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Division of Dockets Management  
HFA-305  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

Re: Possible Role of Independent Third Parties in Industry-Sponsored Tobacco Product Research; Establishment of a Public Docket; Request for Comments  
**Docket No. FDA-2013-N-0305**

Dear Commissioner Hamburg:

The Tobacco Control Legal Consortium is pleased to submit these comments to assist the U.S. Food and Drug Administration (FDA) in designing an effective third party governance system for tobacco product research. Specifically, we address the FDA's consideration of the recommendation in the Institute of Medicine's report, "Scientific Standards for Studies on Modified Risk Tobacco Products," that sponsors of Modified Risk Tobacco Product (MRTP) applications use independent third parties to undertake one or more key functions in tobacco product research (third party governance).

Founded in 2003, the Tobacco Control Legal Consortium ("the Consortium") is the leading source of legal technical assistance on tobacco control policy in the United States. The Consortium promotes evidence-based and legally sound approaches to tobacco control policy, and provides legal technical assistance to federal, state, and local public health advocates, officials, and attorneys across the country. The Consortium's team of attorneys, based at the Public Health Law Center in St. Paul, Minnesota, provides legislative drafting and policy assistance, prepare educational materials, and file legal briefs as *amicus curiae* in key cases before the highest courts of the nation.

The Consortium strongly supports the use of independent third parties for tobacco product research, for MRTP applications as well as other types of tobacco product research necessary for effective tobacco product regulation. As shown by the evidence described below, the tobacco industry has a long history of secretly conducting scientific research on the health effects of tobacco use and suppressing information that may damage its image or decrease the sales of its products. Industry efforts to suppress evidence of the catastrophic health effects of tobacco products have included public disparagement of any research finding a link between tobacco use and disease and death, as well as attempts to discredit the researchers who publish such findings.<sup>1</sup> In the latter half of the twentieth century, the mounting evidence of the health effects of tobacco use became undeniable and the public finally began to question the motives of the tobacco industry. In response, the tobacco companies conspired to create front groups that

appeared to be legitimate, independent third-parties and used them to continue to disseminate false information.<sup>2</sup> Based on this evidence, we urge the FDA to implement a system of third-party governance for all tobacco product research. We also recommend that steps be taken to prevent the tobacco industry from playing any role in the selection of those independent parties. The tobacco industry has demonstrated a keen ability to hide behind third parties and use them to further its own agenda; thus, it is not enough to simply use third parties for tobacco product research. Those third parties must be completely independent of tobacco company interests.

The issue of establishing third-party review of tobacco product research is all the more important in light of the FDA Center for Tobacco Products' continued assumption that the tobacco industry's goal as a "stakeholder" in the federal regulatory process is fair and effective regulation. The evidence of tobacco industry deception about the health consequences of using its products, marketing to youth, and its use of front groups is relevant not only to the FDA's consideration of third-party oversight of research, but also to tobacco industry involvement in the larger regulatory process. This evidence highlights the need for independent third-parties in tobacco product research and any other FDA undertaking that involves input from the tobacco industry.

The tobacco industry has a long history of deceitful behavior that is well-chronicled. The industry's behavior and tactics are documented by many sources, including a massive archive of internal industry documents housed at the University of California San Francisco. In addition, Judge Gladys Kessler's landmark 2006 opinion in *U.S. v. Philip Morris* provides a comprehensive compilation of the tobacco industry's deception.<sup>3</sup> In this case, the government charged the tobacco industry defendants<sup>4</sup> with violating the Racketeer Influenced and Corrupt Organizations Act (RICO). Many of Judge Kessler's findings are directly relevant to the issue of whether the tobacco industry can be trusted to perform scientifically valid research and therefore must inform the FDA's consideration of third-party governance of tobacco product research. That ruling should also inform the FDA's decision-making in its regulation of tobacco products. Any decisions made or regulations promulgated by the FDA should give appropriate weight to Judge Kessler's findings that the tobacco industry has been and continues to be populated by a small group of racketeers that conspire to violate the law to protect their profits and avoid responsibility for selling an addictive and deadly product.

This comment will briefly lay out the history of the tobacco industry's manipulation of scientific research and its use of third-party front groups to disseminate doubt and false information. A much more detailed history is available in Judge Kessler's full opinion, most of which is devoted to findings of fact regarding the tobacco industry's deceptive practices. This comment will describe the tobacco industry's secret research on the harms of tobacco use that it suppressed for decades; its public statements contrary to its own research and the research of others; its knowledge of the addictiveness of nicotine and denial of that knowledge; its deliberate marketing to youth; its creation of various front groups in the U.S. and abroad to generate illegitimate research and disseminate false information; and its continued manipulation of scientific research after Judge Kessler forced the industry to cease its collaborative efforts to create and disseminate junk-science.

