent cells into the middle cell. The premise is that cells of the same type (e.g., within the same

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mathematical choices introduced any significant questions about the reliability of the data, or test results. As in most of the in-house Reynolds lab testing, the concentration of Eclipse condensate was substantially greater than for the tobacco-burning cigarettes, and again stated only within a given range, i.e., 0-250 ug/ml TPM for Eclipse, and 0-75 ug/ml TPM for the conventional cigarettes.

[50] The testimony of Dr. David Doolittle (one of Reynolds' chief scientists) at trial, that he recalled the SCE tests having shown less genotoxicity for Eclipse across any and all bases of comparison, appears to have been incorrect. Given the complexity of the data and the passage of time, and his testimony as a whole, any such mistake does not impugn his credibility.

organ) need to communicate with each other to remain viable, and do so by exchanging molecular fluids, and thus any introduced agent or substance which inhibits that transfer is probably more cytotoxic. Across all of the different measurement bases, the Eclipse condensate resulted in no, or less inhibition of inter-cellular dye transfer than condensate from both Kentucky reference cigarettes. This assay also tended to indicate that Eclipse would be less cytotoxic than conventional tobacco-burning cigarettes.

42. Another *in vitro* test performed by Reynolds was the "LDH assay," which measured the propensity of smoke condensate from Eclipse and the reference cigarettes to result in apparent cell membrane breakage, or injury. LDH (lactate dehydrogenase) is a constituent of the plasma membrane encompassing all cells; if greater amounts of LDH are measured after introduction of the smoke condensate, the premise is that the introduced agent has caused cell membrane injury, and is thus more cytotoxic. Again, the Eclipse condensate resulted in lesser measured amounts of LDH than condensate from both Kentucky reference cigarettes. This assay also tended to indicate that Eclipse would be less cytotoxic than conventional tobacco-burning cigarettes.

43. Another lab test for possible cytotoxicity was to test for negative effects on "gene expression," i.e., the ability of the cell to direct itself as to how it will develop into a particular type of cell. This function would again relate to the overall theory of cancer incidence due to, *inter alia*, faulty gene replication. This assay tests for negative impact on, or injury to "messenger RNA" in cells treated with an introduced substance (e.g., smoke condensate), compared to untreated cells. It is a relatively new type of genetic analysis, and was first used by RJRT in the early to mid-2000s, with a published article in 2005, just before this action was filed by the State. Here the Reynolds' scientists performed the test on cultured human bronchial epithelial cells. Generally, they found lesser RNA impacts, changes, and/or injury in cells treated with Eclipse condensate than for the Kentucky "light" cigarette, but the results were less clear for Eclipse vs. the Kentucky "ultra-light" (1R5F). These tests were not a major factor in Reynolds' cited support for their ad claims for Eclipse, and were never known to, or considered by the Eclipse expert panel.

44. Another cytotoxicity test performed in-house by Reynolds was to test for cell secretion of the so-called "IC-8 protein," which is suspected of being an inflammatory agent. Generally, the Eclipse condensate appeared to inhibit IC-8 protein secretion more than the conventional reference cigarettes, and/or introduction of condensate from tobacco-burning cigarettes would cause cells to secrete more IC-8 protein than Eclipse "smoke." Again, these tests were not a major factor in Reynolds' cited support for their ad claims for Eclipse, and were never known to, or considered by the Eclipse expert panel.

45. Almost all of the in-house *in vitro* tests performed by RJRT scientists were later reported in legitimate (although industry-concentric) scientific journals and publications, with some level of peer review and comment. In the

view of the Reynolds' scientists, and as later confirmed by the Eclipse expert panel, the totality of the laboratory, or *in vitro* testing performed in-house by RJRT generally, and consistently (with the 2 exceptions noted above) "pointed in the same direction" and was supportive of the proposition that Eclipse was potentially less cytotoxic, less genotoxic, and/or less mutagenic than conventional tobacco-burning cigarettes. The court's independent review of that body of scientific data and testing results, as set forth in the testimony and the many exhibits, and conducted with such rigor as a 1970s "American studies" major (with a senior thesis on Orson Welles, the WPA and his Mercury Theater Project in the 1930s) can bring to the exercise, leads to the finding that these tests were adequately and properly performed, and that they do generally support the proposition just stated.

46. When confronted by the considerable adverse evidence that the FTC method does not, and cannot replicate actual human smoking behavior (which premise Reynolds does not dispute), and thus should not have been the basis for generation of all the smoke and smoke condensate used in both the *in vitro* and *en vivo* testing, Dr. David Doolittle defended his, and Reynolds' choice to continue to use the FTC method on two grounds: First, that the FTC method was still the most widely used and universally recognized protocol for machine-generated tobacco smoke, and thus the testing results would be the most widely comparable among, and between both historic testing data, and future test results. Second, because it is his view, and that of many others in and outside the industry, that the most harmful constituents of tobacco smoke are the by-products of incomplete combustion;[51] and because it is the "quality" rather than quantity of the smoke (and smoke compounds) that is most deleterious to human health, then therefore the more intense machine-generated smoking profiles, which the State and its experts generally advocated for, would produce "whole smoke" and condensate that was probably less toxic than that produced under the FTC method with an arguably less intense smoking regimen.

47. In other words, RJRT contends that continued use of the FTC method for their laboratory tests arguably resulted in a "worser case" scenario than if other regimens had been used, and the *in vitro* and *en vivo* lab results which suggest Eclipse "smoke" to be less toxic are for that reason actually more persuasive, not less. The court finds some logic to this assertion, at least insofar as it relates solely to the lab test results and scientific data itself, and at least sufficient to preclude any finding that RJRT scientists were acting in any un-scientific, or duplicitous fashion in choosing to still use the FTC method for their various laboratory assays. And, as discussed further below, the court need not ultimately resolve the competing contentions on this point,[52] because the lab test

[51] There is incomplete combustion (i.e., "pirolysis") even though the temperature of the "fire cone" in a conventional cigarette, at the "burn line," can be as high as 700-800 degrees C.

[52] The court also need not settle the dispute as to which machine-smoking regimen was "more like" human smoking behavior. For example, a competitor's own smoke chemistry vs. human behavior testing of Eclipse indicated that, unlike conventional tobacco-burning cigarettes where

data, as solid and promising as it might have been, was inadequate to support its extension to the ad claims made for Eclipse regarding actual effects on human health and disease.

B. *En Vivo* Tests

48. The principal lab tests performed by Reynolds (and one outside contractor) using Eclipse "smoke" and condensate with lab animals, were "mouse inhalation" studies using standard white lab rats (the Sprague-Pauley type) and Syrian Golden hamsters; and dermal tumor promotion, or "mouse skin painting" studies, using SenCar mice. RJRT (and other) scientists conducted 7 "sub-chronic"[53] mouse inhalation studies, and 6 skin painting/tumor promotion studies; each one took about 1 and ½ years to complete, cost around $1 million each, and were substantially completed by the mid to late 1990s, with published results from 1997-1999.

49. There is no recognized, or reliable method, or laboratory model for inducing lung cancer in lab rodents by inhalation using machine-generated smoke. During the inhalation tests, the rodents would be observed for any changes in body weight, or in respiratory patterns. At the end of the 13-week period for the inhalation studies, the rodents would be dissected and assessed for nasal, larynx, lung and other abnormalities, and blood and DNA samples would be tested. The protocol was that groups of lab rodents (60 in each group, with 30 males and 30 females) would be placed in sealed compartments hooked up to automatic-smoking machines (all set at the FTC method) so that the "whole smoke" would be immediately, and directly sent to the sealed rodent containers.[54]

50. Each group of rodents would be exposed for a specific amount of time to designated low, mid and high concentrations of either Eclipse "smoke" or smoke from one of the conventional tobacco-burning reference cigarettes, which

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maximum "tar" and TPM readings occur in the last few puffs, in Eclipse those peaks occur around the 5th puff using the FTC method (consistent with RJRT's own "bell curve" showing maximum TPM production at puffs 6-9), thereby suggesting that one of the more intense protocols would have been more equivalent.

[53] That term refers primarily to the length of the study, generally 13 weeks, as opposed to long-term testing of 1 year or more. Because the primary purpose of such studies is to look for disease markers, or indicators, rather than incidence of any disease itself, RJRT scientists, and its experts who testified at trial, believe that the short-duration lab testing still produced reliable results. In context – i.e., because the Reynolds testing data all generally "points in the same direction" and indicates Eclipse could be a useful PREP, but does not ultimately illuminate the key issue of human disease incidence, as discussed below – the court finds that specific contention to have been established.

[54] It is preferred, and some effort would be made to keep the rodent's nose aligned with, and closest to the smoke induction port in the container, but one can only imagine the success of that effort. There is no contention that this issue substantially undermined the test results.

here was just the Kentucky "light" cigarette (then K1R4F).[55] All settings, and timing were computer controlled. The metric for the induced "whole smoke" was the designated WTPM per liter of outside air, with a goal of inducing smoke equivalent to around 10% of the rodent's body weight. Each test thus required 6 groups of rodents, or 360 total, and consumed about 500,000 cigarettes (both Eclipse and conventional). These tests were primarily performed using the 7-026 Eclipse prototype, which is the version marketed from initial introduction in 1996 until replaced, and not the 5-014C version highlighted in Table 4 above, and sold in Vermont from mid-2006 until withdrawn in late 2008.

50. The inhalation studies did not look at, or test for any cancer-related endpoints, but only potential respiratory disease indicators. Primarily with regard to respiratory and lung-related functions, comparison of Eclipse with the Kentucky "light" cigarette indicated generally, and consistently, in a statistically significant range for most measurements, that Eclipse induced fewer, or less potent indicators of lung inflammation, or other cell injury. Microscopic examination of nasal, larynx and lung tissue showed less hyperplasia (i.e., increases in the number, or size of epithelial cell layers) in the Eclipse-exposed rodents than those exposed to the Kentucky cigarette, and conversely a greater number of macrophages (an inflammation-triggered cell response) in the latter.[56]

51. Dermal tumor promotion, or "skin painting" studies using lab mice is an established, and well-recognized method to test for the possible carcinogenic effect of designated chemicals and compounds; the test depends on, and generally demonstrates the basic toxicological "dose-response" relationship. The SenCar mice which are used have been bred for this purpose for years, and are commercially, and consistently available. The protocol here was for a 30-week test, in which groups of mice (all female, 40 mice in each group) are designated, with one group being the control. All of the mice are treated initially during the 1st

[55] The Reynolds scientist primarily responsible for these tests defended their decision not to perform rodent inhalation comparative testing also using the Kentucky "ultra-light" cigarette (K1R5F), at least in part, on the grounds that it would not have been "useful" because it might "possibly" just produce equivalent results, and thus would be a "waste" of both lab animals and large numbers of additional cigarettes (the Kentucky reference cigarettes were becoming harder to obtain in large quantities), and because "light" cigarettes in the 6-12 mg "tar" range now make up the vast majority of cigarettes sold, and consumed in the United States. However, to the extent that the Eclipse ad claims were intended to apply to all smokers, even those relative few who might be smoking "ultra-lights," this rationalization is less than compelling, especially where Table 4 above shows the Eclipse vs. K1R5F to result in significant increases in several smoke constituents (e.g., "tar" increases by 156%), and it is conceded that tobacco smoke is by itself a complex carcinogen for which constituent chemicals and compounds cannot be isolated as to their probable carcinogenic effect. But, for the reasons discussed throughout this decision, it is ultimately of little determinative weight because the totality of the testing, even accepted "as is" and in the light most favorable to Reynolds, does not adequately support the marketing claims.

[56] Another inhalation study contracted out to Battelle Labs (formerly the Battelle Memorial Institute, in Columbus, OH), using the Syrian Golden hamsters but a different Eclipse prototype, showed even more significant reductions, from 71% to 94% on most measurements.

week with a tumor production stimulant, or known animal carcinogen (i.e., DMBA), and then during the next 29 weeks the SenCar mice in each of the test groups were externally treated (3X per week) with various enhanced concentrations (e.g., at 10, 20, and 40 mg "tar") of Eclipse condensate vs. the Kentucky "light" smoke condensate. The control group mice were treated on the same schedule with acetone. All condensate was produced using the FTC method, for the reasons previously articulated by RJRT scientists, and only the K1R4F cigarette was used as a comparison, again for the reasons just noted above.[57]

52. At the end of the 29 weeks, each test consistently demonstrated reductions in the gross number of tumors[58] and in the number of SenCar mice with at least one tumor, in the groups of mice treated with Eclipse condensate, compared to mice treated with the K1R4F tobacco condensate, ranging from 67% to 94%. In the mid-level condensate testing, the reductions for Eclipse across all groups averaged 93-94%. All of the results were statistically significant, and the tests were adequately and properly performed by RJRT scientists. These mice were also dissected, and their lung and heart tissues (in addition to the hyperplasia analysis noted above for the inhalation subjects) showed significantly lower numbers of "DNA adducts" at the end of 29 weeks in the mice treated with Eclipse condensate. These mouse "skin painting" studies, and other related tests were again consistent with, and pointed towards, and in favor of the contention that Eclipse "smoke" was likely to be less carcinogenic than smoke from conventional tobacco-burning cigarettes. However, none of the *en vivo* lab tests with rodents actually tested for, or had as their end-point the incidence of any disease, even in animal form, especially lung cancer which is the greatest cause of death attributable to smoking.

C. "Human Behavior" Smoking Studies

53. "Intake" is the entire amount of tobacco smoke inhaled by the smoker; "uptake" is the amount taken into, and absorbed by the smoker's organs, primarily the lungs (and then indirectly into the bloodstream), and is calculated by subtracting the volume of exhaled smoke from the intake. The actual smoke "yield," intake, and uptake for real smokers under everyday conditions are not necessarily, and typically are not equivalent to the "puff volume," puff duration, puff frequency, and intervals between puffs which can be set for the automatic smoking machines to produce cigarette smoke for lab and other testing.

54. In a number of "human behavior" studies, conducted in-house by RJRT and using primarily Reynolds' own employees, and in the outside clinical studies of Eclipse (discussed below), it was generally observed that smokers who switch to Eclipse have difficulty learning how to "smoke" Eclipse. It is more

[57] However, one of the RJRT scientists responsible for producing the machine-generated smoke and smoke condensate, conceded on cross-examination that some known human carcinogens (IARC category 1) present in Eclipse "smoke," were not captured by the Cambridge filter pads.

[58] All tumors were identified and included in the study results, whether benign or malignant.

difficult, and takes longer to light it up, generally resulting in 2-3, and as many as 5-6 "extra" puffs initially when Eclipse is used by "real" smokers. Also, when the Eclipse is finished – it is difficult for the smoker to actually tell, because there is no visible cue since the outside paper and tobacco column do not burn down towards the filter end – it was observed that generally most smokers using Eclipse will take 2-3 empty, or "extra" puffs. During the entire course of "smoking" the Eclipse, it was also typically observed that many, if not most smokers took more rapid, and/or deeper puffs. All of these "real world" attributes for using Eclipse could result in an increase of up to 500% more total "smoke" volume, or intake, compared to machine-generated smoke from a conventional tobacco-burning cigarette.[59] Of course, in Eclipse that larger overall volume would include a proportionately greater amount of "simple" water and/or glycerol vapor.

55. At least two of the in-house smoking behavior studies conducted by Reynolds also included taking urine samples from smokers who switched to Eclipse, and then using the collected human urine as the reactive agent in further Ames assays on the salmonella bacteria, using the same protocols as discussed above. The results were published in 2002 and 2006, respectively. The first study involved some 67 participants, while the latter had only 20 human subjects. Each study was very short-term, lasting only 1 week; besides the objective observations of actual smoking patterns, and questionnaires filled out by the participants, the urine samples were taken at the beginning, when the subjects had still been smoking their "usual brand" of conventional cigarette, and then during and at the end of the week-long test period after switching to Eclipse. An important requirement for the validity of all such testing is that all participants' diets also be rigorously controlled.

56. Again, the test results showed lesser mutagenicity (i.e., fewer revertants) associated with the subjects' urine after switching to Eclipse, than the urine samples at the beginning of the week related to conventional cigarettes. The obvious criticisms, which the court finds to be valid, are the small number of participants, the short length of the studies (before participants had been able to settle into any regular, and sustained use of Eclipse), and the reliance on Reynolds' own employees rather than smokers from the general public.[60] Also, it

[59] Another finding from Reynolds' own human behavior studies illustrates the fallibility of trying to predict actual human health consequences from laboratory analysis alone. Testing of the "experienced" employee Eclipse smokers indicated higher levels of NNAL, a metabolite of NNK (a tobacco-specific nitrosamine, suspected of association with cancer), when the chemistry data alone (using the FTC method), *see* Table 4 above, indicated a lower amount of NNK in Eclipse "smoke" itself.

[60] The court does not find, or even mean to suggest that any of the employees faked, or altered any test results, or skewed their own reports, or their compliance with the test protocols. Rather, it is more likely than not the opposite: RJRT employees, recognizing the potential importance of the research, would be more scrupulous in adhering to the test rules – especially the diet restrictions, which could be more easily accommodated in the Reynolds' cafeteria – and in taking the time and

was generally acknowledged by all the expert witnesses, that there is incomplete correlation between mutagenicity and whether the same chemical or compound is carcinogenic, even just in relatively simple salmonella bacteria; while probably most carcinogens are mutagenic, the reverse is not always true, and thus testing for mutagenicity is not necessarily equivalent to testing for carcinogens.[61] Nonetheless, as a general proposition less mutagenicity is better, and these results were still consistent with, and added to the "total weight of the evidence" which suggested that Eclipse could be a true potentially reduced exposure product.

57. The urine mutagenicity results from the in-house Eclipse human behavior studies, based on observed effects in salmonella bacteria using standard Ames assay techniques, were the principal basis for the marketing claim(s) included on the special Eclipse website, *see* below, which prominently suggested that "tests had shown" Eclipse "smoke" could result in up to 70% reductions in adverse effects on human DNA.

D. Outside Clinical Testing

58. During the mid to late 1990s[62] Reynolds sponsored, and paid for five (5) different clinical studies at various universities, primarily related to assessment of Eclipse "smoke" on lung function and other lung disease issues. Although the general topic was of course proposed by RJRT – i.e., can switching actual human smokers to Eclipse result in any observed improvements in the symptoms of, or markers and indicators for tobacco-related pulmonary disease(s)? – the actual research studies were designed, and entirely overseen and conducted by the outside researcher (and her or his staff and graduate research students) under each university's research guidelines. These outside clinical studies were conducted at Tulane, University of British Columbia, Wake Forest, University of Rochester, and the University of Nebraska. Even though RJRT paid a total of some $3.3 million to fund these studies, Reynolds had no control over how they were conducted, and no control over the reported results

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effort to "smoke" the Eclipse "properly," and not "cheat" with a conventional cigarette, than would smokers in the general population left on their own to experience Eclipse.

[61] Moving up the chain, there is maybe a 60-80% congruence (and perhaps as little as 50% on the low end) between mutagenic and/or cytotoxic effects in bacteria, and animal carcinogenicity, and then additional incomplete correlation between animal and human carcinogens.

[62] In some instances, where there were published results of these studies in recognized peer-reviewed journals, the articles were not publicly available (e.g., in 2002, and as late as 2005) until after Reynolds had already decided, and begun to make its health-related claims in 2000. Reynolds did receive the unofficial results of these studies before publication, as the reports, or abstracts of these studies played a substantial role in the on-going evaluation conducted by its Eclipse expert panel, *see* below.

(although RJRT scientists would occasionally receive "progress reports" about the studies as they were under way).[63]

59. Two of the three essential marketing claims made by Reynolds regarding Eclipse relate to pulmonary disease, i.e., bronchitis and emphysema. A general understanding of how cigarette smoke relates to pulmonary function, and how smoke affects throat and lung tissue, is thus helpful. Cigarette smoke is inhaled through the mouth and throat and drawn into the trachea, which then splits into 2 branches for the three lobes of each of the right and left lungs. The airways then continue to split and divide (up to 18 times) on each side into numerous bronchi and then smaller bronchioles, until they end in large numbers of alveolar sacs within each lung. The size of the entire surface area created by this lung structure, and the thinness and elasticity of the alveolar tissue needed to accomplish the necessary interchange of oxygen into, and carbon dioxide from the blood, are each of a magnitude difficult to describe in prose. Lung function is further complicated by the necessary presence of hair-like cells called cilia, and associated mucus glands, which work together to constantly clean the lungs and move dust and other impurities up and out of the lungs. Given such a complex organic, and biological structure, and the fact that the lungs must continue to function every second of every day for the entirety of a person's life, repeated introduction of foreign substances is undoubtedly likely to result in impaired function, and if continued, permanent impairment and disease, and sometimes eventually death.

60. Cigarette smoke causes irritation of the bronchial and alveolar surfaces, leading to mucus (and macrophage, or white blood cell) and/or sputum production to combat the perceived source(s) of irritation. If the irritation is persistent, inflammation of the lung tissue then results, leading to narrowing of the airway passages, and diminution of the cleaning function of the celia and the ability of the alveoli to perform the necessary blood/gas interchange. Both of those consequences negatively impact air, and oxygen intake, and the corresponding ability to expel carbon dioxide. If the inflammation is sustained and substantial, permanent damage can occur. Bronchitis (sometimes called "chronic") is a pulmonary disease generally defined to include significant, and permanent inflammation and narrowing of the bronchial airways, due to permanent thickening of the bronchi walls due to collagen accretion and scar tissue. Emphysema is a pulmonary disease generally defined to include permanent scarring, or fibrosis, and enlargement of the alveolar cells due to the constant action of macrophages (and other biological reactions) in response to sustained inflammation. The alveoli lose their necessary elasticity, and overall lung volume is reduced because of the enlarged sacs. Chronic obstructive pulmonary disease ("COPD") is a "constellation" of lung-related diseases, including either or both of bronchitis or emphysema, which is largely associated with cigarette smoking.

[63] None of the outside clinical studies were conducted using the current Eclipse prototype, 5-014C/2005, which has been the "current market product" since mid-2006.

61. The presence, and severity of COPD is typically measured by the volume of air that can be forcefully expelled by the lungs in 1 second, known as FEV1. Any reduction in expected FEV1 (tables of average FEV1 values are available keyed to age, gender, weight and other variables) of 20% or more is considered significant; however, given the lungs' incredible reserve capacity, a loss of FEV1 of 70% or more is generally needed before the impairment is considered to be disabling. After age 25, even non-smokers experience some gradual loss of FEV1 over time. For smokers, there is an even more rapid, and predictably significant decline in lung function over and above natural aging. And, among smokers, there is another subset of about 20-25% who suffer an even more substantial decline in FEV1 and develop COPD, bronchitis, and/or emphysema.[64] However, there is no complete medical understanding to explain the cause, or development of COPD in that subset of smokers; in other words, there are no recognized indicators which can generally predict which smokers (approximately 1 out of 4) will go on to develop COPD, just as there is no established, or accepted methodology for indentifying which heavy smokers (approximately 1 out 10) will go on to develop lung cancer. In each case, currently unpredictable genetic factors (and possibly other unknown circumstances, such as environment) appear to influence the incidence of actual disease. Inflammation caused by repeated exposure to cigarette smoke is, however, clearly associated with COPD, and generally the progression and/or severity of the disease are related to the amount and/or toxicity of the cigarette smoke.

62. There is at least one NIH (National Institute of Health) study which indicates that smokers who have some level of COPD, but not yet disabling, who quit smoking altogether, can after about 1 year see some improvement in their FEV1, and after many years of continued non-smoking their rate of FEV1 decline will approach that of the average non-smoker. However, for smokers who already have disabling COPD, complete smoking cessation will only "freeze" in place the existing, substantially diminished level of FEV1; there will be no improvement in lung function, even over time, although the likely, or projected onset of death from respiratory failure can be delayed or postponed.

63. Although FEV1 is certainly associated with, and the best available measurement for the presence of COPD, currently there is no direct, and recognized correlation between any particular level of FEV1 and the onset, or incidence of disease, either COPD generally, or bronchitis or emphysema specifically. Accordingly, the outside clinical studies supported by Reynolds properly focused on identifying so-called biomarkers of exposure and/or effect (i.e., disease indicators, or symptoms) for pulmonary disease, and then assessing the impact on those biomarkers of actual smokers switching from their "usual brand" to Eclipse.

[64] Smokers over age 70 have a greater than 40% chance, or risk of developing COPD.

64. The study conducted by Dr. Frampton (Mark, not Peter) at the University of Rochester in 1998 tested 1-pack-a-day smokers who switched to Eclipse,[65] for lung function, and biomarkers of inflammation and other "cellular stress" indicators (e.g., white blood cell counts). It involved only 10 smokers total – 9 male, 1 female, all recruited by an RJRT consultant – for a period of 4 weeks, who were tested for FEV1 at the outset, at 2 weeks, and again at 4 weeks.[66] They were also subjected to so-called "bronchial lavage" at 2 and 4 weeks, in which lung tissue and cells are harvested from the human subject's lungs by introduction and then immediate removal of a neutral fluid with a device inserted down the throat, under topical anesthesia sprayed into the throat just before the lavage.[67] There was no discernible, or statistically significant improvement in FEV1 at 2 or 4 weeks.

65. With regard to measurement of "epithelial permeability" of the recovered lung cells, the Frampton study measured cell "leakage" (an indication of cell damage) by measuring the "clearance time" for DPTA. The DPTA molecule can traverse the cell lining, and can be radioactively screened, and measured; a longer "half-life" (the calculated, not actually observed time for ½ the DPTA to exit the lungs) indicates less cell injury. The DPTA is introduced into the lung by an aerosol spray, and then Gamma-ray type screening takes place continuously over the next 30 minutes. The results at 2 weeks showed some statistically significant improvement on a mean, or average calculation basis (i.e., 4 of the 10 subjects showed dramatic improvement, while 6 had no, or only marginal improvement[68]). At 4 weeks, however, the results were not statistically significant; only 3 had some further improvement in cell clearance times, 2 were essentially the same, and 3 actually showed deterioration.[69]

66. Dr. Frampton also measured for "oxidative stress" by testing for associated enzymes (e.g., neutrophils); that measure actually showed some

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[65] The Eclipse cigarettes were supplied by Reynolds for all of the outside clinical studies; it was a prototype that preceded 5-014C.

[66] By the 4th week, 9 of 10 of the subjects had "mostly" switched completely to Eclipse. However, only 3 of the 10 participants "fully complied" with the instruction to use only the Eclipse.

[67] The incredibly invasive nature of these procedures will explain, in part, the limited number of human volunteers willing to participate in these studies.

[68] Those subjects with the "worst leakiness" showed the least degree of improvement.

[69] Even though not statistically significant, RJRT's pulmonary disease expert (Dr. Tashkin) testified at trial that these results were still "clinically relevant" and "important" because they "support the hypothesis" that reduced exposure to smoke toxicants from Eclipse was likely to reduce inflammation. No one can, or really did argue with that characterization; however, it is a further, and much bigger step towards also supporting the Eclipse ad claim, that it "present[s] less risk of … chronic bronchitis, and possibly emphysema." Dr. Tashkin ultimately agreed that DPTA clearance itself is not a validated predictor for developing COPD.

worsening after switching to Eclipse, at best a cautionary signal.[70] As measures of inflammation, the study also tested for exhaled nitric oxide,[71] and the amount of induced sputum. The WBC measurements looked not only at the number, but also the degree of "activation" of the white blood cells and other leukocytes. Overall, the results of the Rochester study (which were later published in a peer-reviewed journal, but not until 2006) suggested that switching to Eclipse could result in, and would be "consistent with" some health benefit and improvement in lung function, i.e., a lessening of indicators associated with lung inflammation. However, Dr. Frampton himself, in his video deposition testimony played at trial, stated that his study results do not demonstrate any link to, or association with the risk, or likely incidence of any pulmonary disease.

67. The Tulane study conducted by Dr. Lopez had a somewhat longer time horizon, at 6 months total (3 months smoking the subject's regular tobacco-burning cigarette, then 3 months switching to Eclipse), but a similarly small number of participants. It was essentially an assessment for the effect of Eclipse on asthma (a respiratory disease involving sudden, and/or chronic airway constriction). Lopez tested regularly for FEV1 over the course of the study, and found no statistically significant improvement after switching to Eclipse. He also tested for metabolites of some known, or suspected carcinogens, but again found no demonstrated reduction after switching to Eclipse. Lopez also did bronchial lavage, and did find a statistical reduction in the total number of epithelial cells in the induced sputum, but that measure by itself is not associated with the incidence of pulmonary disease, or even any particular respiratory symptom. He found no other demonstrable changes in the bronchial lavage cells themselves, after switching to Eclipse. Subjects also self-reported some subjective assessments of their own lung function after switching to Eclipse, which were generally positive. The Tulane study was not published, but was presented in summary from to one of the Eclipse panel meetings, *see* below. At best the Tulane study demonstrates that Eclipse causes no different, or worse harm or injury in the lungs, or to lung function, than conventional cigarettes.