## **I. The History of Deception: Hiding the Truth and Lying to the Public**

The pattern and practice of suppression of truthful information in the tobacco industry runs deep and wide. In her ruling, Judge Kessler found that the tobacco industry “attempted to and, at times, did prevent/stop ongoing research, hide existing research, and destroy sensitive documents in order to protect their public positions on smoking and health, avoid or limit liability for smoking and health related claims in litigation, and prevent regulatory limitations on the cigarette industry.”<sup>5</sup> The tobacco industry has a long history of hiding its own damaging research while publicly attempting to cast doubt on any research that might make a connection between tobacco use and disease. Judge Kessler’s findings confirmed this history:

From at least 1953 until at least 2000, each and every one of these Defendants repeatedly, consistently, vigorously—and falsely—denied the existence of any adverse health effects from smoking. Moreover, they mounted a coordinated, well-financed, sophisticated public relations campaign to attack and distort the scientific evidence demonstrating the relationship between smoking and disease, claiming that the link between the two was still an “open question.” Finally, in doing so, they ignored the massive documentation in their internal corporate files from their own scientists, executives, and public relations people that, as Philip Morris’s Vice President of Research and Development, Helmut Wakeham, admitted, there was “little basis for disputing the findings [of the 1964 Surgeon General’s Report] at this time.”<sup>6</sup>

Following the Surgeon General’s report in 1964, it became clear that the overwhelming evidence that smoking caused disease could no longer be suppressed. Rather than acknowledge the evidence and attempt to find a solution to the problem that would potentially save lives, the tobacco industry attempted to sow doubt to enable it to continue to sell its addictive and deadly product. The strategy was summed up by one executive who said, “[o]ur basic position in the cigarette controversy is subject to the charge, and may be subject to a finding, that we are making false or misleading statements to promote the sale of cigarettes.”<sup>7</sup> The industry would continue to deceive the public until a court forced its hand. The industry refused to publicly acknowledge the dangers of tobacco use until Judge Kessler issued her opinion in 2006, which was upheld but slightly modified by the Court of Appeals for the D.C. Circuit in 2009<sup>8</sup> and denied appeal by the U.S. Supreme Court in 2010, rendering Judge Kessler’s ruling final.<sup>9</sup>

### **A. Deception Regarding the Addictiveness of Nicotine**

The industry was well aware of the addictive properties of nicotine and made every effort to suppress the relevant evidence. Judge Kessler concluded that:

Defendants have studied nicotine and its effects since the 1950s. The documents describing their research into and resulting knowledge of nicotine’s pharmacological effects on smokers -- whether they characterized that effect as “addictive,” “dependence” producing or “habituating,” -- demonstrate unequivocally that Defendants understood the central role nicotine plays in

keeping smokers smoking, and thus its critical importance to the success of their industry.<sup>10</sup>

Not only was the industry aware of the effects of nicotine but they used this knowledge to their benefit and to the detriment of tobacco users. “Indeed, Defendants purposefully designed and sold products that delivered a pharmacologically effective dose of nicotine in order to create and sustain nicotine addiction in smokers.”<sup>11</sup> Judge Kessler found that:

Despite the extensive and detailed knowledge possessed by Defendants for decades about the addictive qualities of nicotine and smoking, Defendants have publicly made false and misleading denials of the addictiveness of smoking, as well as nicotine's role in causing that addiction, and have suppressed the research results and data they produced and possessed contradicting such denials.<sup>12</sup>

At every opportunity, rather than tell the truth and potentially benefit the public, the tobacco industry has opted to suppress the truth and disseminate false information:

As that evidence shows, Defendants themselves possessed, from their own in-house and external research, information that led them to conclude, long before public health bodies did, that the primary reason people keep smoking cigarettes is to obtain the drug nicotine, which is addictive. Defendants intentionally withheld this data (including many of studies on the physiological effects of nicotine in animals and humans, and much of their research on the determinants of nicotine dosing in cigarettes) when there were major public efforts to review and synthesize all available information. This occurred with the preparation of both the 1964 and 1985 Surgeon General's Reports and numerous congressional investigations. Defendants also engaged in a decades-long, elaborate, sophisticated, well-funded public relations offensive, denying and attacking the consensus conclusion they had long ago reached internally, but that the less well funded public health community was belatedly reaching, that smoking is addictive primarily because cigarettes effectively deliver nicotine.<sup>13</sup>

Even as the tobacco industry's top executives were brought before a congressional subcommittee in 1994, they continued to deceive the government and the public and deny the addictiveness of nicotine.

REP. RON WYDEN<sup>14</sup> (D-OR): (Off mike) Thank you, Mr. Chairman. . . .  
 Let me begin my questioning on the matter of whether or not nicotine is addictive. Let me ask you first, and I'd like to just go down the row, whether each of you believes that nicotine is not addictive. I heard virtually all of you touch on it. Just yes or no. Do you believe nicotine is not addictive?  
 MR. CAMPBELL<sup>15</sup> (?): I believe nicotine is not addictive, yes.  
 REP. WYDEN: Mr. Johnston?  
 MR. JOHNSTON<sup>16</sup>: Congressman, cigarettes and nicotine clearly do not meet the classic definitions of addiction. There is no intoxication.

REP. WYDEN: We'll take that as a no and, again, time is short. If you can just - I think each of you believe nicotine is not addictive. We just would like to have this for the record.

MR. TADDEO<sup>17</sup> (?): I don't believe that nicotine or our products are addictive.

MR. HARRIGAN<sup>18</sup> (?): I believe nicotine is not addictive.

MR. TISCH<sup>19</sup> (?): I believe that nicotine is not addictive.

MR. SANDEFUR<sup>20</sup> (?): I believe that nicotine is not addictive.

MR. DONALD JOHNSTON<sup>21</sup> (?): And I, too, believe that nicotine is not addictive.<sup>22</sup>

There is no person or body that the industry will not attempt to deceive when the potential regulation of tobacco is at stake.

### **B. Deception Regarding Marketing to Youth**

The tobacco industry has also publicly maintained that they do not market to youth. However, tobacco industry documents reveal otherwise:

Every year, over 400,000 people die of smoking related diseases. In addition, there are a relatively small number of people who quit smoking each year. In order to sustain and perpetuate themselves, Defendants must bring in new smokers to replace those leaving the market. . . .

The only way Defendants can sustain themselves is by bringing in large numbers of replacement smokers each year. Carl Schoenbachler, current president and CEO of BATC (a former parent of B&W Tobacco and holding entity for B&W Tobacco) acknowledged that although the company has a stated policy of not marketing to non-smokers, "it was a reasonable conclusion" that B&W would become unprofitable if non-smokers did not become smokers.

The majority of people who become addicted smokers start smoking before the age of eighteen, and many more before the age of twenty-one. Ellen Merlo, Senior Vice President at Philip Morris, admitted that she was aware that over 80% of smokers start smoking before they turn eighteen. A 1989 RJR document titled "Camel Y&R Orientation" discussed the "strategic importance" of young adult smokers ("YAS"): "YAS are the only source of replacement smokers. Less than one-third of smokers start after age 18." The document further stated: "To stabilize RJR's share of total smokers, it must raise share among 18-20 from 13.8% to 40% ... ASAP." In a September 20, 1982 memorandum, Diane S. Burrows, RJR Marketing Development Department researcher, stated, "if a man has never smoked by age 18, the odds are three-to-one he never will. By age 21, the odds are twenty-to-one."<sup>23</sup>

Perhaps the best summary of the tobacco industry's attitude towards marketing to children comes from Bennett LeBow, President of Vector Holdings Group: "if the tobacco companies really stopped marketing to children, the tobacco companies would be out of business in 25 to 30 years because they will not have enough customers to stay in business."<sup>24</sup>

## II. Industry Front Groups Provided Veneer of Credibility

In an effort to bolster its credibility, the industry sought another avenue through which to disseminate false information. In an attempt to provide greater legitimacy for its illegitimate science, the tobacco industry conspired to create several organizations that appeared to be independent of tobacco industry interests. These industry front organizations each had a stated purpose of conducting independent scientific research but the actual purpose of each organization was to provide the industry with an additional platform to deny the harms of tobacco use.<sup>25</sup> It is this history of deliberate deception through the use of fake, independent third-parties that the FDA must thoroughly understand in order to create a useful third-party governance system. Any amount of tobacco industry interference in tobacco product research will compromise the integrity of the research and, in turn, compromise the integrity of tobacco product regulation.

### A. Tobacco Industry Research Committee/Council for Tobacco Research

One of the tobacco industry's first attempts at creating a third-party organization was the Tobacco Industry Research Committee (TIRC), later renamed the Council for Tobacco Research (CTR). The creation of TIRC was infamously announced on January 4, 1954 in an advertisement titled, "A Frank Statement to Cigarette Smokers," that ran in 448 newspapers across the country.<sup>26</sup> The organization was created in the wake of the Reader's Digest article "Cancer by the Carton," and was an effort to counter the growing body of scientific evidence linking smoking to lung cancer. The alleged purpose of the organization was to fund independent scientific research to determine whether or not there was a link between cancer and smoking. As described by Judge Kessler:

The Frank Statement set forth the industry's "open question" position that it would maintain for more than forty years -- that cigarette smoking was not a proven cause of lung cancer; that cigarettes were not injurious to health; and that more research on smoking and health issues was needed. In the Frank Statement, the participating companies accepted "an interest in people's health as a basic responsibility, paramount to every other consideration in our business" and pledged "aid and assistance to the research effort into all phases of tobacco use and health." The companies promised that they would fulfill the obligations they had undertaken in the Frank Statement by funding independent research through TIRC, free from any industry influence.<sup>27</sup>

Unsurprisingly, neither TIRC nor CTR ever funded a study that found such a link, even after the 1964 Surgeon General's report described the scientific consensus on the issue. Instead, the organizations attempted to foster doubt about the health effects of smoking. Specifically, the industry used the organization to churn out illegitimate science that it used as a veil for an agenda of furthering doubt to perpetuate the sale of tobacco.<sup>28</sup>

TIRC focused its energies and resources in two areas -- public relations and scientific research. First, it served as a sophisticated public relations unit for Defendants, especially in relation to growing public concern about the risks of

smoking, by repeatedly attacking scientific studies that demonstrated the harms of cigarette smoke and insisting on the notion of an “open question” regarding cigarette smoking and health. Second, it developed a scientific research program that focused on basic processes of disease rather than evaluating the risks and harms associated with smoking -- the very subject that the industry had pledged to pursue through TIRC. From the outset, the dual functions of TIRC were intertwined, with the scientific program of TIRC always subservient to the goals of public relations.

....

Virtually none of the research funded by TIRC/CTR centered on immediate questions relating to carcinogenesis and tobacco that could resolve the question of the harms brought about by cigarette smoking. Although some TIRC/CTR-funded researchers explored alternative hypotheses, TIRC/CTR did not typically pursue direct research on cigarettes and disease. Rather than addressing the constituents in tobacco smoke and their demonstrated effect on the human body, TIRC/CTR directed the majority of its resources to alternative theories of the origins of cancer centering on genetic factors and environmental risks. The major thrust of TIRC/CTR was to emphasize that human cancers were complex processes, difficult to study and difficult to understand, and to focus on the “need for more research.” Although research funded by the [CTR Scientific Advisory Board] was irrelevant to the immediate questions associated with tobacco smoking and health, it did “create the appearance of [Defendants] devoting substantial resources to the problem without the risk of funding further “contrary evidence.”<sup>29</sup>

TIRC/CTR was the result of the tobacco industry’s first endeavor to create a front group and its success led to the creation of other similar groups.