68. The clinical study conducted at the University of British Columbia looked again at lung function, or FEV1, over the course of approximately 3 months; no significant improvement was reported after switching to Eclipse. This study also tested for white blood cell counts; smokers generally have elevated WBC counts, and this study found no significant difference attributable to switching to Eclipse. This study was also unpublished, and not subjected to peer review. It supports the same conclusion as the Tulane study, above.

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[70] Dr. Tashkin, RJRT's pulmonary expert at trial, passed these results off as simply "interesting" and "going in different directions" making him "unsure how to interpret" the findings, while also remarking they were not measures of "actual lung inflammation" in any event. The witness's effort to downplay adverse test data was not convincing.

[71] The Frampton study was also another source for RJRT's continued concern about elevated levels of carboxy-hemoglobin, which led to the design changes in the 5-014C prototype.

69. The Wake Forest study, completed by Dr. Duncan Hite in 1999 (it had first been proposed in 1994/95) at cost of over $1 million to Reynolds, was more extensive. Although the results were ultimately not published, it was presented to and relied on more heavily by the Eclipse expert panel than some of the other outside clinical studies. It involved 23 smokers who switched to Eclipse, plus a group of 11 non-smokers for a control group; they were studied for up to 12 months, at baseline, 1 month, 6 months, and 12 months, although there was a significant loss of participants such that only 18 smokers remained at 6 months and 5 smokers were left at 12 months. Hite used treadmill stress tests, also used bronchial lavage to harvest lung cells, a bronchoscope to observe the inside of the lungs, and took periodic blood samples. Hite looked at many different potential markers for both pulmonary and cardio-vascular disease,[72] including neutrofil and leukocyte (similar to WBC) counts, lipoproteins (for cholesterol), blood platelet aggregation and clotting factors, other blood gases,[73] nicotine/cotinine[74] levels, EKG (on the treadmill), FEV1, both number and "quality" of alveolar macrophages in the lung tissue,[75] more urine mutagenicity testing,[76] and a biologically-occurring lung cell surfactant compound (OHDHG) which is a mixture of fat lipids and proteins. The theory behind the last measurement is that lesser amounts of lung cell surfactant are associated with increased inflammation and compromised lung function, because properly functioning alveolar cells must maintain the correct balance of surface tension in order to perform the oxygen/blood gas interchange.

70. The Wake Forest study, similar to the other outside clinical studies, did not find any statistically significant improvement in FEV1 after switching to Eclipse, even over the longer periods involved. The Hite study did find a favorable statistical correlation after switching to Eclipse in the total number of macrophages (i.e., fewer),[77] and macrophage fluorescence (i.e., less active), at

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[72] Inasmuch as Reynolds ultimately made no affirmative health claims for Eclipse related to cardio-vascular disease, these points of the Wake Forest study were of interest, but not material here. Also, Hite did do some urine mutagenicity assays under the Ames protocol, which is more relevant to potential cancer effects, but those results were not statistically significant.

[73] The Hite study was one of the principal sources for the concern about elevated carboxy-hemoglobin in Eclipse smokers, an issue ultimately irrelevant here, but the primary reason for the change in mid-2006 to the 5-014C prototype.

[74] Cotinine is a metabolite of nicotine that is more readily measurable in the blood.

[75] A higher number of these "scavenger cells" would indicate more inflammation. Then, when subjected to auto-fluorescence, the "activity level" of the macrophages could be detected, the premise being that more active antibodies would also indicate more inflammation. At baseline, his smokers had 4-5 times the number of macrophages as the control group non-smokers; at 6 months, compared to non-smokers that number had dropped to "only" 3-4 times greater.

[76] Those samples were coded and sent back to Reynolds for actual analysis, consistent with the same protocols discussed above.

[77] Generally, smokers show 3 times the number of macrophages as non-smokers. RJRT's pulmonary expert agreed that no definitive studies exist yet that correlate the number of alveolar

least at 6 months. The cell surfactant measurements were also more favorable after switching to Eclipse (same). However, neither of those measures – alveolar cell surfactant, or macrophage fluorescence and/or absolute number of macrophages – is a validated, or accepted biomarker for the incidence of any pulmonary disease, nor even necessarily a recognized indicator for the presence of COPD, bronchitis, and/or emphysema. The Hite study did strongly suggest, if not confirm that real smokers who switch to Eclipse would adjust their smoking patterns in order to achieve the desired levels of nicotine, by consuming greater numbers of Eclipse; at 6 months, the reported number of Eclipse "smoked" was, on average, almost double the baseline number of "usual brand" cigarettes smoked at the outset of the study.[78] Dr. Hite (who was also a member of the Eclipse expert panel, *see* below) characterized his own work as a "pilot study" and said that some "longer study" would be needed to demonstrate any "role in disease itself" for lung surfactants. He agreed that macrophages are "markers of inflammation," and there is a "loose association" between inflammation and tobacco-related lung diseases, but he expressly disagreed with the premise that an increased (or decreased) number of macrophages could, or should be considered as a "biomarker" for the actual incidence of any disease itself. Dr. Hite stated that his own study data does not support any statement that Eclipse "reduces the risk" of any pulmonary disease.

71. Two University of Nebraska clinical studies overseen by Dr. Stephen Rennard (one published, the other presented to the Eclipse panel) were the most extensive, and perhaps the most important, or at least influential outside studies which Reynolds and the Eclipse expert panel relied on to support the marketing claims eventually made for Eclipse. These studies primarily focused on potential markers for pulmonary disease, which relates to 2 out of the 3 health benefit claims made in the Eclipse ads. It is also important to review these results in some detail, and assess them against Dr. Rennard's own testimony here (by video deposition), because he is a medical doctor who still has some clinical patients, but is now a principal researcher, with 15+ years studying COPD (of which cigarette smoking is "the major cause"), and a prior stint at the National Institutes of Health (1977-1984).

72. Dr. Rennard was also a member of the Eclipse expert panel, and also a co-author of a subsequent, and more recent article in 2006 (discussed in more detail below) by several influential, and generally respected researchers in this field regarding the existence (or not) of validated disease biomarkers against which to compare any PREP developed by any of the tobacco companies. Thus,

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macrophages with either an increased, or reduced risk of developing COPD; that measure alone is not a valid disease predictor.

[78] Also, at 6 months a number of participants reported they were still occasionally smoking a conventional tobacco-burning cigarette, thereby suggesting that "real world" smokers might not be able to, or would choose not to use Eclipse as their only cigarette, and thus also suggesting that the purported health effects, even if otherwise scientifically established, would not necessarily be fully realized in every smoker who switched to Eclipse.

while Reynolds often did attack the credibility of other researchers, and the State's expert witnesses at trial, as being part of some "quit or die" cabal unwilling to even acknowledge the possible existence of a genuine tobacco PREP, or as having consistently, and repeatedly testified against tobacco companies in other litigation, Dr. Rennard cannot be dismissed by that tactic.[79]

73. Rennard's initial study (i.e., the later published version), agreed to in 1996 and actually conducted from 1997-98, was based on 12 "heavy smokers" (2+ packs per day)[80] who were largely asymptomatic and not yet suffering from any diagnosed disease (COPD, bronchitis, or emphysema), who volunteered to switch to Eclipse over a period of 8 weeks.[81] Most of the participants were already smoking "light" or "ultra-light" rather "full-flavored" cigarettes. By the end, Eclipse use was on average 90-95% of the total number of cigarettes consumed, and subjects were generally smoking the same total number of cigarettes per day, around 43-45. Because the study involved invasive techniques such as repeated blood tests, the bronchial lavage, and a bronchoscopy exam, each participant had to sign a written waiver, and the entire study design, and protocols, were first reviewed and approved by the University's ethics research committee. Rennard (together with his staff and associates) designed the study and chose the potential disease markers, and end-points to be tested for.[82]

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[79] The State, on the other hand, attempted to discredit Dr. Rennard's studies because, *inter alia*, the University of Nebraska received some $1.7 million to fund his research, or he got all of those wonderful free trips, and a small honorarium, for each Eclipse panel meeting (*see* below). Those attacks were equally simplistic, if not insulting. Of course it takes millions of dollars to do painstaking, effective scientific and/or medical research, and an accomplished professional like Dr. Rennard deserves to be compensated for his personal time. There is simply not one grain of evidence here to suggest that his connections with Reynolds influenced his reported test results or his testimony, or that Dr. Rennard was anything other than, perhaps, the single most credible, and compelling witness over 26 days.

[80] So-called "heavy smokers" make up only 2-3% of the smoking population. This type of subject was intentionally selected on the theory that any positive effect from Eclipse was more likely to show up in a shorter amount of time with heavy smokers. Given the ultimate use of the study which Rennard himself acknowledges, *see* below, it was a reasonable premise, but it certainly does not indicate equivalent results for the entire range of actual smokers to whom the Eclipse ad claims were directed.

[81] He started with 18 candidates, then reduced it to 13 subjects, but one of the latter did not complete the full study. There was, of course, no means of determining whether any of those 12 final participants actually fell within the cohort of some 25% of smokers who are apparently predisposed to develop COPD.

[82] Dr. Rennard had previously done two cigarette-related studies in the late 1980s and early 1990s, in which he looked for measurable results of reduced lung inflammation from switching to so-called "low tar," or light cigarettes (all conventional tobacco-burning cigarettes). He concluded then (i.e., 1990) that most indicators of inflammation were positively influenced by the switch, except for "ultra low tar" cigarettes, where the results actually suggested an increase in some inflammation markers, probably caused by the "smoker compensation" effect that switchers ended up smoking more cigarettes to maintain their desired nicotine levels.

74. One of those potential indicators of disease, or at least of precursor lung inflammation, which Rennard studied was the presence of "goblet cell metaplasia" in the lung cells recovered by the lavage. Goblet cells are essentially the mucus-producing cells; sustained lung inflammation from cigarette smoke will not only cause more goblet cells to be present, but will also result in deformities to their shape, and cell structure.[83] The lavage from a smoker with more lung inflammation will generally show a greater proportion of goblet cells to "normal" epithelial cells (in non-smokers, the proportion is typically about 10%). More goblet cells will crowd out, or reduce the effectiveness of the hairy cilia cells, thus causing more coughing, which in turn promotes even more irritation, all symptoms common to COPD and other respiratory disease.

75. Rennard's results at 4 and 8 weeks, after switching to Eclipse, demonstrated a statistically significant decrease (as much as 20%) in the presence of goblet cells. However, although statistically valid and all but one subject showed some decrease, the reduction in the number of goblet cells was not consistent over all of the study subjects, and the most pronounced effect was from only a relative few of the 12 participants. Observable differences in the shape or structure of the goblet cells was less quantifiable. Testing for goblet cells is not itself a validated marker, or risk factor for any pulmonary disease.

76. Dr. Rennard also tested for the presence of NNAL, a metabolite of tobacco-specific nitrosamines (i.e., NNK, *see* Table 4 above), which are suspected of being potential carcinogens.[84] He also tested for the presence of alveolar macrophages (an approximate 35% reduction),[85] and did other sub-clinical testing for cytoxicity and/or DNA effects, similar to the in-house studies conducted by Reynolds (*see* above). In blood testing he found a "trend" suggesting a slight uptick in cotinine levels, in turn suggesting some "compensatory smoking" to maintain nicotine dependence. The data on exhaled CO (carbon monoxide), with peaks earlier on, also suggested that smokers would "smoke" Eclipse more intensely at first, and then perhaps moderate after they became acclimated to the product. Using smoke condensate from both an earlier Eclipse prototype and the Kentucky "light" cigarette, he also attempted a "highly

[83] Cell deformation, and/or abnormal cell growth, is characterized in 3 progressively severe stages: dysplasia, metaplasia, and finally hyperplasia.

[84] One of RJRT's earlier "human behavior" studies, which tracked employees who switched to Eclipse for some 30 months (i.e., the so-called "Buddy Brown" study) indicated some increase in measured NNAL; while not statistically significant, that result tends to undercut Reynolds' essential premise that all of the data trended in the same "less is better" direction. However, it is unclear whether that study was before, or after Reynolds began its company-wide goal of reducing nitrosamines in all of its tobacco products. A later "NNAL Update" (August 2, 2002) reached a more definitive "Conclusion: Smokers of Eclipse are exposed to similar levels of NNK as smokers of tobacco-burning cigarettes." In other words, Eclipse did not result in any significantly reduced exposure to that suspected carcinogen.

[85] Two of the 12 subjects showed much more dramatic reductions, but that alone does not skew the data, or the fact that the results were statistically significant.

sophisticated" and "difficult" test on "live" bovine lung cilia cells (the cow cells can only be kept alive for 5+ hours in a special solution); the results suggested less damage to the cilia cells from Eclipse.

77. During the bronchoscopic exam of the subjects, Rennard employed an accepted "bronchitis index" based on objective visual scoring of 4 standard measures: tissue redness, swelling, mucus secretion, and friability/flexibility of the lung tissue.[86] A photographic record of each exam was created, and the scoring could be counter-checked by another lab assistant. After switching to Eclipse, at the end of 8 weeks there were substantial, and statistically significant reductions in the bronchitis index scores, by an average of 46%, with a correlation in excess of 0.9.

78. Rennard also used a subjective symptoms questionnaire with each participant. This is a standard research technique; although the responses are not objectively verifiable, when there is consistency between measured test results and subjective symptom reporting, the latter tends to confirm the materiality of the former. These subjective results would not separately constitute scientific evidence supporting the ad claims made for Eclipse. In Rennard's study, 9 out of 13 of the original participants generally reported a decrease in negative symptoms, and a perceived improvement in lung function, after switching to Eclipse; 4 reported essentially "no change." However, actual testing for FEV1 showed no actual statistical improvement.[87]

79. The second, non-published study conducted by Rennard at Nebraska was to test for any improvements in potential disease markers for smokers who already had disease symptoms, e.g., chronic bronchitis. This study design was modified to include somewhat more moderate smokers, at 25-30 cigarettes per day, and for a longer period, for up to 3 months. It was designed for 30 subjects, but eventually Rennard was only able to enroll 20 participants. He did not finish the study because Reynolds changed the available Eclipse prototype while it was under way, and he did not feel the results would be valid. However, preliminary measurements were generally positive, along the same lines as the earlier study; e.g., observed reductions in DNA-related cell damage, measured from baseline at the onset of the study, were from 75% to 56%.

80. Dr. Rennard's final assessment of his own study evidence and data, was that it "all moved in the same direction" and therefore provided "general support" for the "concept," or "plausible hypothesis," that because Eclipse might result in less inflammation in the lungs, and reduced indicators of such inflammation, Eclipse "could be" associated with less pulmonary disease. But the absence of any established relationship between any of those markers and the

[86] Subjective notations of pain were also recorded during the bronchoscopy exams.

[87] It is generally accepted that any medically significant improvement in FEV1 would take a year, or more to accomplish; the 8 weeks of the Nebraska study was of course too short.

etiology of respiratory disease prevented Dr. Rennard personally from making any statement, or offering any actual opinion about Eclipse and the risk of contracting any particular disease.[88] As stated in the abstract to the published study (*see* 4 Nicotine & Tobacco Research, 467-476 (2002)), Rennard was ultimately comfortable with just the following summary public comment: "Eclipse may be a strategy to reduce the health risks for heavy smokers unwilling or unable to quit."

81. However, the detail in the article itself was more equivocal. "The effect of Eclipse on the health risks of smokers remains to be determined. It is likely that even in the absence of outcome data, Eclipse will be perceived as a reduced-risk alternative to cigarettes because of its marked reduction in toxins …. Since this product is now available commercially, information relating to the health effects of Eclipse is urgently needed …." *Id*., pg. 474. He concluded in his published article that "its use and promotion should be subject to appropriate regulation." *Id*.

82. Dr. Rennard's testimony at trial – taken in mid-September 2008, just weeks before the trial commenced, and with 9 more years of Eclipse studies behind him since the critical January 1999 meeting of the Eclipse expert panel, *see* below – was similarly equivocal (even on direct examination by Reynolds' counsel), and ultimately not supportive of any definitive statements about the actual disease risk presented by Eclipse.

> [F]irst of all, there's very limited amounts of evidence available for Eclipse, but that evidence that is available suggests that it has the potential to reduce toxin exposure, and that it may be associated with reduction in inflammation and so that's not a bad idea. Exactly what the benefits are are completely uncertain. (Tr., 9/12/08, pg. 143)

On cross-examination by the State's attorney Dr. Rennard was more certain, and clear about the limiting conditions on his overall conclusions:

> Q: [T]he particular measurements that you and your colleagues made in this case; that is, the bronchitis index, the recovery of alveolar macrophages, the changes in goblet cell metaplasia, none of those have been validated or accepted as measures that predict changes in disease risk. Do you agree with that?
> A: That's correct. And there's not very much more data that we've contributed. There are other individuals that have contributed some data to this, and I would say that there are other people that would – would think that these are plausible – plausible suggestions. But you're correct, they're not – there's not a wealth of evidence to be able to establish a very

[88] As discussed further below, Rennard did "sign off" on the Eclipse expert panel's final report in April 1999, and its blessing of the unqualified "presents less risk" formulation; any apparent inconsistency is addressed there.

unambiguous consensus that these are validated as surrogates in that sense. (Tr., 9/12/08, pgs. 255-56)

* * *

Q: In other words, we don't know what the relationship is between the amount of inflammation and increase in inflammation and a potential increase in disease risk?
A: Okay. So if you're trying to – if the question is would an increase of the bronchitis index of 2 predict a decrement in lung function of 20 – whatever the units would be in those things – no. There – there's not an information base to be able to – to make that calculation or even to make an approximation of – of that kind of calculation. But I think there's evidence to suggest that as a general direction they probably go in – in those directions.
Q: But similarly there isn't evidence to show that kind of clear corresponding relationship between decrease in inflammation, whether it's as measured by the bronchitis index or – or some other measure and decreases in disease risk?
A: I think that there is even less data on the impact of reductions and inflammation on future changes than there is on the presence of inflammation and future changes. (Tr., 9/12/08, pgs. 257-58)

83. In further testimony, although in response to leading questions, there is no doubt that Dr. Rennard agreed with the following:

Q: [A]m I correct that you concluded that the short term nature of your study did not establish a health benefit for switching to Eclipse?
A: Yes.
Q: Am I correct that you concluded that it's possible that individuals who have already developed clinically evidence disease may derive less benefit from a reduction in exposure?
A: Yes.
Q: And you concluded, as we've just been discussing, there are clear limitations to using intermediate biological markers to predict potential health benefits?
A: Yes.

* * *

Q: [Y]ou concluded that it's not at all clear that the favorable change that you observed, the change in inflammation in heavy smokers, would have been found in a study of lighter smokers, true?
A: That's also correct, yes.[89]
Q: And then finally you concluded that the effect of Eclipse on the health risk of smokers remains to be determined?
A: Correct. (Tr., 9/12/08, pgs. 259-60)

[89] Recall, of course, that at least domestically in the United States, "light" and "ultra-light" smokers now make up some 70% of the adult smoking population.

84. On redirect examination, Dr. Rennard remained resolute in his characterization of the limits of his own research:

> But we do know that quitting smoking[90] decreases your risk of getting COPD or having COPD progress, and so [that] study supports the concept that Eclipse would reduce the risk inasmuch as what we demonstrated in [our] study was a reduction in – as a reduction in inflammation, and that's presumably the mechanism by which reducing toxin exposure is going to lead to a reduced COPD risk.
>
> Now, what we can't say is the – is the question [that] was asked before. How much of a reduction in inflammation is – can be translated into how much of a reduction in COPD risk, and we don't know that from either of these studies in that our study just showed that in this group of smokers who volunteered to be in the study and then quit smoking, we don't know if they're going get COPD or not. We also don't know if they're going to continue to remain abstinent from their smoking.[91] We don't know all of those things from the future, and so we really can't say what the relationship is between the reduction in the inflammation and the subsequent disease risk.
>
> But since from epidemiological studies we know that people who do quit smoking have less risk, then it would be reasonable to say that that supports the general concept that Eclipse, which also reduced inflammation albeit not to the same degree as I recall it, would also have the same general aspects. . . .
>
> It's quite impossible though, I think, to try to draw any inferences about the magnitude of the effect or the likelihood of a – of a benefit in any given individual, but – but, yes, I think … it would be in general support of a concept. (Tr., 9/12/08, pgs. 291-93)

85. It is clear that Dr. Rennard ultimately recognized, and insisted on long-term (i.e., "well beyond" the 2 months of his 1st study) epidemiological data as the necessary requisite, and required reference point, for drawing any conclusions about actual disease risk, or likelihood of disease incidence as to any given individual. He agreed with the characterization of his work on Eclipse as a "pilot study" from which one could draw some "useful conclusions" as to lung inflammation indicators, and that Eclipse "probably exposed" smokers to "smaller doses of smoke toxicants." Although it was certainly in his opinion a "very reasonable proposition," neither his own study, nor any other data provided

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[90] As previously alluded to, and discussed further below, there is epidemiological evidence that complete smoking cessation does have demonstrable health benefits, and eventually a non-smoker's disease risk profile will pretty much return to that of a non-smoker. There is no generally accepted long-term data on smoking reduction, and the more recent epidemiological evidence on "light" cigarettes indicates no such correlation. *See infra*.

[91] In context, when Dr. Rennard talked here about "smokers … who quit" and whether they would "remain abstinent," since he was talking about his own studies it seems he was referring to smokers who stopped smoking conventional tobacco-burning cigarettes and switched to Eclipse for at least the duration of the study.

to the Eclipse expert panel, "proved" or established that Eclipse in fact presented less risk of developing COPD, than smoking a conventional tobacco-burning cigarette.

86. Dr. Rennard did follow-up telephone interviews with all 12 subjects who completed the study; none of them continued to use Eclipse, and all had gone back to smoking their "usual brand" of conventional cigarette. He has never advised any of his clinical patients who are smokers with COPD or other respiratory disease, that they should switch to Eclipse.

III. General/Other Scientific & Disease-Related Evidence

87. Dr. Rennard, and RJRT's principal expert witness at trial on respiratory disease (Dr. Tashkin), essentially agreed that lung inflammation is central to the pathogenesis of COPD and other respiratory diseases, so therefore indicators of less inflammation, if substantial and able to be maintained over a sufficiently long and sustained period, are likely to be associated with a reduced risk of eventually contracting pulmonary disease. However, that etiology, and progression from the presence of inflammation to the incidence of pulmonary disease itself is still not fully understood, and cannot be predicted with any precision. The inability to accurately describe, explain, or predict the progression from inflammation to disease itself, means that most scientists, and medical experts in the field will not rely solely on biomarkers of inflammatory exposure to quantify a given person's risk of contracting respiratory disease.

88. COPD, and other tobacco-related chronic respiratory diseases generally require a persistent presence of at least 2 years to be diagnosed as such. None of the outside clinical studies relied on by RJRT were sufficiently long-term to draw any definitive conclusions about the lasting effects of Eclipse "smoke" on the persistence of COPD and other pulmonary diseases. None of the in-house RJRT lab tests had the incidence, or even presence of any particular disease as the study end-point.

89. Although inflammation is clearly associated with respiratory lung disease, there was general agreement that inflammation, by itself, is not directly correlated with development of lung cancer. Accordingly, none of the outside clinical trials, which focused almost exclusively on indicators of lung inflammation, provided any scientific support for any of the ad claims regarding Eclipse "present[ing] less risk of cancer."

90. Lung cancer was essentially unidentified as a significant, and distinct cause of death before 1900. Commercial manufacture of cigarettes began in the 1890s; prior to that time, the consumption of tobacco had been primarily in the form of pipe tobacco, cigars, and chewing tobacco. Consumption of manufactured cigarettes continued to rise steadily, except for slight dips during the Depression, and again in the early 1950s, after which cigarette smoking accelerated because of new designs and products.

91. The incidence of male lung cancer steadily increased, generally along with the increasing consumption of manufactured cigarettes, from the 1930s through the 1950s, with the respective graphs showing generally a 20-year lag between former and the latter. As much as 85-90% of lung cancer is attributable to cigarette smoking; there is a consistent, and steady progression in the "relative risk" of contracting lung cancer (an "absolute risk" over 4 times that of non-smokers) correlated to the total number of cigarettes smoked per day, as well as the length of time a person has smoked cigarettes. Those conclusions are based on a large American Cancer Society epidemiological study of 1 million smokers over 12 years (1959-1972).

92. It is generally understood, and accepted that there is a general, and positive "dose-response" relationship for the incidence, and progression of lung, and other tobacco-related cancers. It is not generally accepted among the entire community of scientists involved with tobacco-related medical and health issues and cigarette research, however, that the general dose-response relationship runs in the opposite, or negative direction. That is, there are no long-term epidemiological studies which in fact demonstrate that a mere reduction in use of cigarettes, or reduction in exposure to cigarette smoke or its constituent chemicals and compounds, will necessarily result in a decreased "relative risk" of contracting cancer, and two more recent studies (involving a relatively large cohort of smokers who decreased consumption by 50%) which suggest there is no such correlation .[92]

93. The dramatic rise in male lung cancer deaths in the 1950s led to increased research – the first comprehensive smoke chemistry and toxicological analysis, lab and animal tests similar to those discussed above, and eventually the American Cancer Society epidemiological study noted above – into the medical effects of cigarette smoking, which culminated in the first Surgeon General's report in 1964, linking cigarette smoking to cancer. After that report, there was initially a "steep decline" in cigarette consumption, then a slight increase in the late 1960s (linked to no particular event), and then another significant decline in cigarette smoking in the United States after 1970 (following the prohibition of all TV ads for cigarettes), which has essentially continued to date. As stated, from 1930 through 2000, the incidence of male lung cancer roughly tracks per capita cigarette consumption, with a 20-year lag. However, even though the smoking population has gradually shifted to and is now predominantly comprised of "light" or "ultra-light" cigarette smokers (70% as of 2006),[93] there has been no corresponding decrease in the number, or rates of tobacco-related disease.

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[92] As noted, there is long-term data which does show that complete cessation of all smoking will eventually (after 15 to 20 years) lower the risk of contracting cancer, and other tobacco-related diseases, almost equivalent to the typical non-smoker.

[93] In 1997, "full-flavored" cigarettes were still 38% of the total sold; more recently, "lights" were more than 50%, and "ultra-lights" about 10% of the market; as noted, as of 2006, full-flavored brands make up only approximately 30% of total cigarettes sold.

94. Although Reynolds made no health-benefit claims related to cardio-vascular ("CV") disease, it is generally understood, and accepted (inasmuch as these diseases are the second biggest group of tobacco-related diseases) that cigarette smoking is associated with an increased risk of contracting CV disease. The general mechanism is that smoke chemicals transferred into the bloodstream cause irritation of the lining of the blood vessels. That irritation in turn leads to narrowing of the vessels, thinning of the vessel walls (and possibly even some "leakage"), and a build-up of plaque. Cigarette smoke is also understood to make blood platelets "stickier," and, as noted, cigarette smokers generally have a greater number of white blood cells. All of these effects are, of course, related to heart attacks or strokes.

95. Between 1981 and 2001, many in the relevant scientific community, including several of the State's experts who testified at trial in this case, generally assumed that the predominant rule of toxicology – i.e., the scientifically established dose-response relationship – would result in tobacco PREPs, and especially "low tar" and "light" cigarettes, having a significant, and substantial positive health benefit for all smokers who chose to use those products. Thus many medical professionals and researchers, including the State's expert Dr. David Burns, actively campaigned during that time for increased production, sales, and use of such PREPs, and have previously testified in a number of tobacco trials to their belief in that assumption and its likely effect.[94]

96. In 2001, the NIH published a monograph (#13) which for the first time unequivocally stated that there was no scientific study, or available data which would support, or establish any correlation between use of "low tar" or "light" cigarettes and any human health benefits, or reduced risk of contracting any tobacco-related disease. The massive switch of smokers to such products over the years had not resulted in any corresponding decrease in tobacco-related diseases. Further epidemiological studies, by the American Cancer Society, and in Britain, had finally announced the lack of any statistical correlation. A 2004 Surgeon General's report adopted the same conclusion, i.e., that "low tar" or "light" cigarettes, although they did reduce the amounts of smoke toxicants on a per cigarette basis, had not resulted in any corresponding decrease in the smoking population in tobacco-related diseases.[95]

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[94] As noted above, in the prior versions of this case leading to the MSA and Consent Decree, the State included allegations in 1995 that RJRT had intentionally "suppressed" development and marketing of the Premier cigarette, and other PREPs, and thus were depriving consumers of impliedly "safer" cigarettes which would have substantial positive health benefits.

[95] There are some studies which show longer-term positive changes, or improvements in disease symptoms, or biomarkers of exposure, from switching over an extended period to "light" or "low tar" cigarettes, primarily for respiratory diseases, similar to the short-term clinical results obtained by Rennard, Frampton, and others.