## **B. Tobacco Institute**

Having TIRC/CTR focus on both objective scientific research and public relations supporting the industry soon created too much potential for the appearance of a conflict of interest for even the tobacco industry to reconcile. To solve the problem, the industry conspired to create an entity solely responsible for public relations that would allow TIRC/CTR to continue to be an avenue for fraudulent scientific research. To this end, the Tobacco Institute (TI) was created to disseminate TIRC/CTR’s false scientific information:

“[T]he Tobacco Institute created, issued, and disseminated press releases, public statements, advertisements, brochures, pamphlets, and other written materials on behalf of Defendants (1) denying that there was any link between smoking and disease; that nicotine was addictive; that cigarette companies marketed to youth; and that environmental tobacco smoke (“ETS”) posed a health risk; and (2) discrediting scientists and public health officials who took a different position on these issues.”<sup>30</sup>

With the Tobacco Institute, the tobacco industry once again attempted to marginalize objective science and poison public opinion with false information. TI became instrumental in furthering the tobacco industry's agenda:

At the December 9, 1982 Tobacco Institute Board of Directors meeting, Tobacco Institute President Samuel D. Chilcote, Jr., discussed the Institute's approach to the upcoming 1983 Surgeon General's Report. The Tobacco Institute's plans included personally passing out summaries of its document on "Smoking and Cardiovascular Disease" to several dozen reporters; having George Schafer, Tobacco Institute Medical Director, on hand to answer the reporters' questions and lend credibility; holding its "own press conference a day or so before the Surgeon General's press conference challenging the contention that smoking causes cardiovascular disease," with Shook, Hardy & Bacon providing assistance; and attempting to "encourage a non-tobacco state congressman to launch an investigation into MRFIT [Multiple Risk Factor Intervention Trials] shortly before the Surgeon General's conference," alleging that it was a waste of 115 million tax payers' dollars, "thereby putting the Surgeon General on the defensive."

....

Similarly, the Tobacco Institute was very active in planning a response regarding the release of the 1987 Surgeon General's Report which discussed the addictive nature of smoking. Suggested strategies for the Tobacco Institute response and the public's potential reaction were carefully considered. Samuel Chilcote wrote informational memoranda about the Surgeon General's Reports for distribution to the Tobacco Institute Executive Committee. Brennan Dawson, Vice President of Public Relations for the Tobacco Institute, also made a presentation at a 1988 Tobacco Institute Communications Committee meeting, about her plans to distribute editorials favorable to the industry about the 1987 Surgeon General's Reports to editorial writers. Dawson also invited additional distribution suggestions from Communications Committee members.<sup>31</sup>

It is clear from tobacco industry documents that while TI was supposed to appear to be an independent third-party, it was the tobacco companies that were behind all of its activities:

Attorneys representing Defendants again played a major role in these efforts to discredit the Surgeon General's Reports and attack other scientific research linking smoking and disease. They meticulously edited and rewrote drafts of Tobacco Institute advertisements, articles, and public statements. Lawyers regularly recommended ideas for articles and provided materials to the Tobacco Institute for consideration.<sup>32</sup>

As with TIRC/CTR and all of the industry's other front groups, TI was never independent from tobacco industry interests and it was never intended to be. The only goal was the appearance of independence to lend credibility to the tobacco industry's positions on science and policy.

### C. Council for Indoor Air Research

In 1988 the Tobacco Institute spun off its Environmental Tobacco Smoke Advisory Group (ETSAG) and renamed it the Council for Indoor Air Research (CIAR). The move was largely to dissociate the new group from the tobacco industry in an effort to create greater legitimacy. The new group funded scientific research although funding decisions that were not made by scientists, but rather by the board of directors, which was comprised of tobacco industry executives. Even though the group purported to objectively study secondhand smoke, the tobacco industry used it as a vehicle to downplay exposure to, and the health effects of, secondhand smoke. The organization focused most of its research efforts on indoor air pollutants other than tobacco smoke,<sup>33</sup> in order to produce data the industry could use to further its agenda of deception and distraction:

CIAR's primary value was to generate data for defensive use in litigation. CIAR Board of Directors chairman Tom Osdene of PM wrote Sam Chilcote of the Tobacco Institute five years earlier in an April 25, 1988 letter that "the purpose of CIAR" was "to provide ammunition" for the industry on the ETS "battlefield." Rupp wrote in a March 1993 letter to Imperial Tobacco: "In sum, while one might wish it otherwise, the value of CIAR depends on the industry's playing an active role (1) in identifying research projects likely to be of value and (2) working to make sure that the findings of funded research are brought to the attention of decision makers in an appropriate and timely manner."<sup>34</sup>

CIAR became a useful tool for the tobacco industry to manufacture data that was favorable for the industry. One executive wrote, "What we have learned over the past five years, the period of CIAR's existence, is that CIAR can make -- indeed, already has made -- an important contribution to the industry's efforts to fight unwarranted smoking restrictions."<sup>35</sup>

### D. Other Front Groups Around the World

TIRC/CTR, TI and CIAR are only the most well-known of the tobacco industry's third-party front groups. The industry has expended considerable efforts to protect its interests all around the world.

Through their recruiting and training of consultants around the world, Defendants created a cadre of seemingly independent consultants to support the industry's position on secondhand smoke and to create the impression that a legitimate controversy existed among independent scientists. The global effort to create and manage this program required intense coordination among the companies and their counsel.<sup>36</sup>

Other organizations established by the tobacco industry and its attorneys to serve as a third-party under the guise of independence has included:

- International ETS Management Committee (IEMC) which was created to fund and manage research on secondhand smoke and to coordinate the tobacco industry's strategy and position on secondhand smoke;<sup>37</sup>

- Tobacco Manufacturers' Standing Committee (TMSC),<sup>38</sup> later Tobacco Research Council (TRC),<sup>39</sup> and later Tobacco Advisory Council (TAC),<sup>40</sup> which was a group of British tobacco companies formed to collaborate with TIRC/CTR regarding global activities;<sup>41</sup>
- International Committee on Smoking Issues (ICOSI), which was an organization created to develop an international position and strategy on health issues related to smoking;<sup>42</sup>
- International Tobacco Information Center (INFOTAB), which was a global clearinghouse for tobacco industry publications that was succeeded by Tobacco Documentation Centre (TDC);<sup>43</sup>
- Center for Cooperation in Scientific Research Relative to Tobacco (CORESTA), which was an international secretariat managing international scientific studies of tobacco;<sup>44</sup>
- Indoor Air Pollution Advisory Group (IAPAG), which was a group of U.S. consultants hired by the tobacco industry and its attorneys to testify at public hearings as expert witnesses on behalf of tobacco industry interests;<sup>45</sup>
- Association for Research on Indoor Air (ARIA) was a group of scientists in the UK hired by the tobacco industry to comment on secondhand smoke issues;<sup>46</sup> Indoor Air International (IAI) was an offshoot of ARIA created to address secondhand smoke issues internationally;<sup>47</sup> and
- Air Conditioning and Ventilation Access (ACVA), later Healthy Buildings International (HBI), which was a ventilation inspection firm funded by the tobacco industry to test indoor air quality and make statements at legislative and regulatory hearings that questioned the adverse health effects of secondhand smoke.<sup>48</sup>

### **III. The Continued Use of Front Groups to Encourage Scientific Misinformation**

As a part of the Master Settlement Agreement and individual state settlements that were signed in the 1990s, the tobacco companies were forced to stop industry-wide collaboration and disband CTR, TI, CIAR and other front groups.<sup>49</sup> However, while this ended the overt collaboration within the industry, it did not end the tobacco industry's scientific misinformation campaign. Each company instead pursued its agenda separately. Philip Morris aligned itself with the Life Sciences Research Office (LSRO).<sup>50</sup> Originally established to research medical issues for the U.S. Army, LSRO began reviewing cigarette additives and potentially reduced-risk tobacco products in 2001.<sup>51</sup> LSRO created expert panels to study both of these topics. Of the panel members assigned to study cigarette additives, seven of fifteen had direct financial ties to Philip Morris and two additional members had indirect, non-financial ties.<sup>52</sup> A similar association was created between the Institute for Science and Health (IFSH) and British-American Tobacco and Brown & Williamson Tobacco (now a part of R.J. Reynolds).<sup>53</sup> Between 2002 and 2004, IFSH granted \$3.9 million to study biomarkers of tobacco smoke exposure, tobacco harm reduction and the toxicity of tobacco constituents.<sup>54</sup> In addition, 97% of all funds granted by IFSH between 2001 and 2005 supported tobacco industry research.<sup>55</sup>

### **IV. The Tobacco Industry's Continued Denial of the Truth**

Despite the arguments proffered by the tobacco industry at the FDA's recent Third Party Governance workshop, the tobacco industry's behavior is not ancient history; it is ongoing and continues to this day. Judge Kessler's 2006 opinion addresses this topic directly:

There is a reasonable likelihood that Defendants' RICO violations will continue in most of the areas in which they have committed violations in the past. Defendants' practices have not materially changed in most of the Enterprise's activities, including: denial that ETS causes disease, denial that Defendants market to youth, denial of the addictiveness of nicotine, denial of manipulation of the design and content of cigarettes, suppression of information and research, and claims that light and low tar cigarettes are less hazardous than full-flavor cigarettes.

Philip Morris, BATCo, B&W, Lorillard, and RJR all deny in this lawsuit and in public statements that ETS causes disease in nonsmokers, contrary to the definitive scientific evidence and their own internal acknowledgments. . . Absent Court intervention, such denials and distortions of material health information and scientific evidence on ETS are, at a minimum, likely to continue.

Similarly, Defendants continue to engage in many practices which target youth, and deny that they do so. Despite the provisions of the MSA, Defendants continue to track youth behavior and preferences and market to youth using imagery which appeals to the needs and desires of adolescents. . . There is therefore no reason, especially given their long history of denial and deceit, to trust their assurances that they will not continue committing RICO violations denying their marketing to youth.

Although Defendants recently began to finally admit that smoking is addictive, no Defendant publicly informs consumers that nicotine is addictive, much less that smoking is a nicotine-driven addiction. To the contrary, the issue is Defendants' refusal to admit publicly that nicotine is physiologically addictive, that smoking is a nicotine-driven addiction, and that, therefore, quitting is not a simple act of willpower. At trial, the General Counsel for Philip Morris, Denise Keane, admitted that the "Smoking is Addictive" statement that Philip Morris removed from cigarette packs after buying three Liggett cigarette brands in 1999 was both correct and material. She also agreed that it is material for people to know that Philip Morris agrees that the nicotine delivered in cigarette smoking is addictive, but it does not say so publicly. The deliberate omission of admittedly material information about nicotine addiction is not a mere "quibble." It is fraudulent, with consequences for those who smoke and those, especially young people, who are considering whether to start smoking. Defendants have thus made clear that, despite their internal research to the contrary, they remain unwilling to admit publicly that nicotine is addictive and that smoking is an addiction driven by nicotine. Such RICO violations are reasonably likely to continue.

Defendants also continue to deny that they manipulate the design and content of cigarettes in order to assure adequate nicotine delivery to create and

sustain smokers' addiction. Such RICO violations are reasonably likely to continue.