97. Further confounding the ability to draw conclusions as to human disease incidence simply from exposure (either increased, or reduced) to smoking chemicals and compounds, based just on the overall toxicological premise of the general dose-response curve, was a more recent epidemiological study (2006) of "heavy" marijuana smokers who showed no elevation in the incidence of actual disease (i.e., lung cancer), even though consumption, and unfiltered exposure to smoke chemicals, was greater than the typical cigarette smoker.[96]

98. Each and every one of Reynolds' expert witnesses at trial, when confronted on cross-examination, to varying degrees backtracked from their general statements on direct as to the applicability of, and inferences to be drawn from the overall toxicological premise of the general dose-response curve and the highly promising nature of RJRT's lab and clinical study results. Each conceded – again, to varying degrees – that any ultimate, and definitive statement associating Eclipse with any positive health benefits and/or a decrease in the risk of contracting any tobacco-related disease, would have to be supported with long-term epidemiological studies of actual human smokers. The trial record here strongly suggested that the minimum length of time to conduct such a study would probably be at least 10 years (with some advocating a study length of 20, or even 30 years), with probably at least 10,000 subjects.[97]

99. Each of the State's expert witnesses was, of course, firmly and unequivocally of that opinion as well, which is then supported by independent sources such as, *inter alia*, the NIH monograph (2001), the Rennard/Hatsukami article on biomarkers for tobacco-related diseases (2006, *see* below), and the Institute of Medicine report on possible tobacco PREPs (also 2001, *see* below). The overall consensus of the relevant, and larger scientific community, derived from the totality of the evidence at trial in this case, was thus, and accordingly is the same as set forth above: that (1) any ultimate, and definitive statement associating Eclipse with any positive health benefits and/or a decrease in the risk of contracting any tobacco-related disease, would have to be supported with long-

[96] Dr. Tashkin initially attempted to discount the applicability of this study, because marijuana smoke is thought to have other compounds (e.g., its "active" ingredient THC) which are "beneficial" to restricting tumor promotion. He finally conceded, however, that this point was uncertain, and could eventually only be shown, one way or the other, by epidemiological data.

[97] A principal "defense" urged by most, if not all of the Reynolds witnesses was that even if epidemiological studies were the "gold standard," they would be so costly, and take so long, that they were essentially, and effectively "impossible" to perform in the context of developing and marketing a consumer product in a highly competitive industry. Although that consideration may play some part in the overall calculus of "good faith" insofar as it relates to Defendant's avoidance of punitive contempt sanctions, *see* below, it plays no part in the basic liability analysis; if epidemiological data is scientifically required to support its Eclipse ad statements, then neither cost nor delay are relevant here, despite Judge Easterbrook's comment to the contrary, *see infra*. And, it must be noted that, having begun Eclipse development in the very early 1990s, Reynolds is now approaching the 20th anniversary of those efforts, sufficient time in which it might well have conducted such a study, or have already completed its so-called "Quality of Life" study, essentially an epidemiological approach which Dr. Rennard has supposedly been authorized to pursue (but has yet to begin) for the past several years, *see infra*.

term epidemiological studies of actual human smokers (or at least validated biomarkers which could be studied instead); and (2) the *in vitro*, *en vivo*, and outside clinical studies relied on by Reynolds are by themselves insufficient to support such marketing claims.

100. Accordingly: (A) the above data and other generally available information, or the lack thereof, when coupled with the admitted facts that (B) the tobacco-related diseases of most concern are diseases of incremental exposure and long-term incubation; (C) tobacco smoke is a highly complex mixture which forms and interacts with itself in non-linear ways (*see, e.g.,* variability in Table 4 above), and with humans (e.g., only 10% of long-term smokers develop lung cancer, and only 25% develop COPD) in still unknown ways; and (D) that unpredictability is further increased by each smoker's individual usage patterns, which cannot be consistently replicated by machine-generated cigarette smoke, all make it more likely than not that drawing inferences, and making definitive statements and ad claims based on those inferences, about the risk of contracting tobacco-related diseases such as cancer or bronchitis – premised largely on the reduction of smoke toxicants and some observed reductions in the precursors, or potential indicators of disease (e.g., mutagenicity (in bacteria), cytotoxicity, dermal tumor production (in mice), and lung inflammation); and based primarily on the overall toxicological premise of the general dose-response curve, but without any supporting epidemiological data – is not ultimately a valid, or sustainable scientific exercise.

101. For example, Dr. Gary Burger, who was the head of RJRT's scientific testing department during the critical times that the health benefit claims for Eclipse were approved in-house at Reynolds, ultimately recognized the limits of the testing they had performed. He testified, and conceded that because of the "lack of congruence" between identified carcinogens and the onset of actual disease, and the many "ways that humans are exposed to cigarette smoke," there is "no model for lab animal testing" that "replicates human cancers." He acknowledged that the urine mutagenicity and chromosome aberration studies "do not equate" to human lung cancer caused by prolonged exposure to whole smoke. When pressed, Dr. Burger "could not say" whether "reducing any particular compounds," or the "relative mix" of compounds in tobacco smoke, would affect, or change the risk of contracting any particular human disease, because of "the complex nature of cigarette smoke."

102. One of Reynolds' chief scientists (Dr. David Doolittle) stated his opinion that all of the available data from the in-house, *in vitro*, and animal testing, and outside medical school studies was "remarkably consistent" in pointing towards less exposure and less inflammation" from Eclipse, and this "total weight of the evidence" was in his view sufficient to support, if not "prove" the Eclipse ad claims that it "present[s] less risk of cancer, chronic bronchitis, and possibly emphysema" without any further epidemiological studies, or long-term data. That position, and opinion is contrary to, and not confirmed by the

consensus of the entire field of medical and scientific professionals familiar with tobacco-related diseases.

103. When confronted with the limited characterizations of their own studies as testified to by some of the outside researchers, such as Drs. Hite or Rennard, *supra*, the Reynolds witnesses would simply say they "disagreed," and would revert to their essential reliance on the "total weight of the evidence" and the basic toxicological dose-response principle. The inability, or reluctance to explain why Drs. Hite or Rennard were mistaken about their own research data, was not credible, or persuasive.

104. Dr. Emmanuel Rubin, an M.D. pathologist and author of the standard pathology textbook used in most medical schools; an author of more than 200 published journal articles; and (at time of trial) lead researcher on two different NIH research grants, was initially emphatic in his support of Defendant's reliance on the evidence Reynolds did have to make the Eclipse ad claims. Dr. Rubin stated it was "far more likely" that Eclipse does "present less risk of cancer, chronic bronchitis, and possibly emphysema." In his opinion medical researchers, and scientists generally are always making "judgment calls" based on inferences and a "more likely than not" standard,[98] when they use terms like "suggest," or "indicates," or "is associated with," and in his view that is all that Reynolds did here.

105. Dr. Rubin agreed that epidemiological studies would be "ideal" and the "strongest form of corroboration" for the positive health benefit claims made for Eclipse, but he then cited the difficulties in obtaining this data, and also the "problem" of "confounders" due to tracking difficulties and other uncontrollable variables (e.g., each participant's divergent personal history (age, gender, and ethnicity), and environmental factors). He relied heavily on his pathology background and expertise to focus more on the "pathogenesis" of the tobacco-related diseases, and how the data Reynolds did obtain showed various interruptions of those pathways to disease. Dr. Rubin also emphasized repeatedly the basic dose-response premise, and how scientists involved in the regulatory process routinely relied on that established scientific principle.[99] He thought the basic principle should be extended to any demonstrated reduction in constituent smoke toxicants, as a "matter of logic" and "common sense," without apparently accounting for (at the very least) the variability of each smoker's own personal smoking patterns and behavior over a span of many years.

106. Dr. Rubin nonetheless pointed to, and relied in part on the available epidemiological studies for tobacco use and consumption, which demonstrated in

[98] At least two of Reynolds' own in-house scientists, however, testified that "more likely than not" was a term rarely used in science, and was not a scientific standard which they recognized.

[99] This contention was also a major piece of RJRT's "defense" in this case; the court finds it is an inapplicable, and unpersuasive analogy, as is discussed in more detail below.

his opinion the essential efficacy of the dose-response principle, without recognizing any inconsistency in dismissing the need for epidemiological studies of Eclipse because they would be "difficult." He also noted that such studies were, in his view, appropriately done on a "cigarettes per day" model, without then confronting the testimony of the in-house RJRT witnesses that their own "human behavior studies" established that "experienced" Eclipse smokers consumed an equivalent number of Eclipse as their previous "usual brand" of conventional cigarette.[100] In other words, Dr. Rubin did not fully explain how, if cigarettes smoked per day remained essentially the same, then smoking Eclipse could, or would actually result in any reduced risk of disease.[101]

107. Even in his direct testimony Dr. Rubin acknowledged that effective biomarkers of actual disease incidence – that is, measurable indicators of some present status or condition, which suggest an elevated risk of developing some disease in the future, e.g., PSA levels for male prostate cancer – must be "accessible in humans" – that is, be able to be measured without unduly invasive medical procedures – and supported by some "demonstrated quantitative correlation with the particular disease in question." How that differs from insistence on biomarkers validated by epidemiological data, was not explained, especially since he later conceded that any disease-predictive biomarkers could only be validated by epidemiological data, and further there are no currently validated biomarkers for lung cancer or COPD.

108. Dr. Rubin endorsed the overall "total weight of the evidence" approach, stating that the "entire body of evidence," and its "consistency," was more important than any one study or test result, without explaining how, or to what degree any particular study, or data set, should be weighted. For example, he "accepted" that machine-generated smoke cannot truly replicate human smoking behavior, but there was no indication how that fact should be accounted for in the "total weight of the evidence" approach. Thus his opinion that the Eclipse laboratory data did show that Eclipse "smoke" was likely to be both less cytotoxic and less mutagenic, even if correct, does not adequately address the ultimate question of whether human disease risk would be reduced by switching long-term to Eclipse.

109. With respect to the mouse skin painting studies, Dr. Rubin stated that the data showing fewer tumors was sufficient "to predict" that Eclipse would be less carcinogenic, "but then you have to prove it." He also accepted that

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[100] Of course, the court has found above that this contention is not supported by the totality of the record evidence here, which establishes that Eclipse users do consume a greater number of cigarettes in attempting to replicate their prior smoking patterns, and nicotine dependence.

[101] Dr. Rubin testified that only 5% of long-term smokers went on to develop some sort of tobacco-related cancer; if so, that would make the incidence of cancer twice as unpredictable as the already significant variable otherwise stated in the evidence, that only 1 in 10 get lung cancer. He did agree, as a pathologist, that smoking is a significant cause of preventable death; he said that 85% of all lung cancers occur in smokers.

mutagenicity in bacterial cells would need to be "validly extended" to human cells in order to draw any definitive conclusions from the *in vitro* tests, but then essentially relied on the general observation that "most" of the "more potent carcinogens" are "known" to be "more potent mutagens." He acknowledged that the RJRT data cannot distinguish, or explain which particular smoke chemical or compound is in fact responsible for any observed mutagenicity effect.

110. Dr. Rubin agreed that the basic dose-response principle is now so well-accepted, and useful in many applications, precisely because it has been confirmed time and again by countless different epidemiological studies. With regard to the more recent epidemiological studies which did not show any positive health benefit, nor any reduction in disease incidence, from merely reducing exposure to cigarette smoke toxicants (e.g., by smoking "low tar" or light" cigarettes, as opposed to complete cessation), he was "skeptical" because those reported results were "so contrary to reason" and the "established dose-response curve," and they "contradicted common sense."[102] He then sought to explain, or resolve the discrepancy on the "assumption" that those consumers who switched to "light" cigarettes were "smoking differently" and thus not actually decreasing their overall exposure to smoke toxicants. Dr. Rubin would not acknowledge that this was precisely one of the contentions urged by the State and its witnesses, that the same phenomenon would likely be true of switchers to Eclipse, thereby undercutting the central thesis of Reynolds' reliance on scientific evidence which fell short of, and did not include any epidemiological data.

111. Ultimately, Dr. Rubin conceded that to make any statement that reduced exposure actually equaled less disease risk, the scientific community would require epidemiological data "to prove the point." However, he still supported Reynolds moving ahead with Eclipse and selling it with the disputed ad claims, because Eclipse was "highly likely" to result in "some reduction" of toxic exposure, and none of the evidence indicated any harm, or downside to consumers from switching to Eclipse. For him, it was a question of "relative risk" vs. "absolute risk," and epidemiological data was needed only to demonstrate, and quantify the latter; that is, even if there was only a 1% improvement in the relative risk, but the additional degree of improvement could not be statistically established, it would still be a net positive if all smokers changed to Eclipse, because it could result in more than 4000 less deaths each year from cigarettes. Because epidemiological studies were "impractical" before marketing the product, Dr. Rubin believes it was an acceptable "scientific judgment" for Reynolds to use the "less risk" marketing claims in order to possibly achieve that

[102] Dr. Rubin also discounted that data because it did not appear in a "quality" medical journal. He was more impressed by a Norwegian study which tended to show a 1/3 reduction in lung cancer among heavy smokers who reduced their cigarette consumption by 50%, even though the results were not statistically significant, because it appeared in the Journal of the American Medical Association, and because it was more consistent with his unshaken belief in the basic dose-response principle.

potential overall benefit.[103] In his view, one needed a lesser degree of confidence in making such a scientific or medical inference, where the severity of the known harm was great.

112. Dr. David Brusick, an accomplished and experienced Ph.D. toxicologist, also testified in support of Reynolds' positive health benefit claims for the Eclipse. He has been a member of several NIH and IARC panels, principal investigator on a number of grants to study potential carcinogens. Despite the numerous criticisms advanced by the State's experts, he stated that all of the underlying studies and testing relied on by Reynolds to support the Eclipse ad claims were generally accurate, reliable, and performed within a reasonable degree of professional competency. As previously stated, the court agrees, and so finds. The many defects urged by the State witnesses have been noted, and discussed above, but in the final analysis those issues are only distractions around the margins of the data; the core results are generally sound.

113. As a toxicologist involved in public policy issues, Dr. Brusick's primary approach, and focus was the fact that regulators repeatedly use, and rely on the basic dose-response principle to make regulatory decisions involving the potential human health effects of any number of chemicals or compounds, even when the body of available data is less than complete, and often no long-term epidemiological studies on those particular substances are available. Thus, in his professional opinion, the simple tautology relied on by RJRT is scientifically sufficient to support the Eclipse ad claims: Eclipse studies show that Eclipse "smoke" presents both quantitatively, and qualitatively less exposure to many, if not all identified cigarette smoke toxicants; exposure to fewer mutagens,[104] inflammatory substances, cytotoxic agents, and known or suspected carcinogens is strongly associated with a reduced risk of contracting cancer; therefore Eclipse does "present[ ] less risk of cancer" than a conventional tobacco-burning cigarette. He holds that opinion – despite recognizing that no one yet knows or can explain the precise etiology of lung cancer from cigarette smoking; that cigarette smoke is a complex mixture in which not all known or suspected human carcinogens have yet been identified, let alone definitively studied separately

[103] Dr. Rubin was not, and is not an "apologist," let alone a cheerleader for the cigarette industry. As will be seen in the discussion below regarding the Eclipse expert panel, he seems to fall in what the court has come to think of as the "realist camp," in that anything which shows any potential for reducing tobacco-related injury and death must, and should be tried with the smoking public, even if the necessary marketing incentives to persuade those smokers to switch cannot be proven with all of the scientific rigor one might otherwise insist on. This camp's obvious credo is the well-known adage that the perfect must not be the enemy of the good (or merely sufficient).

[104] Dr. Brusick acknowledged, however, that not all of the chemicals and compounds in Eclipse "smoke" (or condensate), which are of most concern as to likely toxicity or carcinogenicity, are in fact mutagenic in the Ames assay, and that the mutagenic properties of specific chemicals is also unknown. He stated that a "large majority" are known mutagens, and thus in his view reliance on the data to draw conclusions about the entire range of Eclipse "smoke" constituents was a "permissible inference." He was ultimately comfortable with the "assumption" that the really "bad" smoke constituents all "went down with Eclipse" because of the overall Ames assay results.

from "whole smoke"; and that actual human ingestion of cigarette smoke is subject to infinite variation from person to person – primarily because of, again, his fundamental belief in the dose-response principle, and the exercise of valid scientific judgment based on reasonable inferences from reliable preliminary data. Like Dr. Rubin, he testified that further epidemiological data is needed[105] only to draw "specific quantitative conclusions" about the absolute change in the degree of disease risk, but not the essential premise that the risk will indeed be lower for smokers who permanently change to Eclipse.

114. Dr. Brusick testified that the dose-response principle is a fundamental equation that can be "used in both directions," that is, it can be used, and relied on "in reverse" to establish negative as well as positive conclusions. In other words, if more X results in more Y, then less X must necessarily also result in less Y. He stated this proposition was "self-evident" and again referred to its prominence in all fields of regulatory activity. As respected and accomplished as Dr. Brusick (and Drs. Rubin, above, and Tashkin (*see* above, and below)) may be, and as inexperienced as the undersigned may be in complex scientific matters, the mere uttering of the word "self-evident" renders that expert witness's testimony less credible.

115. Dr. Brusick opined that measuring exposure to smoke toxicants on a "per mg/tar" basis in the underlying *in vitro* and *en vivo* tests was the preferable, and most accurate means of applying the dose-response principle to the Eclipse analysis. However, he then had no persuasive explanation for the effect (which he acknowledged) of the most likely scenario that actual human smokers of Eclipse will consume more of them, and "smoke" them more intensely (e.g., in order to maintain desired nicotine levels), thus substantially increasing the overall intake of, and exposure to "tar" than what is produced by machine-generated smoke using the FTC method in all of those studies. Moreover, if the fundamental logic of the "reverse" application of the dose-response principle is so "self-evident" as Dr. Brusick claimed, it arguably would not have been necessary to perform any of the other studies and tests – the "human behavior" studies, the lab and animal studies, the outside clinical studies, all at a cost of many millions of dollars and many years of delay – beyond the basic smoke chemistry analysis of Eclipse. The latter, by itself, would have then been sufficient to establish that Eclipse is more likely than not to expose Eclipse smokers to lesser amounts of those chemicals and compounds of most concern, and thus sufficient to support the Eclipse ad claims of "less risk of cancer, chronic bronchitis, and possibly emphysema." Yet all of the RJRT witnesses, and the Eclipse expert panel, *see* below, agreed that the additional *in vitro*, *en vivo*, and short-term clinical studies were necessary to achieve the "total weight of the evidence" on which the Eclipse ad claims are based.

[105] Also like Dr. Rubin, Dr. Brusick emphasized the cost, delay, and difficulties, including the many "confounders," inherent in attempting an epidemiological study of the length and size required to quantify any demonstrable change in disease risk form switching to Eclipse.

116. At the time of trial in this case, Dr. Tashkin, RJRT's pulmonary disease expert, was actually in the process of setting up, and directing an NIH-funded study (in concert with 4 other medical research centers) on potential biomarkers for COPD. That project will in fact be a long-term epidemiological study, because such a study is ultimately the only acknowledged means for developing reliable data on the relationship between identified indicators, or precursors of disease, and the actual incidence of disease itself. In his testimony here, Dr. Tashkin acknowledged the "obvious limitations" of, *inter alia*, the Rennard and Frampton clinical studies: neither was "representative" of the "entire population of smokers," each study's small size and short length, and neither study has been replicated by others. Even in his direct testimony he stated only that the Rennard and Frampton clinical studies "taken together" are a "convincing argument" for the proposition that Eclipse "reduces delivery" of toxic compounds associated with lung inflammation. He agreed they were "preliminary studies" which would have to be extended by "large cohort" and "case control" studies – i.e., long-term epidemiological studies – in order to "prove conclusively" that switching to Eclipse in fact "present[s] less risk" of contracting COPD.[106]

117. Thus Dr. Tashkin ultimately stated his agreement with Hatsukami and Rennard, *see* below, that no validated biomarkers yet exist for COPD, which is precisely the reason for his current NIH grant and study. He also ultimately agreed with Dr. Rennard's own assessment of his study data, that Rennard's results (e.g., reduced numbers of goblet cells, and macrophages) were "only suggestive" of "potential biomarkers" for COPD which are associated with tobacco smoke and cigarette usage.

118. The National Academy of Sciences is a "private, nonprofit, self-perpetuating society of distinguished scholars engaged in scientific . . . research," pursuant to a Congressional charter first adopted in 1863. That charter requires the National Academy to "advise the federal government on scientific matters" as requested by Congress or executive branch agencies. Exhibit VT-1972, "Clearing the Smoke: Assessing the Science Base for Tobacco Harm Reduction" (Nat. Academy Press 2001), at iv.[107] The Institute of Medicine ("IOM") was established

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[106] Like many of the RJRT scientific witnesses, Dr. Tashkin also emphasized the "practical difficulties" in conducting such an epidemiological study prior to any marketing decision. As with many of the witnesses here, Dr. Tashkin clearly aligned himself with the "realist camp," in his willingness to make (in his view) scientifically justifiable inferences from the data RJRT did have.

[107] At trial there were major kerfuffles around admission of the IOM report, as well as the deposition of Stuart Bondurant, M.D., the chair of the IOM committee studying tobacco harm reduction. Although there were other procedural, and more technical evidentiary grounds for exclusion asserted by Reynolds (all of which were denied by the court), the primary basis seemed to be that the IOM committee, and their report, were simply "biased" against tobacco companies. (For example, another committee member was Dr. Peter Shields, one of the two principal expert witnesses for the State in this case on medical and scientific issues.) That contention, of course, ultimately goes to the weight to be accorded to the evidence, not its admission. As discussed below, ultimately the question is not whether the conclusions of the IOM report – as well as those

in 1970 by the National Academy "to secure the services of eminent members of appropriate professions in the examination of policy matters pertaining to the health of the public." *Id.*

119. An IOM committee was selected in 1999, at the request of the Food and Drug Administration, to "assess the science base for tobacco harm reduction," made up of 12 members from around the country with expertise in various disciplines, including pathology, psychology, epidemiology and internal medicine, pulmonary and critical care medicine, and cancer genetics and epidemiology. Of the twelve members, 8 were M.D.'s and 4 were Ph.D.'s; nine were on the faculty of, and affiliated with major U.S. universities, while 3 were affiliated with private research or consulting organizations. There were also 4 additional liaison, or consulting advisors (one M.D., two Ph.D.'s, and one law professor (L.L.B.) (all four of those individuals were also from major university faculties), and five staff assistants and report writers (two Ph.D.'s and one M.D.). *Id.,* pgs. v-vi.[108] The overall task was to review and evaluate all of the available study data and literature relevant to the question of whether tobacco PREPs could result in reduced harm (defined as any "lower[ing of] total tobacco-related mortality and morbidity") to actual smokers.

120. Reynolds was given an opportunity to submit materials and information to the IOM committee, both generally on the topic of tobacco PREPs, and Eclipse itself.[109] In a letter (dated May 4, 2000) with more than ¼ inch of attachments, Dr. Gary Burger (*see* above, and below) responded on RJRT's behalf to various generic questions that the IOM committee had posed. In addressing what study "endpoints" should be utilized "for assessing harm reduction through use of reduced risk products," Dr. Burger unequivocally stated Reynolds' position that "an epidemiological approach is inappropriate for the study of risk reduction vis-à-vis reduced toxicity cigarettes." Exhibit VT-0654 (Bates pg. # 5026). The reasons cited were the lengthy time period required (at least 10, if not 20 years); the large number of participants needed; various "confounders" such as, *inter alia*, "the degree of non-compliance on a reduced risk cigarette [which could]

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of any other expert who testified here – are in fact entirely correct (or not), but rather whether the views expressed are representative of what the entire scientific community knowledgeable about tobacco-related disease and tobacco PREPs would consider necessary to support health benefit claims like those made for Eclipse.

[108] There were also 22 individuals who reviewed, and supplied comments on all or parts of the entire IOM report, or were responsible for coordinating that independent review process; 16 of the 22 were affiliated with major U.S. universities. One such reviewer was Dr. Rennard, *supra*. (He had been invited to be a member of the committee, but declined, fearing that his association with Reynolds as an independent researcher would taint the committee's conclusions.) Another reviewer, of perhaps greatest concern to Reynolds, *see* preceding fn. 107, was a representative from the "Campaign for Tobacco Free Kids."

[109] As is discussed further below, RJRT had already begun making its health benefit and "less risk" claims for Eclipse in mid-2000, and thus the issue was already well-known within the larger community interested in tobacco-related disease assessment, and reduction.

vary from smoker to smoker"; and the likely phenomenon that study participants "willing to make [the] trade-off in terms of taste, sensory impact and ease of lightability" to remain compliant with a PERP-only regimen "may not be behaviorally or demographically comparable to the average smoker" and already suffer from "pre-existing chronic health conditions" which might predispose them to "increase[d] … risk for lung cancer and COPD."[110] *Id.,* pgs. 5026-27. Reynolds did not address the fundamental question whether epidemiological studies were scientifically required in order to make a "less risk" claim as to actual incidence of human disease, but rather objected essentially on the same grounds still asserted here, i.e., that epidemiological studies were simply "impractical," if not logistically and commercially "impossible."[111]

121. The 2001 IOM report acknowledged the essential dose-response principle, and the preliminary data and studies which had been generated by Reynolds (and others) throughout the 1990s. With regard to cancer and related diseases, the report stated:

> There are sufficient laboratory and human data to suggest that harm reduction for cancer might be an achievable goal for persons who cannot stop smoking. . . . [R]eduction in exposure to tobacco smoke and tobacco products to the lowest possible levels may provide some benefit to individual users and to the general population. However, there are insufficient data from which to conclude how much reduction in exposure would yield a measurable benefit and which individuals would benefit.
>
> A systematic and thorough assessment of PREPs and cancer risk will require analysis of data obtained from well-designed laboratory and human studies. In laboratory animals, the shape of the dose-response curve differs for different tobacco constituents, indicating that the dose-response relationship of tobacco smoke is complex. . . .
>
> However, while there are sufficient data to conclude that a dose-response relationship exists for the use of tobacco products and cancer risk, the precise dose-response relationship is really not known in part because exposure is not accurately measured, without considering actual smoking behavior. . . . Thus, data are insufficient to predict the harm reducing effect of a change from nay intensity of smoking to a PREP. There

[110] These last statements alone would seem to concede that the "average smoker," to whom the Eclipse ads were in fact addressed, would be unlikely ever to actually achieve the "reduced risk" health benefits touted by Reynolds.

[111] "Epidemiology 'studies the incidence, distribution, and etiology of disease in human populations' with the goal of gaining a better understanding of disease causation and disease prevention in groups of individuals. . . . To this end,

> [e]pidemiological evidence identifies agents that are associated with an increased risk of disease in groups of individuals, quantifies the amount of excess disease that is associated with an agent, and provides a profile of the type of individual who is likely to contract a disease after being exposed to an agent."

Estate of Albert George v. Vermont League of Cities & Towns, 2010 VT 1, ¶ 18 (Jan. 15, 2010) (cits. omitted).

> are sufficient data to suggest that dose-response relationships differ as a function of gender. Race, age, and ethnicity, although the actual risk levels have not been sufficiently defined to draw definitive conclusions about risks among groups. Based on these types of data and possible modifiers of cancer risk (e.g., genetic susceptibilities, diet, lifestyle, occupation), it is likely that PREPs would affect risk differently in different people and not at all in some.
>
> Regression of risk using PREPs might eventually bring a smoker to a risk equal to some lower level of lifetime exposure to conventional products. However, there are insufficient data to validate this assumption or indicate that a decrease in risk would be measurable for some or all smokers.

Exhibit VT-1972, at 163-64.

122. With respect to *in vitro* and lab animal studies, the IOM report concluded that such data "may be useful for the assessment of the carcinogenicity of tobacco-related PREPs." However, it then stated unequivocally:

> Such studies are not alone sufficient to support claims of potential harm reduction. No claim of potential harm reduction should be allowed without adequate human clinical and epidemiological studies.

Exhibit VT-1972, at 165.

123. With regard to respiratory disease, the conclusion(s) of the IOM report were similar:

> It is generally accepted that cessation of smoking slows or stops the progression of lung diseases related to smoking and it is plausible that decreasing smoking [and/or reduced exposure to smoke toxicants] will reduce the severity of chronic lung diseases and the incidence of respiratory infections. . . . There is a need to determine dose-response relationships more precisely and to develop biomarkers of respiratory disease. . . . There are currently no specific molecular biomarkers of the ... respiratory diseases due to smoking tobacco products. No unique molecular or genetic defect specific to tobacco-related respiratory disease has been identified.

Exhibit VT-1972, at 170.