In addition, Defendants have a continuing interest in suppressing research and information and destroying documents which could prove detrimental to their public and litigation positions. Although it is difficult to prove such suppression or destruction, the Court strongly believes such RICO violations are reasonably likely to continue.

Contrary to their internal documents, Defendants also continue to deny that low tar cigarettes are just as hazardous to smokers as full-flavor cigarettes, in part because of smoker compensation. In 1998, Philip Morris, RJR, B&W, and Lorillard jointly stated to the FTC that compensation was so "weakly documented" that the FTC should not require disclosure warnings to alert consumers, and that they were "unaware of evidence," other than that presented in Monograph 7, that consumers viewed low-tar cigarettes as safer. Defendants are well aware from their own research that a majority of smokers believe that low-tar cigarettes are healthier, are willing to buy them for precisely that reason, and are willing to sacrifice taste for what they believe to be less harmful cigarettes. Nonetheless, to this day, Defendants still deny that, as Monograph 13 found, low-tar cigarettes are just as dangerous as full-flavor cigarettes. These RICO violations are likely to continue.

Finally, despite Defendants' claims that they have materially altered their management and are now "new" companies, the evidence demonstrates that they have not changed their policies or personnel in any meaningful way. For example, Philip Morris' current top executive staff is composed entirely of veteran employees with an average of fifteen to twenty years of company experience. The assertion that such longstanding, faithful employees will usher in dramatically new corporate policies seems reasonably unlikely.<sup>56</sup>

It should be noted that *U.S. v. Philip Morris* is still actively being litigated by the tobacco industry. Even though the Supreme Court declined to hear the case in 2010, effectively upholding the findings of fact that chronicle the tobacco industry's misdeeds,<sup>57</sup> the case continues as the industry attempts to block the remedies handed down by Judge Kessler. As recently as January 25, 2013, the tobacco industry appealed Judge Kessler's order establishing language for the "corrective statements" that are mandated by her 2006 opinion.<sup>58</sup> This kind of delay tactic is standard operating procedure for the tobacco industry, and there have been numerous other attempts to appeal the remedies from this case, to extinguish the court's jurisdiction, and to have the case dismissed.<sup>59</sup> If the tobacco companies were interested in being good corporate citizens, if the industry had transformed itself as it would have us believe, it would finally accept the court's ruling and cease all of its wasteful appeals and attempts to evade the imposed remedies. The industry has not changed and there is no reason to believe that it will change. Despite the tobacco industry's assertions at the FDA's recent Third Party Governance workshop, ancient history is actually current news.

## V. Conclusion

The tobacco industry's history of deception regarding the health effects and addictiveness of tobacco products and its targeted marketing of youth, combined with its use of front groups to produce and disseminate scientific misinformation, shows that it cannot be trusted to conduct legitimate scientific research, nor to participate in the process of selecting independent third-parties to oversee scientific research. The use of third parties to conduct tobacco product research, as recommended by the Institute of Medicine, is an important step to ensure that the integrity of the research process is not compromised. Importantly, the tobacco industry must also have no part in the selection of independent third parties.

Moreover, it is vitally important that the FDA understand that the acts described in this comment were not isolated incidents. The tobacco industry has perpetuated deception, fraud, and junk-science for decades and will continue to do so, given the opportunity. Neither the Master Settlement Agreement nor the landmark ruling in *U.S. v. Philip Morris* have changed the tobacco industry's behavior; thus, it is highly unlikely that the passage of the Tobacco Control Act and the creation of the Center for Tobacco Products have changed the tobacco industry's agenda or tactics.<sup>60</sup>

This is particularly true in the context of the tobacco industry's most recent activities. Since the passage of the Tobacco Control Act, the tobacco industry has challenged the constitutionality of the Act itself,<sup>61</sup> the constitutionality of the FDA's graphic warning regulation<sup>62</sup> and the legitimacy of the Tobacco Products Scientific Advisory Committee.<sup>63</sup> The industry has also attempted to use the Act's narrow preemption provision to stamp out novel tobacco control policies at the local level, so far making this argument in two lawsuits in New York City<sup>64</sup> and one in Providence, RI.<sup>65</sup> Finally, the tobacco industry has also attempted to argue that the passage of the Tobacco Control Act extinguishes the court's jurisdiction in *U.S. v. Philip Morris*<sup>66</sup> – despite the fact that the industry simultaneously (in another suit<sup>67</sup>) challenged the constitutionality of the very laws that supposedly restrained it from future RICO violations.<sup>68</sup> All of these actions demonstrate that the industry cannot be trusted to participate in the creation of meaningful regulation or to comply in good faith with laws or regulations that do survive the industry's attempts to block them.

The Tobacco Control Legal Consortium urges the FDA to contemplate the past actions of the tobacco industry when it considers how to implement the Institute of Medicine's recommendation of using independent third-parties for tobacco product research.

Respectfully,



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<sup>1</sup> U.S. v. Philip Morris USA Inc., 449 F. Supp. 2d 1, 35-143 (D.D.C. 2006).

<sup>2</sup> See, e.g., *id.* at 34-146 (describing the “creation of the enterprise”, including the formation of the tobacco industry front groups); *id.* at 146-207 (describing the industry’s efforts to suppress evidence of and deny the serious adverse health consequences of smoking, including use of its front groups); *id.* at 208-307 (describing the industry’s efforts to suppress evidence of and deny the addictive properties of nicotine, including use of its front groups); *id.* at 692-800 (describing the industry’s efforts to suppress evidence of and deny the hazards of ETS to nonsmokers).

<sup>3</sup> *Id.* For an overview of industry practices from the findings section of the case, see TOBACCO CONTROL LEGAL CONSORTIUM, THE VERDICT IS IN: FINDINGS FROM UNITED STATES V. PHILIP MORRIS (2006) available at <http://publichealthlawcenter.org/sites/default/files/resources/tclc-verdict-is-in.pdf>.

<sup>4</sup> Philip Morris, Inc., now Philip Morris USA, Inc., a division of Altria Group Inc.; R.J. Reynolds Tobacco Co., now a division of Reynolds American, Inc.; Brown & Williamson Tobacco Co., a wholly owned subsidiary of British American Tobacco plc, which merged with R.J. Reynolds Tobacco Co. and became part of Reynolds American, Inc.; Lorillard Tobacco Company; The Liggett Group, now part of Vector Group Ltd.; American Tobacco Co., which merged with Brown & Williamson, prior to the merger between Brown & Williamson and R.J. Reynolds Tobacco Co.; Philip Morris Cos., now Altria Group, Inc.; British American Tobacco Investments Ltd.; The Council for Tobacco Research U.S.A., Inc.; and The Tobacco Institute, Inc.

<sup>5</sup> *Philip Morris*, 449 F. Supp. 2d at 801.

<sup>6</sup> *Id.* at 208.

<sup>7</sup> *Id.*

<sup>8</sup> U.S. v. Philip Morris USA, Inc., 566 F.3d 1095 (D.C.Cir.2009) (per curiam).

<sup>9</sup> *Philip Morris USA, Inc. v. United States*, 130 S.Ct. 3501 (2010) (denial of certiorari).

<sup>10</sup> *Philip Morris*, 449 F.Supp.2d at 219.

<sup>11</sup> *Id.* at 219 (citation omitted).

<sup>12</sup> *Id.* at 271.

<sup>13</sup> *Id.* at 289 (citations omitted).

<sup>14</sup> Ron Wyden, Member of the U.S. House of Representatives from Oregon’s 3<sup>rd</sup> District from 1981-96.

<sup>15</sup> William Campbell, President and Chief Executive Officer of Philip Morris USA (now a division of Altria Group Inc.).

<sup>16</sup> James W. Johnston, Chairman and Chief Executive Officer of R.J. Reynolds Tobacco Co. (now a division of Reynolds American, Inc.).

<sup>17</sup> Joseph Taddeo, President of U.S. Tobacco (now a division of Altria Group Inc.).

<sup>18</sup> Edward A. Horrigan, Chairman and Chief Executive Officer of Liggett Group (now part of Vector Group Ltd.).

<sup>19</sup> Andrew H. Tisch, Chairman and Chief Executive Officer of Lorillard Tobacco Company.

<sup>20</sup> Thomas E. Sandefur, Chairman and Chief Executive Officer, Brown and Williamson Tobacco Company (now part of Reynolds American, Inc.).

<sup>21</sup> Donald S. Johnston, President and Chief Executive Officer of American Tobacco Company (now part of Reynolds American, Inc.).

<sup>22</sup> *Nicotine and Cigarettes: Hearing Before the Subcomm. on Health & the Env’t, of the Comm. on Energy & Commerce*, 103<sup>rd</sup> Cong. 43-44 (1994).

<sup>23</sup> *Philip Morris*, 449 F. Supp. 2d at 561-62 (citations omitted).

<sup>24</sup> *Id.* at 562 (citation omitted).

<sup>25</sup> *Id.* at 36-143.

<sup>26</sup> *Id.* at 39.

<sup>27</sup> *Id.*

<sup>28</sup> *Id.* at 41-62.

<sup>29</sup> *Id.* at 49-50 (citations omitted).

<sup>30</sup> *Id.* at 70 (citations omitted).

<sup>31</sup> *Id.* at 74-75 (citations omitted).

<sup>32</sup> *Id.* at 75-76 (citations omitted).

<sup>33</sup> *Id.* at 735-46.

<sup>34</sup> *Id.* at 741 (citations omitted).

<sup>35</sup> *Id.* at 741 (citation omitted).

<sup>36</sup> *Id.* at 759.

<sup>37</sup> *Id.* at 746-52.

<sup>38</sup> *Id.* at 123-25.

<sup>39</sup> *Id.* at 125-26.

<sup>40</sup> *Id.* at 126-29.

<sup>41</sup> *Id.* at 123-29.

<sup>42</sup> *Id.* at 129-32.

<sup>43</sup> *Id.* at 132-36.

<sup>44</sup> *Id.* at 136-37. CORESTA is still an active organization with ties to the tobacco industry. It lists several tobacco companies as board members including R.J. Reynolds Tobacco Company. See CORESTA, *A Presentation of CORESTA*, 6 (Annex 1) (2013), [http://www.coresta.org/Home\\_Page/PresentationCORESTA\(Sept13\).pdf](http://www.coresta.org/Home_Page/PresentationCORESTA(Sept13).pdf).

<sup>45</sup> *Philip Morris*, 449 F. Supp. 2d at 757-58.

<sup>46</sup> *Id.* at 762-64.

<sup>47</sup> *Id.*

<sup>48</sup> *Id.* at 766-67. Healthy Buildings International is still an active organization that may or may not still have ties to the tobacco industry. Among its listed clients is a Philip Morris International company, PMI Global Services. See HEALTHY BUILDINGS INTERNATIONAL, *Recent Clients*, <http://www.healthybuildings.com/clients/recent-clients> (last visited Feb. 20, 2013). Current CEO, Richard Silberman, and current president, Simon Turner, have both had ties to the Tobacco Institute. See Memorandum from Daniel J. Wahby, Tobacco Institute to John R. Shear, Councilman, St. Louis County (Apr. 26, 1993) available at <http://legacy.library.ucsf.edu/tid/dyc29b00/pdf>.