124. Among the "Principal Conclusions" of the 2001 IOM report was the following:

> The science base for assessing tobacco harm reduction is incomplete. . . .

> **Conclusion 2**. *PREPs have not been evaluated comprehensively enough (including for a sufficient time) to provide a scientific basis for concluding they are associated with a reduced risk of disease compared to conventional tobacco use.* (One exception is the use of nicotine replacement therapy for maintenance of [smoking] cessation . . . .) Carefully and appropriately conducted clinical and epidemiological studies could demonstrate an effect on health. However, the impact of PREPs on the incidence of most tobacco-related diseases will not be directly or conclusively demonstrated for many years.

Exhibit VT-1972, at 231, 232.

125. Elsewhere in the IOM report, in discussing "Principles of Harm Reduction" generally, the committee did include an "observation[ ]" that, because "[p]ublic health advocates opine that tobacco is a 'special case'," then "the burden of proof for a benefit of novel, potential exposure or harm reduction tobacco products entails special considerations beyond that required of many other scientific questions." This remark has not surprisingly generated particular concern on Reynolds' part, *see* fn. 107 above, and would tend to indicate some presumptive bias on the part of at least some committee members and/or editors of the report. While certainly a comment that indicates more editorializing than one would expect in an objective scientific assessment, in context that statement does not significantly detract from the extensive review and discussion of the underlying scientific principles, and available testing data and studies, which should be utilized to determine whether any PREP has met its burden to establish a reduced-risk claim, regardless of how rigorous that "burden of proof" should be. In essence, this remark appears to have been an opening policy argument to the FDA (which had requested the IOM report) as to how strict the FDA should be in formulating any regulatory response to PREPs (assuming the FDA were to obtain such authority, as it now has), and not a comment on the underlying science of PREP evaluation, which makes up the vast bulk of the 2001 IOM report. RJRT's objections to the IOM report are not convincing, and the court does find it to be credible, and persuasive with respect to the specific issues in this case.

126. Although Reynolds in 2001, and since then (including trial of this case) has publicly resisted the conclusion that epidemiological data is required to support its Eclipse ad claims, at a recent May 7, 2007 annual TMA Meeting and Conference, one of its chief scientists responsible for analyzing smoke chemistry – Dr. Michael Borgerding, also a witness at trial here – made a presentation on Reynolds' "Guiding Principles and Beliefs." Among many other statements in a multi-page Power Point presentation, Dr. Borgerding acknowledged, and incorporated into his own remarks the same "IOM guidelines" discussed above. He stated that the "biological plausibility" of the claim that any "demonstrated reduction in exposure would be anticipated to result in a measurable execution in morbidity and/or mortality" would have to be supported by "subsequent clinical or epidemiological studies," development of "short-term biomarkers of effect" based on actual "data in smokers," and "[q]uantitative risk assessment."

127. With regard to quantitative risk assessment, Dr. Borgerding in his Power Point subsequently defined that term to mean "a statistically significant decrease in calculated risk" which would "reflect our exiting knowledge of relevant epidemiology associated with disease . . . ." He concluded his remarks with the following statement differentiating a reduced exposure cigarette from a true reduced risk product (emphasis in the original):

> Data from the array of tests must be sufficient to establish that the product exhibits biologically meaningful reduced exposure – the basic foundation.
>
> Epidemiological or other human studies must lead to significant scientific agreement that reduced toxicant intake from use of the reduced exposure product results in a meaningful reduction in a valid measure of chronic disease or a serious adverse condition associated with tobacco use.

In his own testimony at trial in this case, Dr. Borgerding eventually acknowledged that the critical distinction between a "reduced exposure" product and a "reduced risk" product, is that any claims suggesting the latter must be supported by "epidemiological or other human studies."

128. Reynolds at trial attempted to distinguish, and downplay Dr. Borgerding's 2007 statements as simply reflecting the "current regulatory climate" and the anticipated inevitability of FDA control over PREP marketing claims (and probable adoption by the FDA of the IOM guidelines), but that effort was feeble at best and not convincing. Although certainly it is understandable that RJRT needed to maintain its consistent denial of the obvious for litigation purposes, it is more likely than not that at least some of Reynolds' own researchers have come around to accept, however reluctantly, that their earlier endorsement of the unqualified Eclipse ad message was not scientifically valid, and simply reflected the triumph of hope over experience.[112] The court finds the views, and opinions stated in the 2001 IOM report to be scientifically sound, cogent, credible, convincing, and consistent with the "total weight of the evidence" presented at trial in this case. The larger scientific, and medical community familiar with tobacco-related diseases and tobacco PREPs would require epidemiological studies to support the affirmative marketing claims for Eclipse made by Reynolds, or at least an intermediate step of validated biomarkers for the indicated tobacco-related diseases, *see* below.

129. Such a recognition of the limited nature of the initial tests conducted by RJRT, and the further need for epidemiological studies would have been nothing new at Reynolds. In an "R.J. Reynolds Tobacco Company Syntax Report," dated 3/10/92, a scientist with its Scientific Affairs Division reported on "the use of short-term bacterial mutagenicity assays in food safety assessments."

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[112] James Boswell, *The Life of Samuel Johnson* (1791) (entry for 1770, regarding a friend's decision to remarry), as quoted in *The Yale Book of Quotations* (Shapiro 2006).

In the section on the Ames assay, Dr. Johnnie R. Hayes, "Master Toxicologist," wrote as follows:

> Bacterial Mutagenicity Assays
>
> Bacterial mutagenicity assays are generally considered to be screening tests to determine the potential of a chemical or chemical mixture to directly interact with DNA to produce a mutation at a specific gene locus. As screening tests, data from bacterial mutagenicity assays are not directly useful for quantitative human risk assessment. However, they are useful for determining the potential for a chemical to interact with DNA to produce highly specific mutations.
>
> * * *
>
> Certain aspects of the bacterial mutagenicity assay systems that increase their sensitivity affect their ability to determine their predictability. For instance, the strains of *Salmonella* used in the Ames assay have been developed to have very poor DNA repair systems. These bacteria are highly sensitive to DNA damage because they cannot repair the damage. The animal models used in carcinogenicity tests have highly developed DNA repair mechanisms and may repair DNA damage before it is expressed. Therefore a test material that is positive in the bacterial assay may be negative in animal studies.
>
> * * *
>
> What is sometimes forgotten in the controversy over the ability of short-term bacterial assays to predict the carcinogenicity potential of a chemical is that genotoxicity is an endpoint unto itself. It may be too much to ask of a simple *in vitro* assay to predict the complex *en vivo* interactions associated with carcinogenicity. However, the bacterial mutagenicity assays will determine the potential of a chemical to interact with DNA to produce a mutagenic event under the conditions of the assay. . . .
>
> Bacterial mutagenicity assays provide a rapid and inexpensive method to screen chemicals for further research and to eliminate those that do not meet specific toxicological criteria. Therefore, even though these assays may not have a high percentage of predictability for carcinogenicity by themselves, they can serve an important function in screening chemicals for their potential ability to interact with DNA.

Exhibit VT-1441 (Bates pg. #s 9848, 9850)(emphasis in original).

130. No evidence was presented which persuasively undercut Dr. Hayes' observation from 1992, when Eclipse development and testing was just beginning, that the Ames assay would at best be useful as a "screening test" to isolate specific tobacco chemicals for further genotoxicity and/or carcinogenicity testing. The persuasive consensus of scientific opinion which the court heard in 2008-2009 was essentially to the same effect. Any attempt by Reynolds to disown the Hayes article, because it "only related to food," or was "ancient

history" that was superseded by more recent advances in toxicology or *in vitro* testing techniques, was not compelling.[113] Most importantly, because of Reynolds' use of "whole smoke" and/or undifferentiated Eclipse condensate for its *in vitro* Ames assays, instead of selecting for further assessment those specifically identified tobacco chemicals or compounds which have first been isolated by use of the Ames assay as a preliminary screening tool, the critical assumption(s) of Dr. Rubin, *inter alia* – that mutagenicity can be equated with carcinogenicity over the entire range of presumably toxic chemicals and compounds exhibited by Eclipse "smoke," without knowing the precise genotoxic interaction of each one, *see* above – are put into substantial doubt.

131. There was also no evidence of how, or to what extent, if any, the Eclipse expert panel later relied on by Reynolds to support the Eclipse ad claims, took into account, or specifically weighted the type of limitations expressed by Dr. Hayes as to the use of bacterial mutagenicity studies.

132. Dr. Dorothy Hatsukami, Ph.D. (University of Minnesota Cancer Center) was the lead author, along with Dr. Rennard, *supra*, and others,[114] of a review article "Biomarkers to Assess the Utility of Potential Reduced Exposure Products," in the journal *Nicotine & Tobacco Research* (vol. 8, no. 2, April 2006). The "Introduction" explained the review of existing studies and scientific literature on the subject, as follows:

> Biomarkers for disease risk are critical in the assessment of potentially reduced exposure products (PREPs) . . . . Because of the long exposure time necessary to determine the effects of PREPs on actual harm and the use by smokers of multiple products for different amounts of time, short-term proxies for disease that can be used in laboratory studies, clinical trial, and population studies are necessary. Biomarkers can be classified as a measure of (a) chemical exposure, that is, a direct or indirect measure of a tobacco-derived constituent or metabolite, that ideally can provide a quantitative estimate of tobacco exposure; (b) toxicity, including biologically effective dose, that is, "the amount that a tobacco constituent or metabolite binds to or alters a macromolecule either in target or surrogate tissue" . . . (c) injury or potential harm, that is, "a measurement of an effect due to exposure; these include early biological effects, alterations in morphology, structure or function, and clinical symptoms consistent with harm"; . . . . and (d)direct measures of heath outcome.

Exhibit VT-1981, pg. 169. The authors' summary conclusion was as follows:

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[113] The 1992 Hayes report was "Accepted by" Dr. Robert Suber (he signed off on the report), who would later be a designated Reynolds' spokesperson on Eclipse and tobacco harm reduction issues, *see* below. The "executive summary" page went to Dr. Gary Burger, *see* above, and below.

[114] Dr. Mark Frampton, of the University of Rochester study relied on in part by Reynolds, was a member of the article's "pulmonary disease biomarkers workgroup," *id*. at 185.

> To date, we have no valid biomarkers that serve as proxies for tobacco-related disease to test potential reduced exposure products. . . . No existing biomarkers have been demonstrated to be predictive of tobacco-related disease, which highlights the importance and urgency of conducting research in this area.

Id.

133. In the body of the article, Hatsukami, *et al.*, wrote as follows in the final "Conclusions" section:

> Several biomarkers show sufficient sensitivity to changes in smoking status to suggest that they may be useful to assess constituent exposure with PREP use in a research setting. Table 5 lists current biomarkers that show differences between smokers and nonsmokers, change with cessation, and exhibit a dose-response relationship that responds to reductions in cigarette consumption. This table by no means describes biomarkers that can be used to assess disease risk for PREPs. The limited number of biomarkers listed in the table highlights the need for more systematic research to determine biomarkers that are reproducible, that show a dose-response relationship to exposure to tobacco and cigarette smoke toxins, that reflect the spectrum of tobacco-related disease states and mechanisms, and that are predictive of disease . . . . The challenges associated with assessing harmful effects of PREPs include the potential introduction of new, unknown toxins; the contribution of new toxins to the inherent toxicity of tobacco and tobacco smoke; and a need for greater understanding of specific tobacco-related mechanisms associated with pathogenesis. We are also limited in understanding the intra- and inter-individual differences in physiology, the complex physiological interactions, and the interactions between susceptibility to disease and the effects from tobacco.

Id., pg. 184. Included in the authors' Table 5, as potential biomarkers not yet validated for disease prediction, were urine mutagenicity, sister chromatid exchange, and the presence of macrophages in lavage lung cells, all three of which Reynolds and its expert panel heavily relied on as a critical part of their "total weight of the evidence" to support the Eclipse ad claims.

134. Dr. Rennard, in his 2008 testimony in this case, reaffirmed his opinion, as stated in the Hatsukami biomarkers article of which he was a co-author, and as previously set forth in the 2001 IOM report, that there are no currently validated indicators for the incidence, or progression of any tobacco-related disease. Thus, even if significant reductions in those indicators, or precursors of exposure or harm could be established by adequate testing, that data would not support a further extension to affirmative claims made about reduced risk of contracting any particular tobacco-related disease.

135. Dr. Brusick, testifying for Reynolds, took issue with the conclusions of Hatsukami, et al., that no current validated biomarkers exist for actual disease incidence. In particular, he argued that, in his opinion, urine mutagenicity should be an accepted biomarker for at least some cancer(s), even without extensive epidemiological data to support it.[115] With all due respect, the court finds that opinion to be at odds with and contrary to the convincing weight of the trial evidence here, especially, *inter alia*, the in-house statements of Reynolds' own employee Dr. Hayes, *supra*, made well before this litigation ever erupted.

136. Regulators, concerned with public health and safety issues, regularly and routinely rely on the dose-response principle to make decisions with respect to discharges of contaminants and exposure to various chemicals or compounds, based on preliminary, or incomplete information and *in vitro* and/or animal testing data such as Reynolds developed about Eclipse, often before there has been the opportunity for long-term epidemiological studies regarding those substances. In such instances, because of the overriding need to act conservatively and protect public health, the use of scientific judgment to draw ultimate inferences as to human disease consequences, based just on the dose-response principle extrapolated from preliminary data, is entirely justified, inasmuch as the decision to restrict, or reduce human exposure to a known or suspected toxic agent or carcinogen can have little, or no adverse consequence; potential human harm or injury will likely be avoided; and no affirmative health benefit claims are being made. No quantitative assessment of comparative, or potential risk reduction is made when using the dose-response principle for this type of regulatory action; the former must be essentially objective, and is either supported, or not, by the scientific data, while the latter depends on not only scientific assessment of available data but also public policy and other more subjective considerations (e.g., cost-benefit analysis) as well.

137. That is, if preliminary test data suggest that exposure to chemical X beyond point Y[116] increases the risk of contracting disease Z (or some other health injury) by some multiplier over the known incidence of that disease (or injury) below that level of exposure, then from a public health and regulatory standpoint it is a permissible inference, both legally and scientifically, to conclude that exposure levels beyond point Y can, and should be curtailed. But it is a different

[115] Dr. Brusick then did cite to what he considered to be epidemiological data from a French study supposedly conducted to assess cancer differences in smokers of "blonde" vs. "brown" tobacco. However, there was considerable dispute over the existence of this study, and whether it was actually published in a reputable journal; that point was never finally resolved.

[116] In the regulatory world, that point, or level of exposure has apparently spawned numerous different descriptive terms, such as the "Reference Dose (RfD)," the "benchmark dose (BMD)," or the no-observed-adverse-effect level/lowest-observed-adverse-effect level (NOAEL/LOAEL)". *See, e.g.,* Exhibit VT-1699, pp. 2951-52. It is often standard procedure in regulatory matters to use a discount factor of 10X whenever extending data from animal studies to potential human risk, and another factor of 3-10X if there is "general uncertainty" of the linkage for any particular substance between animal and human exposure levels, to calculate the human NOAEL.

matter entirely to use that preliminary data to conclude, based on inference and "scientific judgment" alone, that exposures to chemical X below point Y do in fact reduce the risk of contracting disease Z. In other words, as noted above, there is insufficient proof on this record that the dose-response principle always works in the opposite, or inverse direction sufficient to support an affirmative claim that reduction of exposure below some given point will result in positive health benefits, or less actual risk of disease for a given individual.

138. Reynolds made much of the fact that the Vermont Department of Health has in recent years promulgated health advisories for the general public regarding the level of mercury that any person should be concerned about ingesting indirectly through consumption of fish caught in Vermont waters, especially pregnant women and young children, without having first done long-term epidemiological studies (with, of course, sufficient and adequate controls) on the consumption of fish with various mercury levels (presumably including no detectable mercury) by children under age 6 and/or pregnant Vermont women. Putting aside the considerable ethical issues which would be raised by attempting to conduct such a study with the usual scientific controls,[117] it is a false and unpersuasive analogy in any event.

139. First, unlike cigarette smoke, which is a highly complex and unpredictable mixture by itself, whose interaction with the human body is then further complicated by infinite variations in style and duration of the act of smoking, the mercury advisories, and the testing data on which they rely, focus on a single chemical or compound with fewer (if any) unpredictable variables in the ingestion of that substance. Reliance on the dose-response principle in the latter situation regarding mercury exposure, is thus more compelling because it is a more straight-forward, and less complicated application of the basic scientific rule. Second, the Vermont (and related federal) mercury advisories are in fact supported by epidemiological studies, at least with regard to exposure effects of mercury on pregnant women and their children. *See* Exhibit VT-1699, pgs. 2952-53 ("three epidemiological studies for which quantitative analyses have become available," with 779 mother-infant pairs, 900 mother-infant pairs, and 38 mother-infant pairs respectively, conducted over 5.5 to 6 to 7 years, respectively). It is not necessary to duplicate, and corroborate those epidemiological findings with similar studies performed just on Vermont women and children.

IV. The Eclipse Expert Panel

140. As previously noted, in the early 1990s Reynolds decided to continue development of tobacco-heating PREP that would be more commercially

[117] The critical distinction with an epidemiological study of cigarette smokers is that cigarette smokers, as Reynolds and the tobacco industry repeatedly emphasize, are making, and have already made the voluntary decision to smoke cigarettes. For Eclipse, the distinction is even more acute, in that the entire premise for the product is that it would potentially benefit smokers who have made a conscious decision not to stop smoking, despite awareness of the considerable, and now well-known health risks and other adverse consequences.

successful than the Premier. By 1996, RJRT had already done substantial design and testing work on what was to become Eclipse, and it first began to publicly share its preliminary data – e.g., smoke chemistry and initial toxicological data, its own human behavior studies, and the first information from some of the outside clinical studies – at what has become known as the "1996 Duke University conference." A number of the witnesses who have testified here, including some of the experts on both sides, and many of the in-house Reynolds scientists, were either in attendance, or made presentations at the Duke conference. The reaction to the preliminary data disclosed at the conference was generally positive, and Reynolds was encouraged to continue its research and development efforts. That conference also generally coincided with the first actual test marketing efforts for Eclipse, also in 1996, *see* below.

141. At meetings at the highest executive levels of RJRT in 1998,[118] after reviewing the lackluster reception given to Eclipse by the general public in the first test markets, *see* below, the decision was made to pursue an enhanced marketing and advertising campaign for Eclipse which would explicitly tout the positive health benefits which the in-house Reynolds' scientists, and head of the RJRT marketing department, believed their data supported. Although it was not the subject of specific testimony or evidence at trial, it may be inferred that this decision was also thoroughly vetted, and advice sought and obtained, as to the legal issues and requirements which would have to be satisfied to publicly make any such ad claims for Eclipse. The science and marketing departments of RJRT were accordingly instructed to put together a panel of outside experts who would review, and evaluate all of the testing data and other information procured by, or available to Reynolds concerning the Eclipse cigarette. The president and CEO of Reynolds told his executives in charge of the Eclipse program that an affirmative, and positive approval for any "reduced risk" claims from such an outside, independent panel, was critical, and essential to his approval to go public with those ad claims.

142. Dr. Gary Burger, head of the RJRT scientific department, was primarily in charge of assembling what became known (at least at first) as the "Eclipse expert panel." (Several years later, its name was changed to the Reynolds "Scientific Advisory Board".) As the chair of the panel, Reynolds was able to recruit Dr. Bernard Wagner, an MD and pathologist with excellent credentials and substantial experience with cigarette testing and tobacco-related disease research. Dr. Wagner had been an outside consultant for Reynolds on the Premier development. His consulting contract with Reynolds, and work on the Eclipse panel, was eventually extended for a total of some 7 years, and Dr.

[118] In 1998, RJRT was still part of the much larger food and consumer products conglomerate RJR-Nabisco, which had been formed in the early 1980s as the result of one of the first, and most spectacular leveraged corporate buyouts. *See* J. Helyar & B. Burrough, *Barbarians at the Gate* (1990). By 1999, the combination of food and tobacco in a single corporation was no longer as positive, especially given the 1998 MSA, and RJRT was spun off into its own free-standing company.

Wagner received almost $2 million in compensation, and/or reimbursement for expenses during that period. As stated previously, the court finds that, although the amounts of money spent on experts and professionals in connection with the Eclipse research and development was huge in absolute terms,[119] as to any particular individual, or person who testified at trial in this case, the money itself had no substantial affect on their scientific judgment or expression of professional opinion(s). Dr. Wagner was a credible, and candid witness.

143. The Eclipse panel was at all relevant times made up of Dr. Wagner, as chair, and eight other professionals with considerable expertise in the area of tobacco-related diseases and tobacco research. It included *inter alia* Dr. Rennard, as discussed above, and Dr. Donald Gardner, a pulmonary toxicologist, and editor/publisher of the journal *Inhalation Toxicology*, which was the place where a number of the articles in evidence here were eventually published. The panel did not, however, include any members with substantial professional expertise in epidemiological studies and quantitative statistical research. Dr. Wagner testified that he did not feel this was any negative, or drawback to the panel's work or conclusions, because he/they "knew" that "at some point" their recommendations and report(s) "would have to be studied in humans" and would "need some epidemiological help." All of the panel members were non-smokers.

144. The first, and most critical meeting of the Eclipse panel was in the Bahamas in January 1999, over 4 days (although the actual presentations, and discussions lasted approximately 2 and ½ days). Each panel member was provided a large, and substantial binder of all the testing data and study results (either in full report form, or in abstract, or summary form) developed to date regarding Eclipse. Presentations were made to the panel by the in-house RJRT scientists who had done much of the *in vitro*, *en vivo*, and human behavior studies, and by several of the outside clinical researchers (including Dr. Rennard) who had conducted research projects (as described above), primarily in abstract/summary form, or by Power Point. All panel members, and the outside, non-RJRT presenters, were provided with all travel, lodging and meals, and a "standard" honorarium of $2000 per day.

145. The "charge" to the Expert panel was primarily developed by Reynolds, i.e., by Dr. Burger, in the fall of 1998 prior to the Bahamas meeting. As later described in its April 1999 report, "the Expert Panel was requested to evaluate all of the pertinent laboratory, animal, and human data which addresses the validity of the assumption that Eclipse effectively presents less carcinogenic risk as compared with tobacco-burning cigarettes." That charge was then broken down into several sub-parts:

[119] In an address to an outside conference, one RJRT executive stated that Reynolds alone had spent "over a billion dollars" on PREP research, testing and development, over the 25 or so years involving both Premier and Eclipse. That staggering sum is reflective not only of the revenue stream generated by cigarette sales, but also the commercial imperatives at stake.

- What is the quality of the scientific evidence? Have the tests, analyses, research, studies and other evidence been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted by current scientific standards to yield accurate and reliable results?
- Does the evidence provide a reasonable basis for concluding that the Eclipse cigarette, as compared with tobacco burning cigarettes, presents to smokers a diminished risk of lung cancer.
- Does the evidence provide a reasonable basis for concluding that the Eclipse cigarette, as compared with tobacco burning cigarettes, presents to smokers a diminished risk of any other disease associated with smoking?
- Does the evidence provide a reasonable basis for concluding that, as compared with tobacco burning cigarettes, the Eclipse cigarette presents to smokers a diminished overall risk of diseases associated with smoking?
- Does the evidence provide a reasonable basis for concluding that, as compared with tobacco burning cigarettes, the Eclipse cigarette presents to smokers any increased risk of diseases associated with smoking?

The first, and last of those specific questions were answered "Yes"[120] and "No," respectively. Those conclusions are substantially supported by, and consistent with the evidence at trial, and will not be reviewed in any detail here.

146. The heart of the dispute here is the available scientific evidence to support an affirmative answer, and response to the middle three questions of the charge to the Eclipse panel. The panel's April 23, 1999 final report, which was drafted largely by Dr. Wagner with assistance from Dr. Burger's staff at RJRT, and signed by each of the panel members in late April or early May 1999, was seemingly unequivocal, and unqualified in its conclusions on those questions:

> 1. Eclipse reduces the risk for inflammatory-based diseases of the respiratory system.
>
> 2. Eclipse reduces the risk for smoking-associated cancer.

Exhibit RJR-0168, at 41. The published version of the panel's report, "A Safer Cigarette? A Comparative Study. A Consensus Report," 12 *Inhalation Toxicology* 1-48 (2000), essentially restated the same conclusion, although perhaps less

[120] As noted, the State presented considerable evidence challenging many of the testing assumptions, and/or methodologies relied on by Reynolds, especially the consistent reliance on the FTC method to generate cigarette smoke for all testing, but those disputes primarily concern the extension of the data to the "less risk" claims and not the testing itself, and in any event the discrepancies (if any) urged by the State were, on this level and within the 4 corners of the tests themselves, essentially marginal.

unequivocally: "The data indicate that Eclipse reduces the risk for inflammatory-based diseases of the respiratory system and, therefore, should reduce the risk for smoking-associated cancer as compared to tobacco-burning cigarettes."[121] Id., at 38, Exhibit RJR-0179, Bates pg # 0265.

147. The language used in the body of the Eclipse panel's report is more equivocal, and less certain as to whether the studies and data confirmed any actual reduction in disease risk. For example, with regard to the lab animal studies, the report stated as follows:

> It is generally accepted that studies designed to reproduce the observations of human lung cancer associated with smoking have not been successful. The scientific literature attests to the lack of reproducibility and weak statistical power limiting discrimination of differences between treated and untreated animals. Thus, chronic inhalation exposures are inadequate to compare the potential tumorigenic effects of different cigarettes.

Id., at 25, Bates pg. # 3839. Elsewhere, the Panel stated:

> Many of the compounds reduced were suspected carcinogens, tumor promoters, cytotoxins, mutagens, irritants, and vapor phase free radicals. Such a decrease in these compounds should be expected to reduce the health risk associated with smoking.
>
> The results . . . suggest that Eclipse may have the potential to significantly reduce the health risk of smoking.

Id., at 39, Bates pg. # 3853. The qualified statements "should be expected to reduce" and "may have the potential to significantly reduce" are simply not equivalent to the stated conclusions of the 1999 report that Eclipse does in fact reduce the "risk of [contracting] cancer, chronic bronchitis and possibly emphysema," as the Eclipse ads claim.

148. The Eclipse expert panel accepted, and confirmed that the available data developed by Reynolds itself, and in at least 2 of the outside clinical studies, showed that after switching to Eclipse, compared to use of conventional tobacco-burning cigarettes, "smokers took more, larger puffs"; "puffs were taken closer together in time"; Eclipse users had "substantially larger total puff volume"; and a "longer (approximately 1.5 minutes) time alight." *Id.*, at 27-28, Bates pgs. 3841-42. There is no specific discussion in the April 1999 report, and none of the panel members who testified at trial recalled any specific discussion during their

[121] Whether the simple tautology stated in that quote is in fact true, or supported by the extensive scientific evidence, is still a matter of dispute, but the court understands the statement to essentially be short-hand for the 2 conclusions stated in the unpublished panel report, which does address the two different strands of scientific support for statements about respiratory disease risk, and cancer risk.

meetings, about how these findings should be weighed, or factored into the panel's reliance on the scientific data which was in turn based on machine-generated smoke using the FTC method, which does not replicate actual human smoking, and would not reflect the differences in actual smoking behavior just noted.[122]

149. With regard to cardiovascular diseases, the panel report noted as follows, in at least partial explanation why no conclusions could be drawn regarding the effect, if any, of switching to Eclipse on risks of heart disease:

> There are no widely accepted animal models for cardiovascular disease development and risk, especially with regard to smoking. However, the observed reductions in the cytoxicity, mutagenicity, and inflammatory potential of Eclipse, coupled with the marked reduction in free radicals, free radical generators, carcinogens, mutagens, and cytotoxins, may result in Eclipse presenting less risk of developing cardiovascular disease, i.e., atherosclerotic plaque formation.

Id., at 35, Bates pg. # 3849. There was no persuasive testimony at trial, and no compelling discussion in the 1999 panel report, why the sense of scientific caution underlying the reluctance to reach any conclusion as to cardiovascular disease – when the cited data otherwise in support was all essentially the same – did not also apply to the panel's recommendations for cancer and respiratory disease.

150. In conclusion, the 1999 panel report stated the following:

> Overall study findings thus far suggest to R.J. Reynolds that Eclipse may present to smokers less risk of developing cancer, chronic bronchitis, and emphysema as compared to tobacco burning cigarettes.
>
> The panel unanimously agreed that humans should not smoke, since cigarettes are associated with risk. However, given the real world, where there are millions of adults worldwide who smoke and will continue to smoke, cigarettes with deceased propensity to induce disease need to be developed. It would seem that such cigarettes could provide a reduced health risk, but not an absolute absence of risk, to those inflammatory and tumorigenic constituents in cigarette smoke. Available chemical and biological data would indicate that the cigarette Eclipse may have the potential to significantly reduce health risk compared to cigarette which burn tobacco. After a decade of development and testing, the total weight of the evidence allows the Panel to make [its] conclusions in response to the specific charges to the Panel.

[122] The panel did accept, however, the claim of RJRT researchers that Eclipse switchers "did not smoke any more cigarettes per day than with their usual brand." *Id*., at 39. As discussed above, the court finds that conclusion is not supported by the record here.

Id., at 37, Bates pg. # 3851.

151. In one of its later reports (June 21, 2006) reviewing the data and approving the change in the actual Eclipse product being sold to the public, to prototype 5-014C/2005 – essentially an update, and reconfirmation of its previous 1999 report on Eclipse – the Scientific Advisory Board ("SAB") finally supplied its own definition of the term "risk" as it understood, and had used that term:

> 3. The SAB discussed and emphasized differentiation between the words "harm" and "risk." The SAB considers the word "harm" as a descriptive term describing an adverse effect such as decline in lung function; whereas "risk" is a mathematical ratio describing disease incidence based on clinical observations of actual disease in thousands of individuals.

Exhibit VT-1105, "Summary, SAB Meeting, San Antonio, TX, January 9-11, 2006," at pg. 4 of 4, Bates # 8103. Although made after the complaint in this case alleging that Reynolds' "less risk" statements on Eclipse were scientifically invalid, that later acknowledgement by the SAB is essentially an admission that no statements about the risk, or incidence of any particular disease can be made without supporting epidemiological studies and resulting human disease data.[123]

152. Applying the definition of disease "risk" formulated by the Eclipse panel/SAB itself, before Reynolds could make any marketing claim about "less risk" of disease to any given smoker by switching to Eclipse, it had to have scientifically valid evidence of the quantifiable likelihood a given smoker using a conventional tobacco-burning cigarette would have of contracting cancer, one of the respiratory diseases, or COPD; the exact same quantifiable, and statistically measurable likelihood of disease incidence in a long-term Eclipse smoker; and a statistically significant, and mathematically measurable reduction in the latter compared to the former. With regard to a huge population of human smokers, the only scientifically valid means of obtaining that quantifiable data is an epidemiological study, which Reynolds concedes it did not have or perform, and argues it should be excused from having to conduct.

153. In their testimony at trial, each of the members of the Eclipse panel/SAB who testified (all by video, or transcribed deposition) ultimately acknowledged the disjunction between the unequivocal nature of the final 1999

[123] The SAB then also noted in its 2006 report that the "Quality of Life" study which Dr. Rennard had been authorized by Reynolds to undertake (but as of late 2008, had not yet actually begun), would be "a significant step towards characterizing the health effects associated with smoking Eclipse compared to smoking conventional cigarettes," *id.*, at 3 of 4, ¶ 2, Bates # 8102, something which one would have thought would already have been completed before making any health benefit claims for Eclipse. Even at a projected length of 6 months and involving several hundreds of subjects, the SAB recognized that "this study will not directly measure disease, [and] the results cannot be directly applied to the risk of specific diseases." *Id.* At most, the "SAB views this study as a health status study that may demonstrate reduced harm . . . ." *Id.*

report conclusions, and the more limited nature of the evidence and study data they actually had. Dr. Wagner stated at trial that the Eclipse panel findings as of January 1999 were in fact only "preliminary," that the lab and animal testing data was sufficient only to say that Eclipse "could present less harm," but not "less risk." He stated that the lab and animal testing data were not sufficient "to demonstrate the hypothesis" that Eclipse actually presented less risk of contracting tobacco-related disease. Dr. Wagner agreed, consistent with the remark in the 2006 Eclipse update report, that any statement about "risk" and the incidence of disease required further epidemiological studies, and that Reynolds did not have any such data, in 1999, or even as of trial. He stated that conducting such studies would be "difficult."

154. Dr. Wagner defended the 1999 report's final conclusions on the grounds that all of the data they did have from the lab, animal, human behavior, and outside university studies was "all moving in the right direction," it was all generally consistent, Reynolds was "on the right track," the "trends" in the data all "appeared positive," and thus the "total weight of the evidence" standard in his view supported the use of scientific judgment, and permissible inference to make the "less risk" claim. However, as Dr. Rennard later explained, the "total weight of the evidence" standard, and concept was not something he was familiar with, and it was simply given to the panel members, without any explanation or definition; he testified the panel did not actually weight any one study, or its reported results, against another. As Dr. Wagner later characterized it, applying the "total weight of the evidence" standard was essentially an "intuitive process," and not based on any particular quantitative analysis.

155. The record here clearly demonstrates there was never any weighting, or discussion by the Eclipse panel of the strengths and weaknesses of any particular study results or data set, or how any anomalies in the data or testing methodologies – e.g., the use of the FTC method for all machine-generated smoke –should be factored into their assessment and analysis. As Dr. Rennard later testified, the final conclusory statements of the panel report "smoothed over" the caveats in the body of the report, and were simply given to the panel for a "yes" or "no" vote, together with the undefined "total-weight-of-the-evidence" standard, and on that basis he felt compelled to go along with the final conclusions as drafted.

156. How does one possibly explain the decision of the Eclipse panel members, and especially its chairman Dr. Wagner, to overlook, or at least minimize the obvious gap between what their training and experience told them was needed to make a definitive, unequivocal, and scientifically supportable "less risk" claim, and the promising, but still preliminary data they actually had? As noted, all of the panel members were non-smokers, and each was personally, and professionally aware of the enormous toll on human health caused by cigarette smoking. Especially for Dr. Wagner, it appears there was additional influence from his own personal experience; he testified that his father was a heavy smoker, who had died of lung cancer. For Dr. Wagner, it was "important to do

something" for committed smokers who could not, or would not quit, and the data did show (and the court has found on this record) that Eclipse did not present any additional, or different risk of harm or disease beyond conventional tobacco-burning cigarettes, while presenting the tangible, and tantalizing possibility that Eclipse might do some good for some smokers, even if they could not (yet) quantify what that potential improvement might be.

157. The panel's definitive statement of its conclusions in the 1999 report appears to have been intended for 2 audiences, i.e., potential consumers, and other tobacco researchers. As for the latter, Dr. Wagner intended the definitive statements at the end of the report to be a strong, and clear signal to other professional researchers, and to the general medical community concerned about tobacco-related disease, that Eclipse (or other similar tobacco PREPs) had passed these preliminary screening thresholds, and that the data supported "going forward" with the necessary, and additional clinical studies and epidemiological research. Dr. Wagner hoped that a strong statement in their report, and the published article to follow, would get other medical schools and universities interested in doing the required additional research to validate Eclipse (or some other PREP) as in fact reducing the risk and incidence of disease from smoking, in order to overcome the reluctance of the larger medical and scientific community to participate in such research which carried the stigma of "cooperating" with the tobacco companies. In other words, Dr. Wagner, and the panel members who all voted in favor of the ultimate definitive concluding statements of the 1999 report, appeared willing to use the prestige, and apparent objectivity and lack of tobacco company bias of the panel members, to "oversell" the results in order to promote, and hopefully obtain the additional clinical and epidemiological research they knew was needed to make that unequivocal "less risk" claim.

158. As for consumers, and the real smokers whom Dr. Wagner and the panel members were genuinely concerned with, it appears that the Eclipse panel was well aware of, and accepted Reynolds' own consumer behavior data from the Eclipse test marketing, *see* below, which indicated that the promising, and potential reduction in disease risk which Eclipse offered, would never be realized by any significant number of committed smokers without a dramatic, and unequivocal statement of its possible health benefits. The 1999 final report adopted the following findings of the Reynolds' human behavior studies:

- Tobacco-heating cigarettes are always rated inferior to tobacco-burning cigarettes on number of sensory attributes and overall acceptance
- Apparently, smokers will not switch to Eclipse without understanding the potential health benefits

Exhibit RJR-0168, at 28, Bates # 3842. Thus, even without knowing the results of consumer perception studies which establish that inserting the words "may" or "could" or other qualifiers in the marketing message would essentially be

ineffective and disregarded by consumers, *see* below, Dr. Wagner and the panel appear to have intuitively understood that a definitive, and unequivocal statement of the "less risk" claim (a) was necessary to persuade any significant number of committed smokers, who were otherwise at substantial risk of contracting tobacco-related diseases, to adopt Eclipse and obtain whatever potential reduced risk benefits there might be; and (b) would in fact be understood in that manner by consumers, even if the "could" or "may" qualifiers were used, as would otherwise be necessary for the sake of scientific validity and adequate support for those definitive statements, given the absence of epidemiological data.

159. Although they each eventually voted in favor of the final 1999 report, and signed it, two of the Eclipse panel members were initially more vocal about maintaining scientific credibility for their ultimate statement, and argued for inclusion of the "may" or "could" qualifiers in the panel's final conclusions. Dr. Martin Cline (an *emeritus* professor of medicine at UCLA, with experience in cancer and hematology) later testified, by deposition in this case, as follows:

> Q. Now, did you consider the statement without the word "may" to be inaccurate?
> A. . . . We don't know whether or not it [the Eclipse] reduces the risk; no one has done the definitive tests. So yes, I would feel that substitution of the word "may" was appropriate.

Cline Deposition (7/16/07), at 126:9-16. He also testified that he basically got tired of debating the point, and signed the report without reading it in detail, or even realizing that the final conclusions omitted any qualifying language:

> Q. Now, is this not a reflection of the fact that you did subscribe to a document that did not have the word "may" in it?
> A. Unfortunately, I probably signed this [the 1999 Eclipse panel report] without reading it.
> Q. Well, having – looking at this now, is this something you believe consequently you would not have subscribed to?
> A. Yes, that's right. I think my opinions were expressed here. And I think probably by the time I got this report, I probably said to myself, "I've had enough of this stuff. If he [Dr. Wagner] wants to do it, fine." But I don't think I read this report.

Cline Deposition (7/16/07), at 129:13-25.

160. Dr. Cline further explained his acceptance of the panel's slightly more conditional conclusion, as stated in the published version of the panel report, *see* ¶ 146 above, as follows:

> Q. The last paragraph reads – . . . "The data indicate that Eclipse reduces the risk for inflammatory-based diseases of the respiratory system and,

therefore, should reduce the risk for smoking-associated cancer as compared to tobacco-burning cigarettes." Is that an accurate statement of the findings of the Scientific Advisory Board?
A. Yes, I think – I was comfortable signing off on that statement, and I still would be.
Q. Is there some aspect of it that causes you concern about the statement made?
A. I don't think the evidence is as strong as the data relating to carcinogenesis, but I think it still is an acceptable statement in the context of "may reduce the risk of inflammatory disease."
Q. Well, the phraseology is "Eclipse reduces the risk for inflammatory-based diseases," but there is a qualifier that says "the data indicate that." Is that a keyword, in your mind, the word "indicate"?
A. Yes. If you had said "the data show that Eclipse reduces the risk for inflammatory disease," I would not have signed off on that.

Cline Deposition (7/16/07), at 140:6 – 141:7.[124]

161. On further examination by counsel for the State, with respect to the Eclipse ad statements themselves, Dr. Cline attempted to explain the distinction he drew from the available scientific evidence and what claims about reduced disease risk could properly be made for Eclipse:

Q. . . . I asked you whether or not this advertisement . . . if it stated, instead of a cigarette that may present les risk of cancer, stated a cigarette that presents less risk of cancer, would be accurate.
A. And I said I thought it would be inaccurate.

* * *

Q. Do you consider that it is a hypothesis that smoker [who] switches to Eclipse will reduce his risk of cancer?
A. It is an hypothesis supported by some evidence, yes.[125]
Q. So the evidence that supports it, would you say, is consistent with that hypothesis?
A. The evidence that we know is consistent with that hypothesis, yes.
Q. All right. But evidence that is consistent with the hypothesis may not have yet risen to the level where it proves the point of the hypothesis; is that correct?
A. . . . I think that is a correct statement. We have not proved the hypothesis that this is – [Eclipse] definitely reduces the risk for cancer. . . .

[124] Dr. Cline went on to note, and discuss the semantic inconsistency of linking cancer risk reduction to reduction of respiratory inflammation, *see* ¶ 146 above, but concluded that the second part of the sentence – again, because of the "indicate" and "should" qualifiers – "was acceptable, even though it's a slight *non sequitur*, in my mind." *Id*.

[125] Dr. Cline had repeatedly testified during examination by Reynolds' counsel that "the evidence is consistent with a position that Eclipse presents less risk of cancer."

It is consistent with it, it is likely that it does, it may possibly; but it does not – it is not proven that it reduces the risk for cancer.

Cline Deposition (7/16/07), at 154:14 – 156:18.

162. Dr. Donald Gardner, the pulmonary toxicologist and editor of the journal which later published the Eclipse panel report, *see* above, was also more ambivalent in his actual trial testimony as to the strength of the definitive, and unqualified conclusions stated at the end of the 1999 report. He repeatedly emphasized the qualified nature of the many other statements made in the body of the report, and his opinion that absolute "less risk" claims were not supported by the available data and study results Reynolds did have as of 1999-2000. With respect to his position in his deposition testimony that qualifiers should have been used in the final statements, such as "may" or "could," Dr. Gardner said:

Q. Well, earlier you gave an answer in which you say "may" –
A. "Could."
Q. – "could be, suggested."
A. Yes.
Q. And you equated those terms as – as meaning the same thing?
A. Yeah. . . . It's – you could put in that context of probability.
Q. Is that how you define it?
A. When I say the word "may," I'm not necessarily putting it as a certain probability that it's going to happen. I use it only as a descriptive term that the data that is present, available, the weight of the evidence, the total accumulation of all the data . . . would indicate this may be less harmful than a conventional cigarette.

Gardner Deposition (5/30/07), at 102:1 – 103:5.

163. Dr. Gardner further explained that use of a qualifier like "may" was necessary to inform both the public, and the larger scientific community, that more studies were needed to make a definitive statement as to actual human disease consequences:

Q. And why would you use the word "may"?
A. Because it indicates to the scientists, to the public, to anyone that at this time our database would indicate that this is less risky than – less harm than a conventional cigarette, but there is going to be more database to follow. There's going to be new studies, additional studies, more evaluations. And at the present time the best we could [say] is it may.

And people that read – the scientific community that reads this, says "may," they understand. It's a preliminary study here. They understand what preliminary means. And it's ongoing. They understand what ongoing study means. So I think people understand when you talk to [scientists] and toxicologists when the say "may," they understand what that word means.

Gardner Deposition (5/30/07), at 107:5 - 25. As a non-Reynolds scientist and representative of the larger scientific community, Dr. Gardner's own understanding, and testimony clearly establishes that the larger scientific community would have considered the Eclipse data to be only "preliminary" as of 1999-2000[126] (and thereafter, inasmuch as RJRT concedes there have been no significant, additional scientific studies of Eclipse), and that further research would have to be conducted before any definitive statements could be made about Eclipse actually reducing the risk, or incidence of any tobacco-related disease.

164. As Dr. Rennard confirmed in his trial testimony, removing any qualifiers from the statements that Eclipse does "present less risk" of contracting a tobacco-related disease, is a "stronger statement scientifically" than a "may present less risk" claim. In his view, the former does "require a greater body of evidence" to support it, including epidemiological studies of actual disease incidence, and development of validated biomarkers for each disease. He ultimately viewed his vote in favor of the 1999 Eclipse panel report as essentially "telling Reynolds" that further development of, and continued research on Eclipse "was a good idea."

165. Dr. Burger, the head of the RJRT scientific department and company liaison to the Eclipse panel, testified in his deposition (taken well after he had retired from Reynolds, in early 2001) that he understood at the time of the final 1999 report, that the affirmative health claims for Eclipse would eventually require "human testing data" to support those statements. In his view, the preferred term, or formulation of the claim was "potential to reduce risk," or "probably reduces risk of some diseases," as being consistent with the evidence they did have. Dr. Burger was troubled, however, by what he considered to be the "irrational, bizarre, naive, and frustrating" position of the larger scientific and regulatory community as insisting on a "30-year study" of "10,000 smokers" since he argued (and agreed with the other principal Reynolds witnesses) that

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[126] In a follow-up summary report by the Eclipse panel (dated April 18, 2000), the statements were apparently less absolute, and more qualified, a point noted by Dr. Gardner.

> Q. And then in the second paragraph it says "Eclipse may have the potential to significantly reduce health risks compared to cigarettes which burn tobacco."
> A. It's interesting, "may, potential."
> Q. That's exactly my question, Dr. Gardner.
> A. That's what it was.
> Q. What does that mean to you?
> A. May potentially have significantly reduced health risks, exactly what it says. It may have the potential. And it's called PREP, potential reduced-exposure product, potential.

Gardner Deposition (5/30/07), at 102:1 – 103:5. Elsewhere, and throughout his deposition testimony, Dr. Gardner cited favorably to the IOM report, *see* above, and generally agreed with its conclusions about the necessary framework for evaluating any PREP cigarette, including Eclipse. He did not express any misgivings about the IOM report, as being biased or unreliable.

such a study would be difficult, expensive, and involve too much delay to complete before any of the potential benefits might be realized by actual smokers.

166. To reiterate, Dr. Wagner, as chair of the Eclipse expert panel, believed the final statements in the 1999 panel report were valid, and appropriate because of the "high degree of correlation" between all of the testing data presented by Reynolds and his expectation that switching to Eclipse "would indicate a good response in humans," and because he was "confident" that Eclipse would not be additionally harmful to humans. However, he ultimately agreed that Reynolds "needed more human data" and that "once you get through the human studies," only then would it be a "fair statement" to make, or "advertise a 'less risk' claim."

167. In an October 28, 2002 letter to Dr. David Doolittle (VP at Reynolds, one of the principal executives in charge of the Eclipse program over many years, *see* below, and a principal RJRT witness here), well after Reynolds' 2000 decision to make affirmative health benefit claims for Eclipse, Dr. Wagner reported his summary of the SAB meeting held on October 13-15, 2002 at the Hilton Hotel at O'Hare airport in Chicago.

> The RJRT Scientific Advisory Board reached consensus that the new data developed by RJRT scientists[127] since our last SAB meeting do not alter any of the conclusions reached in our manuscript [as actually] published in *Inhalation Toxicology*. Indeed, the SAB concluded that the new data provided additional substantiation for our key conclusion that "Overall study findings reviewed by the panel suggest that Eclipse may present to smokers less risk of developing cancer, chronic bronchitis, and emphysema as compared to tobacco burning cigarettes. . . ."
>
> The Scientific Advisory Board is pleased at the continued progress that RJRT has made in developing technologies that offer the potential for reducing the risks of smoking.

Exhibit RJR-0203, Bates pg. # 4898. The qualified, and not absolute, nature of the scientific and medical claims which the SAB was at that point comfortable with endorsing for Eclipse in 2002 (and thereafter), is obvious. However, Reynolds did not change any of the Eclipse marketing or ad statements, and continued to rely on the absolute and unqualified final conclusions from the unpublished April 1999 panel report, especially in promoting the "Scott ad" in 2003 and 2004.

168. As noted above, the Reynolds Scientific Advisory Board continued to meet periodically, and review updated, or new information from RJRT concerning Eclipse. Those meetings occurred by telephone conference, or by 1-2 day gatherings in various locations (e.g., San Francisco, CA (3/29-31/01); Grand

[127] This would appear to be a reference to the continuing smoke chemistry analyses done by RJRT for the various new prototypes of the Eclipse, including the 5-104C/2005 version which was later approved, and sold commercially from mid-2006 to the present. *See* discussion above, and below.

Resort & Spa, Traverse City, MI (6/29-30/05); San Antonio, TX (1/9-11/06)). As discussed, one of the major decisions taken later (in 2006) was to approve the change in the version of Eclipse actually being sold to consumers, to the 5-014C/2005 prototype. This change, and the consistent marketing thereafter of a "stable market product," was supposed to be the basis for the more intensive clinical study, the "Quality of Life" ("QOL") study to be undertaken by Dr. Rennard, *supra*, but that study has not yet been commenced.

169. In the summary of the "Conclusions" from the 2005 Traverse City meeting of the SAB, the report highlighted a number of the things which the SAB and Reynolds scientists did not yet know about Eclipse and its relationship to actual human disease risk, and some of the additional efforts that should be undertaken to fill in those gaps, including the absence of any validated biomarkers for tobacco-related diseases, and the above-mentioned QOL by Dr. Rennard:

> 4. With the increasing use and importance of *in vitro* toxicology, the SAB suggested that new models be developed utilizing human cells as targets for important molecules involved in tobacco toxicology. Such studies may be of value in making risk assumptions for humans.
>
> 6. RJRT is in a unique position of having collected data from multiple chemical, in vitro, animal and human studies as regards the same cigarette. A vigorous attempt should be made by RJRT scientists to correlate these various endpoints in an effort to maximize the utility of these data. In this regard, RJRT should develop a protocol for measuring useful biomarkers of exposure in Eclipse smokers. Dr. Steve Rennard will develop a "quality of life (QOL)" study [of] Eclipse smokers. RJRT scientists should participate in such a study.
>
> By combining the Eclipse Biomarkers of Exposure study with the QOL evaluations, a more comprehensive and unified picture will evolve. . . . Finally, the SAB recommended that RJRT consider using the database on Eclipse smokers to monitor potential health effects when smokers switch to Eclipse.
>
> 8. It is now clear that RJRT will need to support more clinical work on Eclipse. This will set the standard for all future potentially reduced risk cigarettes.

Exhibit RJR-0289, Bates pg. #s 9329-9330. These are all items that one logically infers would, and should have been completed before making any affirmative health benefit claims, i.e., that switching to Eclipse in fact reduced the risk for any given smoker of developing the referenced tobacco-related diseases. *See also* ¶ 151 & fn. 123, *supra*.

170. Despite Dr. Wagner's reference in October 2002 to certain "new data," essentially no significant, or additional study or test data of any real substance in support of the Eclipse health benefit claims – i.e., directly correlating Eclipse with the incidence, or risk of human disease – was presented to the SAB from 2000 through 2006, beyond what was relied on by the Eclipse panel for its April 1999 final report.

V. Eclipse Marketing & Actual Eclipse Ad Message

171. During the 1990s, domestic cigarette sales in the United States were generally declining, and Reynolds' sales losses were somewhat steeper than its competitors. Over the decade, RJRT suffered a 36% decline in its market share domestically; by 2000, Reynolds' total market share was down to 23.5%, from an earlier market share of 29.5%. Consumer studies showed that continuing, if not escalating concern over the obvious, and sometimes deadly health risks of cigarette smoking were in part responsible for the decline, as well as the increasing cost to consumers (which was driven in part by increasing cigarette taxes in most states, which in turn were being levied both for revenue reasons and to discourage cigarette smoking). Development, and successful sale of a genuine PREP cigarette (e.g., Eclipse) was thus viewed within the industry generally, and within Reynolds, as a means of reversing its cigarette sales decline and recapturing market share, as well as simultaneously offering a product to its customers which would genuinely offer them a potentially reduced risk of contracting tobacco-related diseases. A 1991 memo within Reynolds proposed a "strategic plan" for "reversing [RJRT's] market decline" by "competing for market share" of "committed smokers" by continuing to develop tobacco-heating products with potentially less risk, including what became the Eclipse.

172. As previously noted, Reynolds first "went public" with its preliminary chemistry and lab data results on Eclipse, at the so-called "Duke conference" in 1996. At the same time, RJRT had already begun its first actual test-marketing on an actual Eclipse cigarette, in Chattanooga, TN. The conference, and RJRT's presentation, garnered some positive press and national publicity, including an August 1996 article in *USA Today*. *See* Exhibit RJR-0749. That newspaper article mentioned that, in 1996, Reynolds (unlike today) still would not concede "that cigarettes cause disease," but it then went on to summarize essentially the same smoke chemistry and lab data presented here, as to reduced exposure to many, if not most of the chemicals and compounds in tobacco smoke thought to be most injurious to human health, and the company's premise that "[i]f cigarettes cause cancer, this one [Eclipse] is less likely to."[128]

[128] The article quoted Dr. Tashkin, *supra*, who had attended the 1996 Duke conference, as follows: "The data that I heard today suggest that Eclipse significantly reduces the carcinogens in the tar phase of tobacco smoke and some of the volatile constituents that are important in causing chronic bronchitis and emphysema." Some 13 years later, at trial, the gist of his testimony was essentially the same, although it took much longer to present than a simple *USA Today* quote.

173. In a sidebar, the 1996 *USA Today* article also highlighted the essential problem that Reynolds was already encountering with Eclipse, just as it had previously with Premier: consumer resistance.

> Eclipse doesn't light up smokers. Chattanooga, TN – Smokers are curious about R.J. Reynolds' Eclipse, but few seem to stick with it after trying it. Test marketing began here in June. "Consumers are hesitant to purchase them," says Joyce Smart of Bi-Lo Supermarkets. Tobacco Mart's Ken Patel says: "We sell maybe a pack in 20 days." "I like the way it tasted and the fact it didn't bother non-smokers as much," says Ann Fuller, who tried them for a week before giving up because they are hard to light. Michael Richards hated it. "I didn't like the taste at all. It had no smoke, no nicotine satisfaction, and it wouldn't stay lit."

The initial marketing, and ad claims for Eclipse made no affirmative health benefit claims, but mainly touted the lack of second-hand smoke, and other "aesthetic" or "cosmetic" benefits.

174. Reynolds used several standard marketing and consumer research techniques to develop the approach to selling Eclipse, including "focus" or "discovery" groups with invited smokers to "teach" them how to "smoke" the Eclipse, including video demonstrations, and lots of free samples. The participants were selected by Reynolds from its own database of smoker s in the Chattanooga area (some 5000-10,000) created from direct mailings and returns from free coupons. The head of RJRT's marketing department concedes there was still "adverse word of mouth" and other negative consumer reaction, despite their efforts to present Eclipse in appositive manner.

175. The Eclipse test marketing continued with another trial in Lincoln, NB, in 1997. Reynolds tweaked its ads (but still no direct health claims), lowered the Eclipse price to be comparable to conventional cigarettes, and tried promoting Eclipse only in "upscale" stores to perhaps capture more "educated" consumers more concerned about the negative aspects of smoking. A third test market was launched in Atlanta, GA in 1998. The results continued to be disappointing, with little consumer acceptance. At that point Eclipse was "not a successful product."

176. As discussed above, during this same period Reynolds was continuing its own in-house, and other "human behavior" studies on Eclipse (as well as further lab and small clinical testing, *supra*), which confirmed, *inter alia*, that smokers who did commit and switch to Eclipse as their "usual brand" of cigarette, smoked it more intensely, with longer and deeper puffs, and on average for 1 and ½ minutes longer than a conventional cigarette.

177. As noted above, by 1998 – after also considering whether to abandon the Eclipse effort entirely – the chief executives at RJRT had decided that it was time to step up their efforts to develop and market Eclipse, including

consideration of whether the scientific data they had generated, and obtained from outside studies, would support making positive health benefit claims. The Eclipse expert panel was set up, and, as discussed above, its January 1999 review of and April 1999 "final report" on the Eclipse testing data was eventually completed, with the final written conclusion that positive, unqualified health claims could be made for Eclipse. As discussed previously, the panel's final report had already noted that consumer resistance to adoption of Eclipse was very high, and without affirmatively communicating to smokers any positive health claims there might not be sufficient incentive to overcome the other negatives for Eclipse, thereby reducing the potential to achieve some of those positive health benefits which the panel thought were possible with Eclipse (while at the same time presenting little, or no downside risk of switching to Eclipse).

178. By early September 1999, following further review and analysis of the test marketing and in-house consumer, marketing, and "human behavior" studies discussed above, the "Eclipse Planning Group" within RJRT had developed its essential "mission statement" – "Develop and coordinate the implementation of a comprehensive plan for the successful launch and long-term market success and growth of Eclipse." Exhibit VT-0355. The document further stated:

> Eclipse Planning Group Goals
> I. Clearly identify and state business and public health goals for the brand
> A. Gain management approval
>
> **Business Goal:** Make Eclipse a viable business opportunity that is well positioned for long-term growth
>
> Business Model
> - Develop a brand concept to motivate educated trial and provide compelling reasons for conversion
> - Create a business channel and model that will make investment and profit hurdles clearly achievable
> - Provide product that will sustain repeated trial and ultimate conversion
> - Create a public environment conducive to trial and conversion
>
> **Public Health Goal:** Provide committed smokers with alternative, consumer-acceptable cigarettes that have the potential to reduce the health risks associated with smoking
>
> Public Health Model
> - Help develop consensus among the public and public health authorities, regulators and legislators that reduced risk cigarettes are desirable as alternatives for smokers who have decided not to quit

- Help develop consensus among the public and public health authorities, regulators and legislators that Eclipse is a reduced risk product
- Help create an environment where the public and public health authorities, regulators and legislators accept (and possibly even encourage) reduced risk cigarettes as alternatives for smokers who have decided not to quit
- Work with public health authorities, regulators and legislators and others to encourage smokers who have decided not to quit to switch to reduced -risk alternatives like Eclipse

Id., page 1, Bates pg. #8869. It was obviously the intention of Reynolds to sell its Eclipse cigarette, at least in part, by enlisting the scientific and regulatory communities, if possible, to endorse Eclipse as in fact a "reduced risk product" even though the totality of the available evidence, and data only supported a claim that Eclipse was a promising, but only potentially reduced exposure product.