<sup>49</sup> Master Settlement Agreement § III(o), 32 (1998).

<sup>50</sup> Suzaynn F. Schick & Stanton A. Glantz, *Old Ways, New Means: Tobacco Industry Funding of Academic and Private Sector Scientists Since the Master Settlement Agreement*, 16 TOBACCO CONTROL 157 (2007).

<sup>51</sup> *Id.* at 158.

<sup>52</sup> *Id.*

<sup>53</sup> *Id.*

<sup>54</sup> *Id.* at 168

<sup>55</sup> *Id.* at 162

<sup>56</sup> *Philip Morris*, 449 F. Supp. 2d at 911-13 (citation omitted).

<sup>57</sup> *Philip Morris USA Inc. v. United States*, 130 S.Ct. 3501 (2010).

<sup>58</sup> Notice of Appeal, *U.S. v. Philip Morris USA Inc.*, 449 F.Supp.2d 1 (D.D.C. 2006) (No. 99-2496), ECF No. 6000.

<sup>59</sup> *British American Tobacco Ltd. v. U.S.*, 131 S.Ct. 57 (2010); *Philip Morris USA Inc. v. U.S.*, 130 S.Ct. 3501 (2010); *U.S. v. Philip Morris USA Inc.*, 130 S.Ct. 3501 (2010); *Altria Group, Inc. v. U.S.*, 130 S.Ct. 3501 (2010); *R.J. Reynolds Tobacco Co. v. U.S.*, 130 S.Ct. 3501 (2010); *Lorillard Tobacco Co. v. U.S.*, 130 S.Ct. 3502 (2010); *British American Tobacco Ltd. v. U.S.*, 103 S.Ct. 3502 (2010); *U.S. v. Philip Morris USA Inc.*, 686 F.3d 832 (D.C. Cir. 2012); *U.S. v. Philip Morris USA Inc.*, 686 F.3d 839 (D.C. Cir. 2012); *U.S. v. Philip Morris USA Inc.*, 566 F.3d 1095 (D.C. Cir. 2009); *U.S. v. Philip Morris USA Inc.*, 2007 WL 1549126 (D.C. Cir. 2007); *U.S. v. Philip Morris USA Inc.*, 2006 WL 4608645 (D.C. Cir. 2006); *U.S. v. Philip Morris USA Inc.*, 793 F.Supp.2d 164 (D.D.C. 2011); *U.S. v. Philip Morris USA Inc.*, 449 F.Supp.2d 988 (D.D.C. 2006).

<sup>60</sup> *U.S. v. Philip Morris USA, Inc.*, 686 F.3d 832, 836-37 (D.C. Cir. 2012). In response to the Defendant tobacco companies' argument that the Tobacco Control Act would restrain it from future RICO violations, the Court of Appeals for the D.C. Circuit stated that:

Of course, that argument assumes the defendants' compliance with the Tobacco Control Act. And in light of the defendants' history of non-compliance with various legal requirements, there was no reason for the district court to make such an assumption. Indeed, the [district] court expressly found the Tobacco Control act was not likely to produce compliance when RICO and the Master Settlement Agreement ("MSA") had failed to do so in the past. The defendants claim the Tobacco Control Act imposes tougher restrictions and penalties than the MSA did, and is therefore more likely to spur compliance, but the Act does not provide for penalties as sweeping as those available under RICO. If the defendants were not deterred by the possibility of RICO liability, the district court reasonably found the defendants were not likely to be deterred by the Tobacco Control Act either.

*Id.* (citations omitted).

<sup>61</sup> *Discount Tobacco City & Lottery, Inc. v. United States*, 674 F.3d 509 (6<sup>th</sup> Cir. 2012).

<sup>62</sup> *R.J. Reynolds Tobacco Co. v. U.S. Food & Drug Admin.*, 696 F.3d 1205 (D.C. Cir. 2012).

<sup>63</sup> *Lorillard, Inc. v. U.S. Food & Drug Admin.*, No. 11-440, 2012 WL 3542228 (D.D.C. 2012).

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<sup>64</sup> 23-34 94<sup>th</sup> St. Grocery v. N.Y.C. Board of Health, 685 F.3d 174 (2d Cir. 2012); U.S. Smokeless Tobacco Manufacturing Company, LLC v. City of New York, 703 F. Supp. 2d 329 (S.D.N.Y. 2010).

<sup>65</sup> National Association of Tobacco Outlets, Inc. v. City of Providence, No. 12-96-ML, 2012 WL 6128707(D.R.I. Dec. 10, 2012).

<sup>66</sup> U.S. v. Philip Morris USA, Inc., 686 F.3d 832 (D.C. Cir. 2012).

<sup>67</sup> Tobacco companies challenged the constitutionality of several key provisions of the Tobacco Control Act in Lorillard, Inc. v. U.S. Food & Drug Admin., No. 11-440, 2012 WL 3542228 (D.D.C. 2012).

<sup>68</sup> See *Philip Morris*, 686 F.3d at 837 (D.C. Cir. 2012) (noting that the scope of the Tobacco Control Act was unclear at the time the district court made its decision, since the tobacco companies had challenged the constitutionality of portions of the Tobacco Control Act in *Commonwealth Brands, Inc. v. United States*, 678 F.Supp.2d 512, 521 (W.D.Ky.2010), *rev'd in part sub nom.* *Discount Tobacco City & Lottery, Inc. v. United States*, 674 F.3d 509 (6<sup>th</sup> Cir. 2012).