179. The "Basic Assumptions" relied on by the Eclipse working group included the following:

- This [next] test market may represent our last chance to make Eclipse a marketplace success
- There are enough conflicted smokers in the U.S. to sustain at least a break-even proposition for this brand even if we convert one or two out of every hundred conflicted smokers
- There are compelling public health reasons for us to make every effort for this brand to be success
- Meaningful claims appear to be critical to achieving market success
- Smokers will try Eclipse and will convert to Eclipse if they perceive that the value of the benefits outweighs the adjustments
- We must develop comprehensive, integrated and aggressive public relations and public health communications plans

Id., page 2, Bates pg. #8870.

180. To gain the "management approval" the team knew was essential to proceed further with Eclipse, and begin the critical marketing effort with affirmative health benefit claims, a meeting with then-CEO Andrew Schindler and several members of the panel was set up later in the fall of 1999, at the company headquarters in Winston-Salem, NC. Dr. Wagner, the chair of the panel, was present, as was Dr. Burger, then the head of the RJRT research department, and the heads of the marketing and sales departments. Schindler needed to obtain face-to-face scientific, and medical confirmation for the "less risk" ad claims the Eclipse team wanted to make for the product. Although not

precisely the same as the "Scott ad" at issue here, *see* above, which was used later in 2003-2004, the group was shown some "mock-ups" which had already been prepared,[129] and were being used even before the fall 1999 meeting, in consumer testing by Reynolds (and outside contractors).

181. Although there was some discussion in the fall 1999 meeting about the use of the word "may," or other qualifiers in the proposed advertising language, the members of the panel, and the representatives of the in-house research and scientific departments, were still essentially in agreement with the final written conclusion(s) of the 4/99 panel report:

> 1. Eclipse reduces the risk for inflammatory-based diseases of the respiratory system.
>
> 2. Eclipse reduces the risk for smoking-associated cancer.

See ¶ 146, above. These opinions were personally expressed to Mr. Schindler, and he was then assured, and satisfied that the medical and scientific data developed to date for Eclipse would support public ad claims affirmatively stating positive health claims from switching to Eclipse. He approved going forward with further test marketing to include such claims.

182. The "re-launch" of Eclipse with the affirmative health benefit claims took place in the spring of 2000, in Dallas – Fort Worth, TX. However, after further discussion within the Reynolds marketing and sales departments, and after apparent consultation with Reynolds' attorneys and/or in-house legal staff,[130] the language chosen, and actually used for all Eclipse ad claims going forward, whether in print, or in the special Eclipse websites (*see* below), was the formulation sued in the 2003/04 "Scott ad," i.e., "a cigarette that may present

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[129] Dr. Wagner in his trial (i.e., deposition) testimony denied that he was actually aware of, or asked to "approve" the specific ad claims for Eclipse. Perhaps it is just a matter of semantics, but the persuasive evidence is otherwise. However, the court understands Dr. Wagner's effort to preserve his self-perception as being scientifically neutral, and this point does not significantly detract from his credibility, and candor otherwise.

[130] Although there was no direct evidence at trial of Reynolds' consultation with outside attorneys, or even in-house legal advisors, concerning the exact language of the Eclipse ads, it is inconceivable that RJRT would have commenced making these public ad claims without such consultation. Its marketing director for Eclipse testified at trial that "the lawyers made them put it [i.e., the word "may"] in" the ads. The record also shows that Reynolds often turned to, and used outside counsel on these types of issues, e.g., to respond to the IOM report, or to present RJRT's position to various regulatory bodies such as the FDA. The circumstantial evidence thus supports such an inference, that the exact language actually used in the Eclipse ads was influenced, at least in part, by consultation over the potential legal issues involved in making such claims, irrespective of what Reynolds thought the scientific evidence actually established, or what the actual consumer perception might be from such ad language. By 1999 and 2000, Reynolds (and the other signatory tobacco companies) were of course subject to the MSA terms, and the provisions of the Consent Decree in this case, which prohibited the use of any "material misrepresentation of fact" in its marketing claims for any tobacco product.

less risk of cancer, chronic bronchitis, and possibly emphysema." Reynolds' executives also thought this qualified claim was more consistent with the actual body of the 4/99 Eclipse panel report, as discussed above.

183. This specific intention to make only a qualified claim about the potential reduction in human disease risk from switching to Eclipse, was clearly and unequivocally articulated by Reynolds at the time, from the top down, beginning with Mr. Schindler himself. At the RJRT annual shareholders meeting on April 19, 2000 in Winston-Salem, Schindler's remarks included the following in connection with the first announcement of Eclipse marketing with positive health benefit claims:

> Now, I want to tell you about the progress we've made toward reducing the risks of smoking. It's a fundamental issue for smokers, our company, and our shareholders. On one hand, there are 45 million Americans who choose to smoke, and the majority of Americans believe cigarettes should continue to be legal. On the other hand, smoking presents significant and inherent risks for a number of serious diseases, and may contribute to causing these diseases in some individuals.
>
> These two facts – that smoking is legal and presents health risks, form the basis for the controversy surrounding cigarettes. These facts also form the basis for our commitment to develop new cigarettes . . . that have the potential to reduce risks to smokers. . . . That's our commitment, and I can't emphasize how important this is for me as chairman and CEO of this company.
>
> As we all know, no cigarette is safe. So we have to have the discipline and integrity to determine when a new cigarette or process van be shown to potentially reduce the risks from smoking. And we have to distinguish that from other product modifications that may not affect the risks from smoking.
>
> Before making any claim that a new cigarette may present less risk of smoking, it must first be substantiated by extensive scientific testing and then verified by independent experts.
>
> We know how to reduce TSNAs [tobacco-specific nitrosamines] in our cigarettes . . . But, we're not going to make any reduced-risk claims, because the science doesn't verify it.
>
> However, we do plan to make potential reduced-risk claims with Eclipse. Our scientific methodology has verified that making a specific reduced-risk claim is the appropriate and responsible action to take.

See Exhibit VT-1488A.

184. In his remarks on 5/19/00 to RJRT shareholders, Mr. Schindler continued to extol Eclipse, and the company's considerable efforts to develop and test the product, but he also repeatedly emphasized the qualified nature of the results, and the actual marketing claims to be made:

> Based in these findings [of the Eclipse expert panel], we want to tell smokers about the potential benefits of Eclipse, and to see if they are interested enough to switch to Eclipse.
>
> I want to talk for a minute about the timing of this announcement. Why now? Why not wait? Because, now we know, and believe smokers should also know, about the potential benefits of Eclipse. It's time to see if this type of cigarette is acceptable to smokers.
>
> I feel confident that we are delivering on our commitment to potentially reduce the risks of smoking. . . . As shareholders, it's important for you to know, not only that we think and care about potentially-reducing the risk of smoking, but also that we act on it.

185. The substance of Mr. Schindler's remarks were repeated, and echoed in other contemporaneous statements made by Reynolds' representatives, in radio and other media interviews, including a nationally-broadcast NPR interview on 4/24/00. In all of their public comments at the time, Reynolds itself asserted, and acknowledged, that for advertising and marketing purposes, the available scientific data they had accumulated only supported a qualified, or conditional statement of possible, or potential reductions in the risk of tobacco-related diseases (e.g., "may result" or "may present") by switching to Eclipse. For example, in its 4/20/00 cover letter to the retailers in the Dallas/Fort Worth area who were going to participate in the new test marketing, Reynolds stated the following:

> 1. Eclipse may present less risk of cancer.
> 2. Eclipse produces less inflammation in the respiratory system, which suggests a lower risk of chronic bronchitis, and possibly even emphysema.

The letter also restated one of the principal motivations for Reynolds to proceed with affirmative health claims, i.e., that smokers were unlikely to overcome the negative smoking experience with Eclipse and to switch to Eclipse, without pushing the positive health benefits:

> [T]he claims we have made to date on Eclipse have not been compelling enough to convince adult smokers to switch to Eclipse. . . . We are trying to determine if our [new health benefit claims] are meaningful enough to adult smokers and if enough smokers are willing to switch to Eclipse to support distribution through traditional channels.

See Exhibit VT-0725.

186. In a prepared Q&A sheet for RJRT representatives who might interact with the media (dated 4/15/00), the company again acknowledged the limited, and qualified nature of any "reduced risk" claims that could, and should be made for Eclipse:

> **Why do you say "<u>may</u>" present less risk of cancer?**
>
> - That is a difficult question to answer, because there is no official standard for what constitutes a safer cigarette. There is no agreed-upon scientific test to compare the relative risks from different cigarettes. . . .
> - You can't quantify the degree of risk reduction. We have conducted various tests that members of the pubic-health community use to support the link between smoking and certain diseases or health risks, as well as additional tests appropriate to investigate the biological effects of cigarette smoke. There is no simple test, or set of tests, that the scientific community has agreed on to measure the relative risk of cigarettes. [131]

Exhibit VT-0391, at 5, Bates pg. #0333. The Q&A sheet also acknowledged that the definitive final conclusions of the 4/99 Eclipse expert panel report were arguably inconsistent with the body of the report. "(Note if you read the complete panel report it also has the 'may' word. By focusing on only the conclusion section, you could think they were more emphatic than the actual report cites.)" *Id.,* at 6, Bates pg. # 0334. RJRT representatives generally followed this internal advice, in making statements about Eclipse in conjunction with the 2000 re-launch of Eclipse with positive health benefit claims, by emphasizing the word "may" and the qualified nature of the ad claims, e.g., a Dallas TV interview (David Iauco said in part "the science" did "not allow" RJRT to "make any definitive claims" about Eclipse's positive health benefits), and 4/24/00 national radio interview with NPR.

187. Some 10 months later, in a presentation to the World Health Organization's Scientific Advisory Committee on Tobacco Product Regulation, one of RJRT's top scientists (Dr. Robert Suber) again reiterated the same points made in April 2000 by CEO Schindler:

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[131] One might argue, quite persuasively, that these statements, indeed admissions by Reynolds in its in-house PR materials, are really all that needed to be said here. If there is no scientifically acknowledged test, or other basis on which to make any quantitative statement about the relative disease risk of one cigarette compared to another, then RJRT already knew there was no generally accepted scientific or medical basis for Reynolds to claim that using Eclipse does in fact "present less risk of cancer, chronic bronchitis, and possibly emphysema" than smoking any particular conventional tobacco-burning cigarette. Perhaps this case could have been tried in an hour or less, instead of 26 days, inasmuch as Reynolds concedes that the Eclipse ads do in fact make an absolute, not qualified "less risk" claim, *see* below.

> [W]e are making potential reduced-risk claims with Eclipse, a cigarette that produces smoke by primarily heating tobacco, rather than burning it.
>
> During the past 20 years, [RJRT] has spent more than one billion dollars developing cigarettes that use tobacco-heating technology.
>
> Using out tiered testing methodology, we have determined that Eclipse may present smokers with less risk of cancer and certain other diseases, such as chronic bronchitis and possibly emphysema.
>
> [T]he [Eclipse expert] panel concluded, as we did, that Eclipse may present smokers with less risk of cancer, chronic bronchitis, and possibly even emphysema.

Exhibit VT-0594, at 4, 5 (dated 2/1/01). Dr. Suber also conceded in his remarks that RJRT's own "behavioral studies indicate that smokers of Eclipse are exposed to roughly twice as much smoke as when they are smoking their usual brand," *id.* at 5, and also "there is no consensus within the scientific community concerning what constitutes a reduced-risk cigarette," *id.* at 6.

188. For Reynolds, the essential dilemma here is that it already knew, before CEO Schindler's statements on 5/19/00, before the other PR statements in media interviews and in the prepared Q&A sheet, and before the re-launch of Eclipse in the Dallas area – from its own marketing and consumer perception studies using the mock-up Eclipse ads making a qualified "may present less risk" claim – that smoking consumers did not understand, or perceive the qualified nature of the ad claims. Reynolds already knew privately, before it publicly emphasized that it was only making a "potentially reduced-risk claim" for Eclipse, that consumers would effectively ignore the word "may" (or any other such qualifier) and understand the essential ad message to be that switching to, and smoking Eclipse would in fact reduce any given smoker's actual risk of developing "cancer, chronic bronchitis, and possibly even emphysema."

189. As the head of marketing for the Eclipse project testified at trial, it was indeed RJRT's intent to have consumers understand that its "less risk" claims for Eclipse were in fact not qualified, and that the intended ad message, the "take home" message for smokers, was exactly what the expert panel had said in its definitive final conclusions to the 4/99 report. All of the key Reynolds' executives believed at the relevant time – i.e., from 2000, when the initial decision was made to include the positive health claims, through at least 2003, when the "national roll-out" of Eclipse began with affirmative health benefit claims – that the "total weight of the evidence" did in fact prove that Eclipse reduced the risk of any given smoker contracting certain tobacco-related diseases;[132] that the expert panel had essentially confirmed that view; and they

[132] As noted, however, since then, and in testimony here, some of those executives have been more equivocal. Dr. Burger, who stated it was "common knowledge" that "his OK" was needed for any such health claims, also testified that he concurred with using the word "may present" in the ads,

affirmatively wanted to provide that message to smokers, both out of genuine concern for their customers,[133] and for profit-making commercial reasons as well. Reynolds was entirely comfortable with its own marketing research that showed consumers were in fact receiving an absolute, not qualified message about the asserted positive health benefits of switching to Eclipse.

190. The Dallas/Fort Worth "roll-out" of Eclipse with the positive health benefit claims did not have the desired effect; there was no identifiable increase in Eclipse sales, consumer resistance was still high, and smoker acceptance, or adoption of Eclipse was "spotty." Nonetheless, Reynolds chose to continue, if not increase its use of the positive health benefit claims for Eclipse, by deciding to "go national" with unrestricted marketing and sales of Eclipse in 2003,[134] using those same ad claims, including the so-called "Scott ad," *supra*, which was included in national media such as *Time* magazine. Copies of *Time* magazine with those ads did reach Vermont consumers in 2003 and May-June 2004.

191. Prior to 2003, Reynolds had designed, and made available on a password-only basis a specific, dedicated website for Eclipse. However, to obtain the password, any person (limited to adults over age 21) only needed to register with Reynolds, and provide a name, physical/mailing address, and e-mail address. As noted above, responses to, and registration with the website were used by RJRT to test-market Eclipse, with on-line sales of Eclipse,[135] e-mailings with further Eclipse marketing statements, direct-mail materials,[136] and free promotional coupons. Registrants on the Eclipse website were also culled to generate participants in some of its controlled marketing studies. Another important part of the Eclipse website were the instructions on how to "smoke" Eclipse, keep it lit, and become used to the Eclipse "experience" to facilitate long-

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because without that qualifier it meant "we have all the evidence we need to prove it," and he knew that was not entirely true. It is unclear on this record, however, whether Dr. Burger was ever privy to, or aware of the consumer studies already conducted by RJRT's marketing department, that showed consumers would essentially ignore the qualifying language.

[133] For example, Dr. Burger also testified that because any insistence on epidemiological studies was (in his view) both unnecessary and "not practical" and would take many years to complete, it would have been "unethical," and "wrong" not to "share the results" of their Eclipse testing with the smoking public, and to "deprive smokers of the choice" to use Eclipse.

[134] While still in test-marketing mode, Reynolds primarily restricted sales of Eclipse through selected, cooperating chains like 7-11 stores, in order to track sales and correlate them with the consumer and advertising studies being simultaneously conducted. With the national "roll-out" in 2003, Eclipse was available through all regular channels of wholesale cigarette distribution and retail sales outlets.

[135] On-line sales of Eclipse were in fact made to some small number of Vermonters, approximately 30 cartons.

[136] It is additionally likely there were also some direct mail, and/or e-mail solicitations to Vermonters generated off the Eclipse website, but again the exact numbers are not known.

term adoption of the brand. As part of the 2003 national expansion of Eclipse sales, the password requirement for the Eclipse website was dropped.

192. The Eclipse website had a general section with information for smokers and consumers, or the public generally, and also another section for medical, public policy and scientific researchers, with more detailed information and copies of the same research and study results developed and relied on by Reynolds for its positive health claims concerning Eclipse. The latter required an additional registration, and another password (apparently, even after 2003, when the rest of the Eclipse website became unrestricted).

193. The public portion of the Eclipse website repeated the advertising slogan that "The best choice for smokers worried about their health is to quit – the next best choice is to switch to Eclipse." At one time, a version of the Eclipse website also repeated the phrase "Eclipse – A better way to smoke," which was also found in some printed ads and other marketing materials.[137] The marketing executive(s) who testified for RJRT in this action denied that they were making any claims that Eclipse was a "safer" cigarette,[138] but these statements essentially carried that essential message, and were understood by consumers to make that point, *see* below.

194. The generally available Eclipse website (from 2003 through 2007) also included the following statements:

> [E]xtensive scientific studies show that, compared to other cigarettes [Eclipse]
>
> - ✓ May present less risk of cancer associated with smoking
>
> Because Eclipse primarily heats rather than burns tobacco, its smoke chemistry is fundamentally different, and the toxicity of its smoke is dramatically reduced compared to other cigarettes.
>
> For example, studies* with smokers who switched to Eclipse from their usual brand showed that Eclipse produced:

[137] The "better way to smoke" statement was perhaps most prominent in the Eclipse "on-sert" which came with each Eclipse pack, between the cellophane wrapper and the rest of the packaging. It is stipulated that these "on-serts" were included with Eclipse packs sold in Vermont. The "on-sert" repeated the basic health claim set forth many times above:

> **SCIENTIFIC STUDIES SHOW THAT, COMPARED TO OTHER CIGARETTES, ECLIPSE**
>
> - May present less risk of cancer, chronic bronchitis, and possibly emphysema

[138] Reynolds did not claim that Eclipse is a "safe" cigarette, and all of its ads and other marketing materials were always careful to include such a disclaimer. The State does not contend otherwise.

- ✓ 17-57% less lung inflammation (after two months in smokers of two packs or more per day)
- ✓ 70% lower smoking-related mutagenicity (DNA changes)**

*These studies did not include smokers of cigarettes with less than 4 mg "tar" by FTC Method.

**As measured in an *in vitro* laboratory test that can be used to detect chemical mutagens that potentially result from smoking.

These website statements, and advertising claims were available to Vermont consumers, and were in fact made to, and received by at least some Vermont consumers, given the purchase of at least 30 cartons of Eclipse off the website.

195. The positive health benefit ad claims made by Reynolds for Eclipse were directed at all conventional tobacco-burning cigarette smokers. As noted previously, this includes the entire U.S. market of cigarette smokers, which at the time generally consisted of around 30% "full flavor" cigarette smokers (i.e., 15+ mg of "tar" per cigarette), in excess of 60% "light" or "low tar" cigarette smokers (7-14 mg "tar"), and probably something more than 10% "ultra-light" cigarette smokers (6 mg or less of "tar" per cigarette). There was no evidence that the Vermont profile of cigarette smokers would be substantially different.

196. Putting aside that the average smoker, or consumer viewing the Eclipse website would have no idea what the "FTC method" was, or what its use and application here meant, Reynolds' concession in its first * footnote that none of its studies involved any "ultra-light" smokers (whose "usual brand" had less than 4 mg "tar")[139] necessarily makes its general statement of "dramatically reduced . . . toxicity" inapplicable to such smokers, yet Reynolds does not dispute that the ad claims were in fact directed at those smokers as well. To the extent that RJRT made "less risk" health benefit claims to smokers using "ultra-light" conventional cigarettes with 4 mg "tar" or less,[140] it essentially conceded on its website that it had insufficient, and inadequate scientific evidence – i.e., no "extensive studies," although it did have other lab data which "pointed in the right direction" – to make that specific claim.

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[139] RJRT, in its basic smoke chemistry tests, *see* Table 4 *supra*, used and relied only on the Kentucky reference "ultra-light" cigarette (K1R5F (later the K2R5F), with 1.42 mg/"tar" per cigarette) for such comparisons, and not any commercially available "ultra-lights". Of course, there must a significant number of smokers who do buy, and use such cigarettes daily, with 4 mg (or less) of "tar", if that category has probably more than 10% market share overall. The court infers, and finds that this marketing message was made to, and received by at least some smokers (including probably at least one Vermonter) to whom it was patently inapplicable.

[140] RJRT's own sales data and marketing research showed that "Eclipse switchers," i.e., those that adopted Eclipse as their usual brand for a sufficiently longer term, were in the same general proportion as the overall market categories for full flavor, light, and ultra-light cigarettes.

197. The website's statement regarding "70% lower smoking-related mutagenicity (DNA changes)" was misleading to the average consumer to the extent it failed to also disclose – especially given the ** footnote which touted an "*in vitro* laboratory test" – that the observed reduction applied only to salmonella bacteria, and not to actual human DNA. The misleading nature of this statement was further emphasized by the prominent display next to the statement, of a graph which purported to demonstrate visually the "70% lower smoking-related mutagenicity (DNA changes)" from switching to Eclipse for only a single week.

198. From 1999 through 2004, Reynolds or its outside contractors conducted some 29 different marketing and consumer perception studies for its Eclipse campaign and the positive health benefit claims in its Eclipse ads, and spent approximately $1.8 million on those studies. As noted above, Reynolds already knew from those study results that the average smoker, and consumers generally, perceived and understood the Eclipse claims regarding "less risk of cancer, chronic bronchitis, and possibly emphysema," to be unqualified and to be asserting that any given smoker who did switch to Eclipse long-term would in fact benefit from, and enjoy that reduced risk of developing tobacco-related diseases, notwithstanding the use of the words "may present" in all of the ads, website statements, and other marketing materials for Eclipse.

199. These findings about the actual Eclipse ad message received, and understood by smoking consumers were independently confirmed by consumer perception studies more recently conducted on behalf of the State, for purposes of, and use in this case. Reynolds has essentially conceded the point for purposes of this litigation – i.e., that smokers, and consumers generally simply ignore the word "may" and any other qualifier, and understand the ad claims to mean that switching to Eclipse in fact gives any, and every such smoker a lower risk of developing the stated tobacco-related diseases – and thus the State's independent marketing research need not be repeated, or recounted in detail.[141] However, it is helpful to review, and restate some of the highlights of those independent findings.

200. So-called "mall intercept studies" were conducted in 2006 with 607 total respondents at 13 different shopping malls in 4 different regions of the country, including two malls in Albany, NY and the Burlington, Vermont area (a total of 50 respondents in the latter two). After administration of a screening questionnaire to obtain background information,[142] the "Scott ad" (*supra*) was

[141] Likewise, the court need not spend much time on the various marginal attacks that Reynolds mounted against the methodology and techniques used by the State's marketing experts in conducting their studies. Much like the State's similar challenges to the methodology and techniques used by RJRT scientists (and outside researchers) for the underlying tests and studies on Eclipse itself, ultimately it was only so much "sound and fury, signifying nothing." Wm. Shakespeare, *Macbeth*, act 5, scene 5, line 24 (R. Arden, Complete Works (2001)).

[142] Only current, active smokers were chosen, with roughly 50/50 gender split, and in age brackets similar to RJRT's own consumer data; there was no distinction for "heavy," moderate, or "light" smokers. Each participant was offered $50 for their time, and taken to a separate room off the

presented to the respondents, as well as a mock-up of the exact same ad with the only difference being the statement that Eclipse is a "cigarette that presents less risk of cancer, chronic bronchitis and possibly emphysema," instead of "may present . . ." a reduced risk. A strong majority, and statistically significant number of the respondents did not perceive, or understand any substantive difference between the two statements, and understood the actual "Scott ad" as making a claim that Eclipse in fact reduced a smoker's risk of contracting the referenced tobacco-related diseases. The qualified "may present" language was not generally understood, and would not be generally understood by the average consumer as stating any limitation on the overall ad message that switching to Eclipse would in fact reduce any given smoker's risk of developing "cancer, chronic bronchitis and possibly emphysema."

201. In the subjective responses to a second questionnaire with open-ended questions, administered after viewing the subject ads, many respondents, without prompting, emphasized the perceived "health benefits" which the ads said would be achieved by switching to Eclipse, and a number of the subjects (although perhaps not statistically significant) stated their perception that Eclipse was a "safer" cigarette than conventional tobacco-burning cigarettes, even though Reynolds asserts it had not, and never intended to promote that specific message.

202. Essentially, the 2006 mall intercept/consumer perception study of the "Scott ad" demonstrated that 69.8% of respondents who saw that ad understood the "may present" formulation in the ad itself to be making an unqualified, or absolute affirmative health benefit claim from switching to Eclipse, whereas 68.5% of subjects who saw the mock-up ad with the word "presents" instead of the words "may present" had the same understanding, or perception.[143] The difference is imperceptible, and establishes that the average consumer would effectively gloss over, or read out the qualifier "may," and understand the Eclipse ads to be making an unqualified statement that switching to Eclipse would in fact reduce any given smoker's risk of developing "cancer, chronic bronchitis and possibly emphysema."

203. Although the consumer perception studies conducted for the State did not specifically address, or tease out the respondents' understanding (i.e., working definition) of the term "less risk," it is more likely than not that the average consumer's understanding of that term would be essentially the same as that eventually adopted, and expressly defined by the SAB, i.e., a reduction in the

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mall concourse to complete the process. There is no contention this was a truly "random survey." There were actually more than 800 participants, but only 607 (74%) could be "validated" with the specific responses by that subject on the main questionnaire, and by follow-up phone calls; 50% validation is the norm for this type of survey.

[143] In the subsequent questionnaire, only 12.1% of the respondents who saw the actual "Scott ad" were able to expressly report any understanding of the qualified nature of the claim. Conversely, of those shown the ad which simply said "presents less risk," 7.5% nonetheless later reported a perception that a qualified claim was made.

mathematical ratio, or chance of actual human disease incidence. RJRT's effort to confuse the issue with a hypothetical reference to an alternate Webster's dictionary definition, was not persuasive.

204. Consumers surveyed in the State's marketing studies generally adopted questionnaire responses which indicated they expected, or assumed there was some sort of scientific substantiation, or support for the Eclipse ad claims, although the responses did not indicate what level, or degree of scientific support the average smoker would assume existed for the statements about Eclipse. Some questionnaire responses, although not statistically significant, suggested that some consumers assumed there was already some degree of prior governmental review, or approval for Reynolds to make such claims about one of its cigarette products.

205. As noted above, Eclipse never has become successful in the marketplace; there were maybe 5000 regular Eclipse smokers in the entire U.S. at the time of trial of this case in late 2008. Thus the positive survey responses to the affirmative health benefit claims which were obtained by Reynolds in its own marketing studies for Eclipse, which were generally confirmed by the State's own consumer survey, have not translated into substantial sales of Eclipse.

206. Although Eclipse is still being sold today, in very small quantities relative to the tobacco and cigarette market as a whole, as noted the "Scott ad" only ran in 2003 and 2004. Reynolds stopped making all affirmative health benefit claims for Eclipse in any print ads by the end of 2006, and in any of its Eclipse websites by the end of 2007.

207. When this suit was filed by the State of Vermont in mid-2005, it followed months of contact, and a June 2005 face-to-face meeting in Chicago, between Reynolds and representatives of a number of state Attorneys General to discuss the science base for, and legal validity of the Eclipse ad claims. The position essentially taken by the State here had been repeatedly communicated to, and was understood by Reynolds. In a memorandum and e-mail circulated by Dr. Doolittle the day after this suit was filed, he continued to acknowledge that only a qualified reduced-risk claim was appropriate,[144] and summarized the reasons why Reynolds had decided it needed to proceed since 2000 with the affirmative Eclipse health benefit claims:

> As you know, several of the State Attorneys' General (AGs) have challenged our scientific conclusion that switching to Eclipse cigarettes

[144] Despite, of course, his testimony here that the "total weight of the evidence" developed by RJRT over almost 20 years "absolutely proved" that switching to Eclipse did in fact reduce the risk of contracting tobacco-related diseases, and that Reynolds had known from the start that its ad and marketing claims for Eclipse were perceived, and understood by consumers to be making such an unqualified, and absolute health benefit message.

may present smokers with less risk of cancer, chronic bronchitis, and possibly emphysema compared to continuing to smoke regular cigarettes.

The AGs position is that there is no wording, no qualifications, no supplemental disclosure language that can be incorporated into Eclipse advertising that will enable the company to communicate accurately to smokers the qualified nature of the claims regarding Eclipse. In short, the AGs contend that any stated or implied risk reduction claim requires long-term epidemiological studies relating to specific diseases. We believe that shorter-term assays and studies can demonstrate in a meaningful and scientifically relevant way the potential for reduced risk in innovative products.

We believe that the AGs position is unworkable and not a help to consumers:

> * Without some reason to smoke a brand like Eclipse (with advertising that communicates the potential for risk reduction) few will smoke it – and the long-term studies the AGs are demanding cannot be conducted!
>
> *The AGs . . . are denying smokers information regarding an option available to them that very well may offer them significant risk reduction benefits.

Exhibit VT-1199, Bates pg. #s 4224-25 (July 27, 2005).[145]

208. From 2000 through 2007, nationwide sales of the Eclipse cigarette totaled approximately 1.2 million cartons (in excess of 240 million Eclipse cigarettes), for gross revenue amounts of around $34 million to Reynolds (about 14 cents per cigarette, or $2.83 a pack). During that same period (2000 through 2007), the total sales of Eclipse in Vermont were approximately 410 cartons, or about $12,000 in gross sales. Active sales of Eclipse in Vermont, through normal sales and distribution channels, apparently ceased as of early 2008 (this point is somewhat unclear), but there were sales in Vermont, and solicitation of sales in Vermont using the challenged marketing statements and affirmative health

[145] The memo also included an excerpt from news stories about the filing of this case, which in turn included a quote from Reynolds' VP and General Counsel that this suit, if "successful," would "shut down research into cigarette which may present less risk to consumers." Although not explained, the premise appears to be the contention that tobacco companies will not incur the incredible expense necessary even to do the preliminary testing and studies (as incurred here by RJRT), let alone the many years of epidemiological studies, if that expense cannot begin to be recovered by selling the product sooner rather than later, which marketing (and revenue-generating) efforts will not be successful without the affirmative health claims. Perhaps this is the unspoken distinction behind RJRT's assertion, made through any number of its witnesses here, that epidemiological studies are "impossible," i.e., while those long-term studies may well be medically and scientifically possible, they are financially and thus practically not doable.

benefit claims prior to, and at the time the complaint herein was filed in July 2005, and continuing for at least 2+ years thereafter.

209. From 2000 (when Reynolds first began making the affirmative health benefit claims for Eclipse) through 2004 (when the "Scott ad" was withdrawn), Reynolds spent at least $16.656 million nationwide for print and other Eclipse advertising, signage, and promotional and marketing efforts.

210. At all relevant times, the advertising, marketing, and promotional materials used by Reynolds for Eclipse, and included on or displayed with the Eclipse cigarette packs themselves, complied with all mandatory disclosure requirements imposed under federal law, including the rotating Surgeon General's warnings. *See* Federal Cigarette Labeling & Advertising Act, 15 U.S.C. §§ 1331-1341.

CONCLUSIONS OF LAW

The ultimate decision facing the court in this action is not to finally (or even preliminarily) resolve the scientific, and medical debate over whether a tobacco PREP like the Eclipse cigarette does in fact reduce the risk that any given smoker switching to Eclipse will eventually develop cancer, chronic bronchitis, or possibly emphysema. The focus here, under the Vermont Consumer Fraud Act ("CFA") and both the Master Settlement Agreement ("MSA") and the Consent Decree which incorporates and implements the MSA, is instead whether Defendant R.J. Reynolds Tobacco Company ("Reynolds" or "RJRT") could lawfully make such an advertising and marketing claim given (A) the clear lack of consensus in the larger medical and scientific community concerned with, and knowledgeable about tobacco-related diseases, that merely reducing exposure to certain smoke toxicants does in fact lower the actual incidence of human cancer, bronchitis or emphysema otherwise caused by smoking cigarettes; and (B) the general understanding in that larger medical and scientific community that such a claim can only be established, and supported by epidemiological data garnered through long-term studies of suitably representative smoker populations. As stated at the outset of this opinion, the State of Vermont has proven by a decisive preponderance of the entire record evidence that Reynolds may not do so, and therefore Reynolds is liable, and judgment will be entered in favor of the State against Defendant, on Counts I, III and IV of the complaint herein.[146]

[146] As noted previously, Count II, which asserts a more general "unfairness" claim under the CFA to the effect that the Eclipse ad statements would induce non-smokers to start smoking, or existing smokers to delay quitting – *see, e.g.,* Decision & Entry Order, pg. 4 & fn. 6 (entered 8/19/08) – has been essentially abandoned by the State, and no evidence supporting that proposition was presented. Judgment in favor of Reynolds, dismissing Count II, will be entered.

(A) Liability of Reynolds Under The Vermont CFA

1. General Principles

- Under Vermont law, a seller of consumer goods is generally liable under the CFA for engaging in "unfair or deceptive acts" where (1) the seller makes a representation, or statement that "had the tendency or capacity to deceive a reasonable consumer," or was likely to mislead consumers; (2) the consumer interprets the message, or statement reasonably under all of the circumstances; and (3) the misleading effect of the statement is material to the consumer solicitation, or transaction. 9 V.S.A. § 2453(a); *see, e.g., Inkel v. Pride Chevrolet-Pontiac, Inc.*, 2008 VT 6, ¶s 9-10; *EBWS, LLC v. Britly Corp.*, 2007 VT 37, ¶ 26, 181 Vt. 513, 523.

- An act of omission, or failure to disclose information that would be material to the consumer's reasonable understanding of the message or statement, has long supported liability under Vermont law. *Vastano v. Killington Valley Real Estate, Inc.*, 2007 VT 33, ¶s 8-9, 182 Vt. 550, 551-52 (mem.); *Peabody v. P.J.'s Auto Village, Inc.*, 153 Vt. 55 (1990).

- It has also been well-established for many years that proof of the intent to deceive, or to knowingly make a misleading statement in connection with a consumer solicitation or transaction, is not required. *See, e.g., Poulin v. Ford Motor Co.*, 147 Vt. 120 (1986); *Winton v. Johnson & Dix Fuel Corp.,* 147 Vt. 236, 243 (1986); *Inkel, supra,* 2008 VT 6, ¶ 10. All that is required on this point is to establish that Defendant intended to make the statement (or omit relevant information), and did so deliberately, and not by mistake or inadvertence.

- Actual injury to the consumer is not an essential element of liability under the CFA, *see, e.g., Carter v. Gugliuzzi*, 168 Vt. 48, 56 (1998), especially where, as here, the State is seeking injunctive and other equitable relief primarily to restrain, and stop such "deceptive acts" under 9 V.S.A. § 2458(a).[147]

- The court must look to the entirety of the statements or representations made, and the overall context and circumstances, to determine the essential message imparted to and reasonably understood by the average consumer, and the "overall impression left by [the] defendant's

[147] As the court has previously ruled in striking RJRT's jury demand in this case, *see* Decision & Entry Order (filed June 6, 2008), in this action the State is principally seeking equitable and injunctive relief, and civil penalties in support thereof, *see* 9 V.S.A. §§ 2458(a), (b), rather than an award of compensatory damages *per se*. As noted above, whether the full panoply of injunctive relief which might otherwise be considered under the CFA will be available in this particular case, given likely preemption arguments under the 2009 federal legislation giving the FDA authority over ad claims such as those here, remains to be determined.

communications." *Jordan v. Nissan North America, Inc.,* 2004 VT 27, ¶ 9, 176 Vt. 465, 470, *citing Kraft, Inc. v. FTC,* 970 F.2d 311, 314 (7th Cir. 1992), *cert. denied*, 507 U.S. 909 (1993). The inquiry is an objective one, to determine what message the typical reasonable consumer would "take away" from the actual communication. *Id.*

- An affirmative statement or representation, or the omission or failure to provide information necessary to make the overt statement not misleading, is "material" if it is likely that the statement, or omission, would have influenced, or affected the reasonable consumer's purchasing decision. *Jordan v. Nissan North America, Inc., supra; Peabody v. P.J.'s Auto Village, Inc.*, *supra*.

- To the extent that Vermont law and statutes are not otherwise clear with respect to the applicable standards, or definitions of what is a prohibited "deceptive act[ ] or practice[ ] … in commerce," our courts are obliged to be "guided by the construction of similar terms … in the … FTC Act … by the Federal trade Commission and the courts of the United States." 9 V.S.A. § 2453(b).

2. Principles of FTC Law Concerning Deceptive Ads

An extensive body of law has been developed over many years by the Federal Trade Commission, and the federal courts with respect to allegedly deceptive or misleading advertising statements, especially marketing efforts related to health or medical claims. That case-law is not directly binding on this court, but is certainly informative, and instructive under 9 V.S.A. § 2453(b) to the extent it is otherwise persuasive. The following precepts may be divined from FTC and federal court cases, as an aid to application of the Vermont CFA here:

- The actual message, and ultimate impression which is conveyed to, and understood by the reasonable consumer is primarily a question of fact, which then may be resolved by resort to "the terms of the advertisement itself or by [extrinsic] evidence of what consumers interpreted the advertisement to say." *FTC v. National Urological Group, Inc.,* 2008 WL 2414317, at *12 (N.D. Ga. 2008), *citing generally FTC v. Tashman*, 318 F.3d 1273 (11th Cir. 2003); *FTC v. QT, Inc.,* 448 F.Supp.2d 908, 957-58 (N.D. Ill. 2006), *aff'd*, 512 F.3d 858 (7th Cir. 2008) (Easterbrook, J.).

- The plain meaning of an advertising claim expressly made by, and in the text of the ad itself may be determined by the court as a matter of law, without the necessity of extrinsic, or even expert evidence to decipher the actual message(s) communicated by the Defendant. *National Urological Group, supra,* at *12. However, "[i]f the advertisement . . . clearly and conspicuously implies a claim the court [also] need not look to extrinsic evidence to ascertain whether the advertisement made the claim." *Id. See*

also, e.g., FTC v. QT, Inc., supra, 448 F.Supp.2d at 958; *FTC v. Febre,* 1996 WL 396117 (N.D. Ill.), at *4, *aff'd*, 128 F.3d 530 (7th Cir. 1996).[148]

- A statement, representation, or omission in marketing or advertising is material if it "is likely to affect a consumer's choice of or conduct regarding a product." *In re Cliffdale Associates, Inc.,* 103 F.T.C. 110, 182 (1984).

- All express claims are presumptively material. *In re Cliffdale Associates, Inc., supra.* When an implied claim is made intentionally and deliberately, materiality is also inferred. *See, e.g., In re American Home Products Corp.,* 98 F.T.C. 136, 138 (1981), *aff'd*, 695 F.2d 681 (3rd Cir. 1982). In any event, all claims or statements (and omissions or failure to provide relevant information) regarding health or safety in connection with the purchase and use of a consumer product, are presumed to be material. *In re Cliffdale Associates, Inc., supra.*

- In determining whether an advertising claim is misleading or deceptive, if the statement(s) are targeted at a specifically identifiable audience, then the court must consider the "overall impression" and actual message likely to be understood by a reasonable member of that targeted group. *In re Cliffdale Associates, Inc., supra,* at 179. Proof that all consumers, or even a majority of reasonable consumers, will in fact understand or receive the allegedly misleading message, is not required. "An ad is misleading if at least a significant minority of reasonable consumers are likely to take away the misleading claim." *In re Telebrands Corp.,* 2005 WL 2395791, at 6 (FTC), *citing In re Kraft, Inc.*, 114 F.T.C. 40, 122 (1991), *aff'd Kraft, Inc. v. FTC*, *supra.*

- In determining whether an advertising claim is misleading or deceptive, the State here need not prove actual, or literal falsity; an alternative approach, which is that followed by the State in this case, is to demonstrate that the ad claim(s) are deceptive and misleading, and thus a violation of the Vermont CFA, by proving that Reynolds lacked a reasonable basis for asserting the truth of its express and/or implied claims about Eclipse. *Cf. e.g., FTC v. Pantron I Corp.,* 33 F.3d 1088, 1096 (9th Cir. 1994); *Thompson Medical Co. v. FTC,* 791 F.2d 189, 193 (D.C. Cir. 1986), *cert. denied*, 479 U.S. 1086 (1987). Where the statements, or claims at issue are "health-related claims, . . . [that] reasonable basis must, at a minimum, consist of competent and reliable scientific information." *National Urological Group, supra*, at *12.

- "[W]hat constitutes competent and reliable scientific evidence . . . is a question of fact" which is in turn primarily dependent on "expert interpretation" and assessment. *National Urological Group, supra*, at

[148] "[I]mplied claims fall along a continuum from those which are so conspicuous as to be virtually synonymous with express claims to those which are barely discernible. It is only at the latter end of the continuum that extrinsic evidence [of what consumers actually understood] is necessary."

*13; *FTC v. QT, Inc.,* 448 F.Supp.2d at 938-39. That is, the court must ultimately rely on, and decipher the competing, and often conflicting testimony of the experts presented by the parties, to determine what the prevailing consensus is in the relevant scientific or medical community as to the required "competent and reliable scientific information" necessary to support a given advertising claim. *Cf., e.g., National Urological Group, supra*, at *10 (the court itself does not decide what kind or degree of support is required, but rather what the "experts in the relevant area would consider to be adequate in determining the amount and type of [scientific or medical] evidence that is sufficient" to support a given claim).

- The actual body, or make-up of the "competent and reliable scientific evidence" which those testifying experts must consider, should be comprised of such "tests, analyses, research, studies or other evidence based upon the expertise of professionals in the relevant area[s], that have been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results." *National Urological Group, supra*, at *13.

- An express, or implied advertising claim is said to be an "establishment claim" if the reasonably understood message of the statement is that it is based on, or "established" by some "level of support for [that] particular claim." *FTC v. QT, Inc., supra,* 448 F.Supp.2d, at 959. The representation that the claim is supported by some specific level of testing or substantiation may itself be express, in the ad itself, or it may also be implied, or inferred from the "scientific aura" or "serious tone" taken from the overall context of the advertisement, *Sterling Drug, Inc. v. FTC,* 741 F.2d 1146, 1152 (9th Cir. 1984), or because the statement(s) "implicitly … refer[ ]" to the existence of, and support by "tests or data," *cf. Astra-Zeneca, Inc. v. Eli Lilly & Co.,* 1999 WL 509471, at *31 (S.D.N.Y.) (Lanham Act suit between two marketers; incorporates same definitions and standards as FTC Act).

- If an "establishment claim" is made in an advertisement or other marketing piece, "the advertiser must [in fact] possess the level of support claimed in the ad" if it expressly states that some specific level or degree of support exists. *In re Thompson Medical Co.,* 104 F.T.C. 648 (1984), *aff'd*, 791 F.2d 189, 194 (D.C. Cir. 1986), *cert. denied*, 479 U.S. 1086 (1987). Where, however, the "establishment claim" is not specific as to the particular type or extent of scientific support for the statement(s), then "the advertiser must possess a level of proof sufficient to satisfy the relevant scientific community of the claim's truth." *FTC v. Braswell,* 2005 WL 4227194, at *8 ( ), *citing In Re Thompson Medical, supra*, 104 F.T.C. at 821-22 & fn. 59.

To summarize the basic principle of FTC deceptive advertising law which is applicable, and controlling here, the court repeats the formulation set forth at

the outset of this decision: "[W]here advertising expressly or impliedly represents that it is based on scientific evidence, the advertiser must have that level of substantiation, and, in particular, must satisfy the relevant scientific community that the claim is true." *In Re Removatron International Corp.,* 111 F.T.C. 206, 299 (1988) (cits. omitted), *aff'd*, 884 F.2d 1489 (1st Cir. 1989). Thus, in order to establish that RJRT has made deceptive and misleading statements in violation of Vermont's Consumer Fraud Act, 9 V.S.A. § 2453(a), the State was, and is required in this case "(1) to establish the particular evidence that would pass muster in the medical (or scientific) community for the types of claims made; and (2) demonstrate that the proffered substantiation failed to meet these standards." *Id.,* 111 F.T.C. at 299.

3. Application to Eclipse Ad Statements

(i) Turning first to one of the key statements made on the Eclipse website from 2003 through 2007, which site was accessible to Vermonters, and actually used or accessed by at least a few State residents (given the purchase of some 30 cartons of Eclipse off the website), there can be little dispute that an express "establishment claim" was made: "extensive studies show that, compared to other cigarettes, [Eclipse] [m]ay present less risk of cancer associated with cancer." The consumer perception studies conducted by Reynolds itself prior to making any affirmative health benefit claims; the consumer surveys conducted by the State's experts for this litigation; and RJRT's concession here, all establish that the overall impression, and essential meaning derived by consumers from that type of statement would be that, in fact, switching to Eclipse would reduce any given smoker's chance of developing cancer. However, not only did Reynolds not have the "extensive studies" it expressly touted to back up that statement,[149] it actually had no such studies at all, because the clear consensus of the entire medical and scientific community familiar with tobacco-related diseases, is that any such statement making a quantitative risk comparison between different cigarettes would require, and can only be based on long-term data of comparative human disease incidence derived from human epidemiological studies. That website statement concerning Eclipse was thus material, misleading and deceptive as a matter of law, and the State of Vermont is entitled to judgment in its favor against Defendant Reynolds, under 9 V.S.A. § 2453(a).

[149] To be sure, Reynolds did have "extensive" preliminary studies, well over several million dollars worth, which consistently tended to demonstrate reduced exposure to many harmful tobacco smoke constituents, and some reductions in some of the harmful toxicological effects (e.g., indicia of lung inflammation) which are thought to be associated with, or possibly even precursors to tobacco-related diseases. To that extent, then, those studies generally met one of the subsidiary standards under FTC law, i.e., that any such tests or studies be "conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results." *National Urological Group, supra,* at *13. But, as the court has found, the many tests and studies on Eclipse done by Reynolds (and its outside researchers), no matter how valid and accurate they might otherwise be, are ultimately not the kind of "extensive studies" which are needed to claim they actually "show that … [Eclipse] present[s] less risk of cancer."

(ii) The other statement on the Eclipse website principally challenged by the State, was that "studies with smokers who switched to Eclipse . . . showed that Eclipse produced ... 70% lower smoking-related mutagenicity (DNA changes)." In context, and together with the large visual graph next to this statement, this representation is perhaps closer on the continuum to an implied rather than express "establishment claim." But the essential message implied, from the text and surrounding circumstances alone, and then reasonably understood by the typical consumer (i.e., smoker), is that mutagenicity in human DNA would be reduced by 70%.

However, Reynolds had (and still has) no medical or scientific studies to prove that particular assertion. Moreover, even though the statement was twice footnoted, RJRT did not use either opportunity to explain to consumers that its evidence related only to salmonella bacteria mutagenicity, not humans; that the tests referred to were, at best, preliminary "screening" assessments which should primarily be used only to isolate, and identify smoke compounds for further intensive study; and that the tests it did have, and referred to here, meant that its more general statement above (i.e., "less risk of cancer") did not apply at all to any smokers whose usual brand was an "ultra-light" cigarette with less than 4 mg of "tar."[150] This second website statement concerning Eclipse was also material, misleading and deceptive as a matter of law, and the State of Vermont is entitled to judgment in its favor against Defendant Reynolds, under 9 V.S.A. § 2453(a).

(iii) Turning now to the principal advertising statement challenged here, in the so-called "Scott" print ad, *see* above – Eclipse is "[a] cigarette that may present less risk of cancer, chronic bronchitis, and possibly emphysema" – the extrinsic evidence presented by the State, and Reynolds' concession, indisputably establish the actual message communicated to, and reasonably understood by the intended, or targeted consumer (i.e., a current smoker of any brand of conventional tobacco-burning cigarette): any smoker switching to Eclipse, including any current "light" or even "ultra-light" smoker, will in fact (not "may" or "might" or "could") experience a lesser chance, or statistical incidence of developing one (or all) of those tobacco-related diseases. Reynolds knew that consumers would understand that message, and deliberately made the "Scott" ad statement with the intent that smokers would understand, and believe there was an affirmative health benefit from smoking Eclipse, i.e., that switching to Eclipse would improve their chances of not developing cancer, chronic bronchitis, or possibly emphysema.

This is an implied establishment claim, because its "scientific aura" clearly implies that it is established, or supported by scientific or medical studies. As

[150] Reynolds did accurately disclose the literal truth, and the 4 mg "tar" limitation in the study, in footnote *. But that disclosure would have no meaning to the average reasonable consumer, who would more likely than not understand those mutagenicity tests, even with the stated limitation, to nonetheless be part of the "extensive studies" cited for the overall "less risk of cancer" statement earlier in the website page .

such, Reynolds must have had in hand the necessary scientific and medical evidence which would convince the applicable medical and scientific community that the claim was in fact true, and that it was in fact supported by that data, and those studies deemed sufficient by the relevant community of experts. The State has proven by a clear preponderance of the record evidence here, that only long-term epidemiological studies will support any such statement, or claim as to any quantitative, and comparative reduction in human disease incidence related to smoking cigarettes, and Reynolds concedes it has no such evidence, or data, or studies. This principal advertising statement in the "Scott" ads concerning Eclipse was thus material, misleading and deceptive as a matter of law, and the State of Vermont is entitled to judgment in its favor against Defendant Reynolds, under 9 V.S.A. § 2453(a).

(iv) Other specific advertising and marketing statements made by Reynolds concerning Eclipse, as identified and challenged by the State in this action, *see* complaint and State of Vermont's Trial Memorandum (filed 10/2/08), at pgs. 4-5, have <u>not</u> been proven by a preponderance of the record evidence to be deceptive or misleading under the Vermont CFA, or wholly without the necessary scientific substantiation and "reasonable basis" required under FTC law. In particular, the following ad claims are not actionable:

- "A cigarette that responds to concerns about certain smoking related illnesses. Including cancer."

The extensive testing data and other studies which Reynolds did produce over almost a decade of research on, and development of Eclipse was intended to, and did address, and "repond[ ] to concerns about" tobacco-related diseases, including cancer. As the court has found, those underlying tests and studies were all primarily performed in an accurate and scientific manner, by legitimate and reasonably objective scientists, and the data actually produced is competent and generally reliable within the 4 corners of the tests and studies themselves.

- "Eclipse produces less inflammation in the respiratory system, which suggests lower risk of chronic bronchitis and possibly even emphysema."

Although certainly not conclusive, and an insufficient basis on which to base any statement as to actual disease incidence, as Drs. Rennard and Hite testified with respect to their own studies, the outside clinical studies which Reynolds did obtain consistently indicated reduced symptoms, and fewer or reduced biomarkers of exposure or effect, with regard to lung and bronchial inflammation in short-term Eclipse smokers. The evidence as a whole at trial established that these reduced markers of effect or exposure, are indeed "suggestive" of a potentially reduced risk of inflammation-related lung disease, i.e., collectively COPD. The State presented no extrinsic evidence that the reasonable consumer would interpret this

particular statement in any manner other than its literal meaning, i.e., that indicia of less lung inflammation "suggests lower risk" of COPD-type diseases by switching to Eclipse.

- "Because Eclipse primarily heats rather than burns tobacco, its smoke chemistry is fundamentally different, and the toxicity of its smoke is dramatically reduced compared to other cigarettes. For example, studies with smokers who switched to Eclipse from their usual brand show that Eclipse produced:
    - 17-57% less lung inflammation (after two months in smokers of 2 packs or more/day)."

Much like the previous statement, this assertion is not literally deceptive or misleading; the "smoke chemistry" of Eclipse is "fundamentally different" than a conventional tobacco-burning cigarette, and the cited study did essentially support, if not demonstrate the claimed % reduction in indicators of lung inflammation. Whether the reduction in "toxicity" of Eclipse "smoke" is indeed "dramatic," that specific characterization is mere "puffery" and not provably deceptive one way or the other.[151] There is continuing dispute and disagreement about the extent to which the chemicals and compounds analyzed on Table 4, *see* above, are indeed the most critical "toxic" elements of Eclipse smoke, but that description was not proven to be misleading by the State. The "smoke chemistry" results shown in Table 4 adequately support that assertion.

- "Because [Eclipse] primarily heats tobacco rather than burning it, testing shows that the smoke is very different from that of other cigarettes. The results of many of these tests have, in fact, been presented at scientific meetings or published in scientific journals."

There is nothing deceptive, misleading, or literally untrue about this statement.

- "Extensive analysis of Eclipse shows that the smoke it creates contains far less of many of the compounds that have been linked to the risk of cancer and associated with certain other smoking-related illnesses."

The evidence as a whole at trial did establish that "many of the compounds" analyzed in Table 4, *see* above, "have been linked to the risk of cancer and associated with certain other smoking-related illnesses." RJRT's analysis of the Eclipse smoke chemistry was "extensive." Whether the demonstrated reductions in "many of the compounds" were such that

[151] *See, e.g., Heath v. Palmer,* 2006 VT 125, ¶ 14, 181 Vt. 545, 549 (mem.).

they were "far less," is an unprovable matter of opinion that is not actionable, *see* fn. 150.

- "Eclipse smoke has '80% less carcinogens' than smoke from conventional cigarettes."

There was debate and dispute about whether the 14 Eclipse smoke chemicals and compounds selected by RJRT for this particular analysis were in fact known or suspected human carcinogens, and also whether the method of analysis (e.g., by total mass weight vs. ug/cigarette) was the most correct or appropriate approach, but the evidence as a whole did show that the 14 chosen compounds did have some basis in accepted lists of identified carcinogens (e.g., the IARC list), and that within the method of calculation chosen by RJRT, the math was essentially correct. This statement was not actionably deceptive.

4. Reynolds' Defense(s)

The court has concluded that the State has carried its burdens of proof and persuasion to establish, as a matter of law, that the three Eclipse marketing statements discussed at points 3(i)-(iii) above, were material, misleading and deceptive under 9 V.S.A. § 2453(a), and that Defendant Reynolds should be held liable to the State on those claims under Count I of the Complaint.[152] To arrive at that conclusion, the court has necessarily rejected several affirmative defenses advanced by Reynolds.

(i) First, RJRT essentially contends that the State's entire case must fail because it is "judicially estopped" from arguing, or even attempting to prove, that Eclipse is not a "safer [cigarette] product [with] reduced physiological consequences" – e.g., that it does not have the affirmative health benefits of "less risk" as asserted in the "Scott" ads – because (A) the State alleged in the complaints which led to the MSA and Consent Decree, over a decade ago in what was basically a single paragraph in two lengthy and extensive complaints (1997, ¶ 217; 1998, ¶ 220), that Premier was such a "safer [cigarette] product," and (B) Premier and Eclipse are both tobacco-heating, not tobacco-burning cigarettes. Without delving into the intricacies of the law on "judicial admissions" and estoppel, this tautological contention suffers from a fundamental, and fatal flaw: Premier, although somewhat similar in concept and certain technology, was not, and is not Eclipse. Reynolds presented no evidence to demonstrate that the

[152] Throughout much of the case, and the early parts of the trial, Reynolds disputed that the "Scott" ads, or the challenged statements in the Eclipse website, were ever available to, or shown or exhibited to consumers in Vermont. Eventually the parties stipulated that these advertising statements were made to and received by at least some Vermont consumers, and that potential factual impediment to the court's jurisdiction was removed from the case. In addition, there was eventual stipulation as well to the number of Eclipse cigarettes actually sold in Vermont during the relevant period. *See* above.

"smoke chemistry" of Eclipse was in fact identical to Premier. It is simply inconceivable that a mere throw-away allegation in complaints more than 10 years old could now estop, and prevent the State from establishing, through extensive scientific evidence which Reynolds has had every opportunity to rebut and contest on the merits, that advertising statements made about an entirely different cigarette product are deceptive or misleading under the Vermont CFA.

(ii) Second, and more important is Reynolds' contention that it is entitled to an absolute defense of "good faith" because it sincerely, and honestly relied on the final conclusions of the Eclipse expert panel as set forth in the April 1999 report, which did literally state as follows:

> 1. Eclipse reduces the risk for inflammatory-based diseases of the respiratory system.
>
> 2. Eclipse reduces the risk for smoking-associated cancer.

See Findings, ¶ 146, *supra*, and Exhibit RJR-0168, at 41. This so-called "good faith" defense is not available here to RJRT, for many different reasons, both legal and factual.

Vermont law under the CFA does not recognize, or incorporate any such defense. Reynolds has not cited any Vermont law, or decision of the Vermont Supreme Court which states as much, or even implies or suggests that any such defense might be recognized, and ignores *Carter v. Gugliuzzi,* 168 Vt. 48, 58 (1998), which explicitly states that "lack of intent to deceive or good faith are not defenses under the Consumer Fraud Act." Since neither intent nor even actual injury to any particular consumer are required elements to prove the State's cause of action under the CFA, *Jordan v. Nissan North America, supra; Peabody v. P.J.'s Auto Village, supra*; and since the focus of and public policy behind the CFA are to protect the consumer's "ultimate exercise of choice" from being distorted by misleading or deceptive information, *id.,* if the statement or message has been proven to in fact be misleading or deceptive – as here, because the State has established that the Eclipse ad claims are accurate and have a "reasonable basis" only if supported by sufficient epidemiological data, which Reynolds does not have – then it would make little sense, and would frustrate that policy rationale, if liability could nonetheless be defeated by a Defendant's "good faith" in making deceptive statements about its product or service. *Cf. also, e.g., Wright v. Honeywell International, Inc.,* 2009 VT 123, ¶ 7 (Dec. 10, 2009) (CFA "is to be liberally construed to protect the public and encourage fair and honest competition," which would include "fair and honest" ad claims by competing cigarette makers attempting to increase market share); *Vastano v. Killington Valley Real Estate, supra,* 2007 VT 33, ¶ 9, 182 Vt. at 552 ("basic purpose of the [CFA] . . is to 'encourage a commercial environment highlighted by integrity and fairness'") (cit. omitted).

This would appear to be an unlikely case in which the Vermont Supreme Court might choose to depart from what is otherwise fairly settled law, and adopt, or recognize a "good faith" defense. Even if one accepts that Reynolds executives did honestly, and without subterfuge or dissembling rely on the stated final conclusions of the Eclipse expert panel in the April 1999 report before deciding to make the public health benefit claims for Eclipse beginning in 2000 – the court readily acknowledges that CEO Schindler and the RJRT marketing executives did have a face-to-face meeting with Dr. Wagner, Dr. Burger, and others in late 1999 to personally confirm that both the RJRT science and research department, and the panel, stood foursquare behind those conclusions – those conclusions were, given the totality of the evidence, a legally insufficient basis on which Reynolds could firmly place its trust and faith.

As repeated countless times by each of the key witnesses involved with the proceedings of the Eclipse expert panel, their ultimate conclusions (as stated in the 4/99 report) were the result of applying a so-called "total weight of the evidence" analysis, and a "more likely than not" standard of proof. Even some of the RJRT scientists acknowledged that the latter was not a medical, or scientific standard which they were familiar with, or routinely applied. As to the "total weight of the evidence" approach, Dr. Rennard was entirely credible in his recollection that the concept was never explained, or defined for the panel by Dr. Wagner, and the panel members were finally required to give a simple "yes or no" answer to the questions as presented. The evidence here persuasively establishes that the Eclipse expert panel never weighed, or balanced any of the respective study results, or particular data against each other on either any qualitative basis, or quantitative scale. Moreover, at least the available written evidence of the panel's proceedings (the 4/99 report, and the later published journal article) demonstrates the panel members never actively discussed, or considered the potential impact of critical caveats to the data, such as the entire dispute over whether machine generation of all Eclipse "smoke" for *in vitro* and *en vivo* testing, which relied solely on the FTC method, would (or would not) accurately capture, or reflect actual human smoking patterns; or the commonly understood limitations of the various Ames assays (i.e., the bacterial mutagenicity studies) to preliminary screening of toxic chemicals to identify such compounds for more detailed and specific testing, and not for definitive results on which to base statements about human health impacts.[153]

Just recently, in *Estate of Albert George v. Vermont League of Cities & Towns, supra,* 2010 VT 1, ¶s 21-22, 31-33 (January 15, 2010), the Vermont Supreme Court has indicated what type, and level of analysis is required in order for experts to rely on a "weight of the evidence" analysis. Although the case

[153] Indeed, far from acknowledging, and forthrightly confronting those arguable limits on the salmonella mutagenicity data, for Dr. Wagner and others at RJRT, including Drs. Burger and Doolittle, it was the urine mutagenicity studies, and the "consistent" results all "pointing in the same direction," which were of particular importance in their view in supporting the Eclipse ad statements.

primarily concerned the trial court's exercise of its "gate-keeping" function to admit (or exclude) expert scientific evidence under VREv 701-703 and *Daubert*, the Court's observations on so-called "meta-analysis" and the "weight of the evidence" approach are trenchant. In order to accept, and rely on expert conclusions and opinions which are in turn based upon a "weight-of-the-evidence methodology," there must be something more than some "undefined reference" to such an approach, and sufficient explanation of the weighting, and other comparative techniques used to allow the court to "discern the scientific method . . . used to reach [the proffered] conclusion[s]." *Id.,* ¶ 21. In other words, there must be some substance behind the curtain, and not merely the pulling of levers and pushing of buttons to generate the appearance of scientific rigor. There must be some there, there.[154]

> Our High Court further explained this requirement in *Albert George*:
>
> As is often repeated, there must be "a scientific method of weighting that is used and explained," . . . and an expert's opinion cannot be based "on subjective belief or unsupported speculation." . . . By detailing the weight given to each component, an expert demonstrates that "the 'weight-of-the-evidence' methodology is truly a methodology, rather than a mere conclusion-oriented selection process that weighs more heavily those studies that supported an outcome."

Id., ¶ 31 (cits. omitted). In explaining why conclusions based on unexplained weighting of multiple studies should be rejected, the Court further stated:

> "the single most serious flaw [in the expert testimony] is the most basic: [the expert] simply has not set forth the methodology he used to weigh the evidence. . . . [B]ecause the weight-of-the-evidence methodology involves substantial judgment on the part of the expert, it is crucial that the expert supply his method for weighting the studies he has chosen to include in order to prevent a mere listing of studies and jumping to a conclusion."

Id., ¶ 32 (cits. omitted). For such a meta-analytical opinion to constitute persuasive and acceptable evidence, the expert must "specify the precise weight he gave to each study or how he reached his conclusion that the studies, taken together, demonstrated a statistically significant result . . . ." *Id.,* ¶ 33. The "total weight of the evidence" approach undertaken, and espoused by the Eclipse expert panel fails those minimal requirements. Accordingly, it seems unlikely that our Supreme Court would reach out in this case to craft a "good faith" defense when

[154] Gertrude Stein, *Everybody's Autobiography*, ch. 4 (1937) (referring to her native Oakland, CA), *as quoted* in *Yale Book of Quotations,* pg. 728 (Shapiro, ed., 2006).

the principal evidence to support Reynolds' "good faith" reliance is inadequate as a matter of law.[155]

Defendant's argument for recognition of a "good faith" defense depends not on Vermont law itself, but rather its interpretation of FTC case-law, coupled with the proposition that those principles are somehow binding under 9 V.S.A. § 2453(b), rather than simply instructive as "guide[s to] the construction of similar terms" which appear in both statutory schemes. Thus, even if the FTC case-law on this issue were as RJRT asserts, this court is doubtful that the Vermont Supreme Court would adopt it because the "good faith" concept is so inconsistent with the fundamental precepts of the CFA. *Cf., e.g., Wright v. Honeywell, supra,* 2009 VT 123, ¶ 7, *citing Elkins v. Microsoft Corp.,* 174 Vt. 328, 341 (2002) (emphasizing that Vermont law under CFA rejects federal case-law on "indirect purchasers," thereby giving more weight to consumer protection purpose of the CFA). But Reynolds appears to be wrong about the FTC case-law it touts. To be sure, the reported Commission decisions from the 1960s, 1970s and 1980s[156] are not entirely clear on this point, and RJRT is able to craft at least a superficial argument based on that lack of clarity, which has "good faith" re-entering the legal analysis as a component of a multi-factor substantiation analysis. *See* discussion below.

However, *Removatron, supra* – the most recent in this line of cases (although now relatively ancient itself, from 1988) – seems to be fairly unequivocal in its rejection of any "good faith" defense when the advertising statements at issue are "establishment claims," either express or implied, as here; RJRT's effort to distinguish *Removatron* on this point is not persuasive; and other federal courts have come to the same conclusion (which then makes § 2453(b) work against, not in favor, of Defendant's contention):

> Respondents quote language from *Pfizer* [and *Kirchner* and *National Dynamics*] that a reasonable basis consists of "such information as would satisfy a reasonable and prudent businessman, acting in good faith, that such representation was true." . . . They argue that regardless of whether the proffered substantiation demonstrates [and supports the claim made],

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[155] Again, the court does not question the sincerity of the members of the Eclipse expert panel, including Dr. Wagner, or challenge the legitimacy of their honest belief that the test data and study results they did have as of early 1999 supported their final conclusions. However, as discussed at some length above, there are extenuating circumstances which perhaps help to explain how the panel members, and Dr. Wagner in particular, felt compelled to reach those conclusions. In any event, their "good faith," and that of Reynolds in turn in relying on the April 1999 report, is irrelevant for the legal reasons just stated.

[156] *See, e.g., In re Heinz W. Kirchner,* 63 F.T.C. 1282 (1963), *aff'd*, 337 F.2d 751 (9th Cir. 1964); *In re Pfizer, Inc.,* 81 F.T.C. 23 (1972); *In re National Dynamics Corp.,* 82 F.T.C. 488 (1973); *In re Bristol Myers Co.,* 102 F.T.C. 21 (1983); *In re Sterling Drug Co.,* 102 F.T.C. 395 (1983); *In re Thompson Medical Co.,* 104 F.T.C. 648 (1984), *aff'd,* 791 F.2d 189 (D.C. Cir. 1986), *cert. denied*, 479 U.S. 1086 (1987).

> in relying on it, the . . . Respondent[s] acted reasonably and in good faith and thereby satisfied the reasonable basis requirement. . . . The quoted language, however, has been taken out of context. . . . Indeed, in *Pfizer* the Commission made clear that the reasonable basis standard focuses in large part on the adequacy of the underlying evidence and is not solely a "reasonable man" test. Thus, the standard . . . evaluates both the reasonableness of an advertiser's actions[157] and the adequacy of the evidence upon which [those] actions were based. *Pfizer,* 81 F.T.C. at 64. Thus, whether Respondents acted reasonably is not controlling . . . [and] their good faith in relying on the proffered substantiation is irrelevant.

Removatron, supra, 111 F.T.C. at 307-308 (cits. omitted; emphasis added). *See also, e.g., FTC v. Direct marketing Concepts, Inc.,* 569 F.Supp.2d 285, 298 (D. Mass. 2008), *citing FTC v. Bay Area Business Council, Inc.,* 423 F.3d 627, 635 (7th Cir. 2005) ("The FTC is not, however, required to prove intent to deceive, and so by extension, the advertiser's good faith is not a valid defense"); *FTC v. US Sales Corp.,* 785 F.Supp. 737, 748-49 (N.D. Ill. 1992) ("The 'reasonable basis' test is an objective standard. An advertiser's good faith belief that [its] claim is substantiated is not enough.").[158]

(iii) Third, Reynolds asserts that it should be excused from compliance with the consensus of the relevant medical and scientific community – i.e., that epidemiological data is required in order to make any comparative, and affirmative health benefit claims for Eclipse[159] – because conducting those epidemiological studies is "impossible." *See* Defendant's Proposed Findings of Fact, Part II(A). While there was considerable testimony, almost all from the Reynolds witnesses, as to the considerable difficulties and expense of conducting

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[157] That required "reasonableness" is then measured objectively, not subjectively. *See, e.g., FTC v. US Sales Corp., infra.*

[158] Even under Reynolds' preferred alternative analysis based on a multi-factored "reasonable basis" approach, *see infra*, the issue of subjective "good faith" would not necessarily result in a different outcome here. In *Sterling Drug, supra,* the FTC, in finding claims for Bayer aspirin to be unsubstantiated, reiterated that point:

> Since Sterling has represented in its ads that Bayer's superiority has been established, it could not have a good faith belief in the truth of that claim unless adequate evidence existed to establish Bayer's superiority. Thus, in this instance, the reasonable basis approach requires the same level of support as the establishment theory. Since we have already determined that Bayer's superiority was not established, we therefore also find that Sterling lacked a reasonable basis for this claim.

Id., 102 F.T.C. at 778.

[159] As discussed above, there is also the intermediate approach of reliance on validated biomarkers for these kinds of tobacco-related disease, but, as also discussed, there are as yet no such biomarkers for tobacco-related cancer, chronic bronchitis or emphysema, and further development of and general agreement on such biomarkers will itself require epidemiological research and data.

such epidemiological studies on Eclipse smokers for an appropriate period of time and with a sufficient number of control smokers and Eclipse switchers, the court disagrees that the trial evidence as whole in fact established that the task was, or would be "impossible" from a purely scientific standpoint.

Rather, the claim of "impossibility" arises almost entirely from the chicken-and-egg, or Catch 22 nature of the exercise, and its interplay with the applicable legal standard under both the Vermont CFA and FTC case-law. That is, Reynolds argues (A) that it cannot convince enough actual smokers to switch to Eclipse, even with the affirmative health benefit claims as an enticement, to be able to perform epidemiological studies with the required minimum sample, or population size;[160] and (B) because the latency period is so long for these diseases, especially cancer, that no reasonable business could support the cost for such extended tests, over 5 to 10 years or longer, without being able to recoup some of that cost by selling the product before the studies are completed. While the court acknowledges it presents Reynolds (or any other tobacco company looking to develop, and market a "PREP" with affirmative health benefit claims) with a difficult practical dilemma, it does not establish "impossibility" as a matter of law sufficient to be an absolute defense to liability under the CFA. *Cf., e.g., Sterling Drug, supra,* 102 F.T.C. at 769 (rejecting defense that "well-controlled clinical study" for Bayer Aspirin "would not be feasible" because it "would be prohibitively expensive" and involve confounding issues such as "200 other brands").

5. Alternative "Reasonable Basis" Test

Much of Reynolds' primary legal argument, or approach to this case turns on its contention that an alternative "reasonable basis" analysis developed in some FTC cases is applicable, and controlling here. For many of the same reasons already articulated in predicting that our Supreme Court is unlikely to engraft a "good faith" defense onto Vermont CFA law under the guise of applying § 2453(b) (i.e., the FTC "guidepost" statutory provision), it also seems unlikely that our Supreme Court will choose to adopt the more complex multi-factored analysis promoted here by Reynolds, when the less complicated approach under *Removatron, supra* – if, and to the extent any additional reference is needed to FTC case-law under § 2453(b) – seems more consistent with the essential legal

[160] Recall that the evidence showed there are now approximately 5000 total Eclipse smokers nationwide. Recall also that this conundrum seemed to be one of the motivating factors for Dr. Wagner and the Eclipse expert panel, i.e., that the only way forward was to market Eclipse with affirmative health benefit claims (in order to overcome consumer resistance), because switching to Eclipse would likely do no different, or additional harm than a conventional tobacco-burning cigarette, and then the necessary epidemiological studies to quantify any reduction in actual disease risk could be accomplished because there would be more Eclipse smokers, and the larger scientific community would be encouraged to do such testing and studies because of the expert panel's positive preliminary report. Of course, Dr. Wagner and the panel members had no inkling, one way or the other, whether that strategy would (or would not) comply with deceptive advertising restrictions.

requirements, and policy rationale, of the Vermont CFA. Accordingly, even if Defendant was correct in its assertions about this alternative analysis, it would not be applicable, or controlling here.

However, on this issue as well Reynolds appears to overreach, and rely on an analytical paradigm which even the FTC, and the majority of federal courts, would not apply here. The alternative multi-factor "reasonable basis" analysis, which was developed, and announced by the FTC in *Pfizer* and *Thompson Medical, supra* fn. 155, is not applicable to, and is not used with "establishment claims," as here, whether express or implied. Instead, this *Pfizer/Thompson Medical* analysis appears to be reserved for, and primarily used to assess the "reasonable basis," and degree and type of required substantiation, for advertising claims which do not make any assertion, or present any message which is cloaked in some "scientific aura" and necessarily suggests the existence of scientific or medical data to support the claim.[161]

> We hold that references to clinical testing, research and cases studies are express claims that the Respondents' representations are supported by scientific evidence. In addition, the [other] claims [relating to health or bodily functions] provide a scientific aura and can reasonably be interpreted as implying a scientific level of support. Accordingly, we find that the net impression of these advertisements and promotional materials is that Respondents' claims were based on competent scientific proof. Given this finding, we need not apply the *Pfizer* analysis in determining the reasonable basis for Respondents' claims.

Removatron, supra, 111 F.T.C. at 298 (cits. omitted; emphasis added).

Instead, when so-called "establishment claims" are made, as here, the standard to be met is much more simple and straight-forward: Defendant "must have that level of substantiation [which would] satisfy the relevant scientific community that the claim is true." *Id.,* at 299. In other words, both FTC approaches ultimately require a "reasonable basis" for the advertising claims, but in the case of "establishment claims" making scientific or medical assertions, either express or by implication, the only reasonable basis is the existence of those scientific or medical studies, and test data, which the particular community of experts would require in order to make such statements. *See also, e.g., In re Sterling Drug, Inc., supra,* 102 F.T.C. at 762 ("the inquiry contemplated by *Pfizer* for reasonable basis claims does not conflict with the more narrowly focused inquiry involved where representations are made that a claim has been established or scientifically proven").

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[161] "'Establishment claims' are claims that the efficacy of [the product] has been scientifically proved, i.e., 'established.' In our . . . recent cases, we stated that we require such claims to be substantiated by evidence sufficient to satisfy the relevant scientific community of the claim's truth. We further stated that the appropriate level of substantiation for *other claims* would be determined by considering factors such as the harm to consumers if the claim were false." *In re Thompson Medical Co., supra,* 104 F.T.C. at 812-22 & fn. 59 (emphasis added).

This distinction may help to explain, at least in part, why Judge Easterbrook's decision in *FTC v. QT, Inc., supra*, heavily emphasized here by Reynolds, is neither influential, nor ultimately helpful to Defendant. After noting that "placebo-controlled, double-blind" studies – such as, e.g., certain types of epidemiological studies at issue here – "are expensive . . . [and] require large numbers of participants to achieve statistically significant results," 512 F.3d at 861, he went on to announce broadly, without any citation whatsoever, the following:

> Nothing in the Federal Trade Commission Act, the foundation of this litigation, requires placebo-controlled, double-blind studies. . . . [A] statement that is plausible but has not been tested in the most reliable way cannot be condemned out of hand.

Id. Judge Easterbrook then continues on with his iodine-soaked band-aid analogy, and concludes – essentially encapsulating (and forecasting) RJRT's entire argument as to why epidemiological studies are not necessary here – that

> [i]t may be debatable how much the risk of infection falls [by using such a band-aid], but the direction of the effect would be known, and the claim could not be condemned as false. Placebo-controlled, double-blind testing is not a legal requirement for consumer products.

Id. He then goes on, however, to recognize that an ad statement which expressly touts (or even just implies) health or medical benefits can be

> misleading unless a reliable test had been used and statistically significant results achieved. A placebo-controlled, double-blind study is the best test; something less may do . . . but defendants have no proof [here because t]he "tests" on which they relied were bunk.

Id., 512 F.3d at 862.

Since in this case the underlying studies and testing of Eclipse accomplished by Reynolds over many years are not "bunk," and were in fact done appropriately and yielded reliable results (within, of course, the inherent limitations of each such test or study), RJRT argues that its claims cannot be found misleading or deceptive under *QT, Inc.,* even if there are no pertinent epidemiological studies on the incidence of actual human disease after switching to Eclipse. The short answer is that *QT, Inc.* simply ignores the entire body of FTC case-law which <u>does</u> require such studies if that is what the relevant scientific community believes is required to support the particular ad claims at issue. *See Removatron, supra.*

Finally on this issue, application of the *Pfizer/Thompson Medical* analysis would in any event not necessarily result in victory for Reynolds. The factors to

be considered in deciding the nature and amount of substantiation (e.g., scientific evidence) that is required in a particular case – none of which are exclusive, and no one of which is necessarily predominant – are as follows:

- The type of claim
- The type of product
- The potential benefits of a truthful claim
- The possible consequences of a false claim
- The cost of developing the necessary substantiation
- The type, and amount of substantiation experts in the field believe would be reasonable

In re Thompson Medical Co., supra, 104 F.T.C. at 821 (fn. omitted). It is, of course, easy to see why Reynolds would prefer this more flexible approach,[162] because it could arguably score big on the last 4 factors, perhaps even enough to overcome an adverse inference under the first two factors.

That is, RJRT argues that (A) the final factor contemplates only that substantiation which the medical/scientific community would find to be "reasonable" under all of the circumstances, rather than absolutely required, and thus the Eclipse expert panel's "total weight of the evidence" and "more likely than not" approaches – each based on the reasonable exercise of scientific judgment with respect to extensive preliminary testing data, and buttressed by the additional expert testimony presented at trial – would be adequate to support the "less risk" claims for Eclipse. Then, Reynolds further contends that (B) even if the otherwise necessary epidemiological studies are not scientifically impossible, the cost, long time horizon and considerable effort to conduct them, and the chance of ultimately generating less than useful data, makes the fifth factor come out in its favor as well. Finally, Defendant posits that (C) the "consequences of a false claim" are negligible, because there is no evidence that switching to Eclipse would result in any worse harm to committed smokers,[163] and (D) the potential "benefits of a truthful claim" are high, because long-term Eclipse use might indeed reduce the risk of some tobacco-related diseases for at least some smokers.

Thus, even if the "type of product" and "type of claim" here – cigarettes, which are an inherently dangerous product which produces physical injury, debilitating disease, and death even when "properly" used, and a positive,

[162] For non-establishment claims, that is "claims that do not assert [or imply] a specific level of substantiation (i.e., a simple claim of efficacy), 'the reasonable basis inquiry has been defined more flexibly'." *QT Inc., supra,* 448 F.Supp.2d at 959, *quoting Thompson Medical, supra,* 791 F.2d at 194.

[163] Recall that the State has presented no evidence on, and has given up its claim under Count II as to "deceptive practices" in marketing Eclipse that might arguably induce smokers to delay quitting entirely, or other cessation efforts, or even possibly influencing non-smokers to start.

affirmative claim that those risks of disease incidence will in fact be reduced by switching to Eclipse – argue strongly in favor of requiring the type, and level of substantiation which the consensus view of the relevant scientific community thinks is necessary for those advertising claims, Reynolds urges the court to ignore the total weight of the evidence in this case in favor of a more "flexible" outcome which would hold that the Eclipse ad claims are nonetheless adequately supported, and not misleading or deceptive. As stated, the court does not think the Vermont Supreme Court would ultimately be "guided" by (*cf.* 9 V.S.A. § 2453(b)) or adopt such an approach under the Vermont CFA, even if it is correct under FTC case-law,[164] and perhaps even logical and at least superficially persuasive, because it is so antithetical to the core premise and public policy basis of the CFA. Accordingly, the court declines to engage in any additional, or extended analysis under the *Pfizer/Thompson Medical* factors. Defendant is liable under the CFA, 9 V.S.A. § 2453(a), for the three specific Eclipse ad statements identified above.

(B) Liability of Reynolds Under MSA and Consent Decree

Under Counts III and IV of the complaint, the State has also proven by a preponderance of the evidence that Reynolds has violated the MSA, § III(r), and the associated incorporation of that provision – prohibiting RJRT from making "any material misrepresentation of fact regarding the health consequences of using any Tobacco Product" – into the 1998 Consent Decree, ¶ V(I). The court sees no reason, even after extensive additional briefing, to reexamine, or repeat at length its earlier determination, in denying RJRT's motion for summary judgment (*see* Decision and Entry Order, at 3-8 (August 19, 2008)), that this prohibition essentially incorporates the same legal analysis as the requirement for substantiation, or reasonable basis, under the FTC Act.

> The court concludes that the prohibition against material misrepresentations of fact in the MSA and Consent Decree applies to, and . . makes it a violation to utter false or misleading statements about tobacco smoking health consequences, whether express or implied. A statement that implies that a health claim can be substantiated, or is of such a nature that a reasonable person would otherwise expect it to have some medical or scientific basis, [is] a misrepresentation actionable under the MSA and Consent Decree if it is proven that the expected substantiation does not exist, or is insufficient or inadequate.

[164] Of course, the court has already concluded that the *Pfizer/Thompson Medical* analysis is inapplicable, and never reached here, because the Eclipse ad claims are "establishment" claims for which the necessary scientific substantiation is in fact required, period. In its post-trial briefing and proposed conclusions, the State then offers a more detailed rebuttal of why even the *Pfizer/Thompson Medical* analysis does not save the Eclipse ad claims; for the reasons stated, the court does not take up that invitation as well.

Id., at 8 (emphasis in original). Accordingly, because the State has proven that the three Eclipse ad claims either expressly or by implication indicate that sufficient, and acceptable medical and/or scientific evidence exists to substantiate the affirmative health benefit claims actually made; that the required substantiation does not in fact exist; and that these claims were therefore material[165] misrepresentations of fact, Reynolds is in violation of § III(r) of the MSA and ¶ V(I) of the Consent Decree, and the State will be entitled to entry of judgment on Counts III and IV of the complaint.

However, while the court has bifurcated the case so that all issues regarding civil penalties, actual damages (if any), remedies under 9 V.S.A. §§ 2458(a), (b), and other potential relief are still open for further litigation, the court does make clear now that the finding of violation, and liability under the Consent Decree is not equivalent to a finding of willful contempt. Indeed, the court concludes that although Reynolds ultimately did not have the required medical and scientific substantiation for the Eclipse ad claims, it did not proceed with deliberate disdain or disregard for this particular obligation under the Consent Decree, and in fact spent considerable sums and expended considerable effort over many years to obtain the evidence it thought would be sufficient to make those claims. Although its demonstration of subjective "good faith" is not a defense to liability, it is enough to ward off a finding of willful contempt. *See, e.g., FTC v. Lane Labs-USA, Inc.,* 2009 WL 2496532 (D. N.J., Aug. 11, 2009) (Not For Publication).

In *Lane Labs, supra*, the FCT sought to hold a maker, and marketer of dietary supplements in contempt of a previously entered consent decree requiring, *inter alia*, that Lane Labs "possess competent and reliable scientific evidence that substantiates [its advertising] claims." *Id.,* at *7. The decree in that case also prohibited Lane labs from "misrepresenting 'the existence, . . results, conclusions . . of any test, study, or research'." *Id.*[166] Without repeating the extensive culling of the scientific evidence which the court there engaged in, the court's ultimate conclusion is instructive:

> [T]he Defendants have undertaken considerable efforts to learn about the products at issue and to make claims that they believed were supported by credible evidence. . . . Defendants have exerted considerable effort to comply with the Consent Orders including seeking expert advise . . . . Based on the evidence . . , it is evident that the materials relied upon by

[165] The court interprets "materiality" here to have the same meaning as under both the CFA and the FTC case-law, *supra*. Clearly these claims were material in that they would tend to influence, one way or the other, the decision of a smoker concerned about the health consequences of smoking – the very population expressly targeted by the Eclipse ads, and the very purpose for which Reynolds chose to make the affirmative health claims – to purchase Eclipse.

[166] One necessarily wonders whether it would have made any difference here if this Consent Decree was more specific, like the one in *Lane Labs*; probably not. As noted by the court previously, this provision in the MSA and Decree appears to have been the result of "purposeful ambiguity."

> Defendants are in hindsight not perfect. This however, does not negate Defendants' efforts to obtain good information and expert advice. . . . Defendants have support for their position. Given that Defendants obtained and provided scientific evidence that experts in the field said could be relied upon and they were never told otherwise, it would be fundamentally unfair to now say that they have been violating the Orders and therefore must pay a prohibitive penalty.

Id., at *9, 10. Of course, Reynolds will be liable for such remedies and relief as the State is able to prove under the CFA, and for noncompliance with the MSA and Consent Decree, but no additional "prohibitive penalty" will be imposed here.

The court in *Lane Labs* applied the standard for contempt which is generally utilized by most courts:

> "The exercise of the power to find and to punish for contempt is [ ] discretionary, and should be undertaken with the utmost sense of responsibility and circumspection." . . . To establish contempt the movant bears the burden of proving by clear and convincing evidence that the respondent violated a court order, . . . "evidence so clear, direct and weighty and convincing as to enable [a court] to come to a clear conviction without hesitancy, of the truth of the precise facts." . . . Where there is any reason to doubt the wrongfulness of the respondent's conduct, a court should not find contempt. . . . Moreover, substantial compliance with a court order is a defense to civil contempt. "[A] defendant may not be held in contempt as long as it took all reasonable steps to comply."

Id., at *6,7 (cits. omitted). This standard is entirely compatible with Vermont law. *See generally, e.g., Socony Mobil Oil Co. v. Northern Oil Co.,* 126 Vt. 160 (1966); *Orr v. Orr,* 122 Vt. 470 (1962); 12 V.S.A. § 122. The court exercises its discretion here, based on the "total weight of the evidence," not to hold Reynolds in willful contempt for its violation of, and noncompliance with the Consent Decree, ¶ V(I).

(C) CONCLUSION

After further proceedings to determine appropriate remedies and other relief under the CFA, MSA and Consent Decree, judgment shall be entered in favor of the Plaintiff State of Vermont, and against the Defendant R.J. Reynolds Tobacco Co., on Counts I, III and IV of the complaint herein. Count II is dismissed.

IT IS SO ORDERED, at Burlington, Vermont, this 10th day of March, 2010.

/s/ *Dennis R. Pearson*
Dennis R. Pearson, Superior Judge