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## STATEMENT OF

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BEFORE THE  
FDA THIRD PARTY GOVERNANCE OF INDUSTRY-SPONSORED  
TOBACCO PRODUCT WORKSHOP  
March 19, 2013**

My name is Matthew Myers. I am the President of the Campaign for Tobacco-Free Kids and I want to thank you for holding this workshop. The issues raised are important.

## SUMMARY

Let me summarize our conclusions first and then explain them in more detail:

1) Section 911 of the Family Smoking Prevention and Tobacco Control Act of 2009 addresses a very critical issue. For more than 50 years the tobacco industry used the promise of potentially less hazardous tobacco products to mislead consumers and keep America smoking with products that were no safer and claims that were deceptive. Section 911 doesn't prejudge whether there is actually a role for Modified Risk Products in reducing the death and disease caused by tobacco; it is solely focused on bring serious scientific rigor to the issue to insure that the tobacco industry will not be able to deceive another generation of tobacco users.

2) Eleven of the twelve recommendations made by the Institute of Medicine focus on what scientific studies need to be conducted and the criteria for conducting those studies to insure that FDA has a sound, objective and transparent scientific basis for making its determinations about specific products and claims under Section 911. We endorse the IOM Panel's analysis that led to Recommendations One through Nine and Eleven and Twelve and we support those Recommendations.

3) The tobacco industry's abuse of science, the scientific process and credible scientific institutions has been going on for over 50 years, is unprecedented in its duration and magnitude, and there is no indication that the industry's behavior has changed. For 50 years the tobacco industry has claimed to be interested in rigorous science, less harmful products and support for respected scientific institutions to insure that the public received the best information possible. Time after time the evidence now demonstrates that they have corrupted the science, produced products that were (and that they knew were) no less hazardous, and found a never ending set of ways to misuse the most credible scientific institutions.

Therefore, if IOM Recommendation is intended to provide pre-approval to an independent third party entity to conduct research related to a specific Section 911 application, we oppose the adoption of IOM Recommendation

Ten as drafted. It is our view that in order to carry out the goals of Section 911 FDA should focus on rigorously implementing IOM Recommendations One through Nine and Eleven and Twelve and hold the tobacco industry or any other applicant accountable for meeting those scientific and governance standards. Today a number of institutions won't accept tobacco industry funding precisely because the tobacco industry can't be trusted not to abuse the scientific process. History shows that if FDA pre-approves entities in advance of the research the tobacco industry will find a way to once again divert the agenda and abuse the process. The comparative examples set forth by the IOM didn't involve an industry with the track record of the tobacco industry or an industry whose behavior and products reflect an inherent conflict with the interests of public health.

In setting forth its policies regarding Section 911 the FDA needs to take into consideration that the product with which it is dealing and the industry it is regulating is different than the other products and industries it regulates. This is not an industry that produces products that saves people's lives or provides consumers with needed nutrition. It is an industry whose products kill one out of two long term users when used exactly as intended, has known about these dangers for decades, has engaged in the most irresponsible corporate behavior imaginable and continually submerged ethical considerations or concerns for the health of the public to its profit seeking goals.

## BACKGROUND

### **Tobacco products are unique and the tobacco industry is unlike any other regulated industry**

The tobacco industry has a unique problem. Cigarettes are the only consumer product that, when used as directed by the manufacturer, kill half of their users. However, it is not just the tobacco product that is unique; it is the tobacco industry's response to this information.

Instead of taking steps to reduce the harm caused by its products or to fully inform consumers or to curtail its marketing or to genuinely cooperate with government to tackle the problem, as U.S. District Court Judge Gladys Kessler found,

“over the course of fifty years, defendants lied, misrepresented, and deceived the American public, including smokers and the young people they avidly sought as ‘replacement smokers,’ about the devastating health effects of smoking and environmental tobacco smoke.”

Judge Kessler also accurately described the industry's approach to science when she concluded that the companies

suppressed research, they destroyed documents, they manipulated the use of nicotine so as to increase and perpetuate addiction . . . and they abused the legal system in order to achieve their goal—to make money with little if any regard for individual illness or suffering, soaring health care costs, or the integrity of the legal system.”

These concerns are particularly relevant to the issues FDA is now considering because:

1) It demonstrates that the tobacco industry's claim that they are now interested in truly producing less hazardous products isn't new. It has been part of their game plan since the first reports that cigarettes caused disease was released, beginning with the notorious “Frank Statement” and repeated with false sincerity on a routine and regular basis since then in the hope that those listening will ignore their previous statements and actions

2) It demonstrates that in an effort to be seen as part of the solution rather than the cause of the problem, the tobacco industry has routinely claimed that it wants to do everything it can to support the development of sound science even while it paid scientists to write reports downplaying the dangers of smoking, suppressed and concealed scientific research, destroyed documents and funded credible scientific institutions to conduct research that it knew would not produce meaningful results.

3) It also demonstrates both a willingness and ability to misuse even those most credible institutions in support of its efforts to distort science and undermine government efforts to reduce the death and disease from tobacco use.

Millions of pages of the tobacco industry's own internal documents as well as Judge Kessler's extensive findings of fact make clear the great lengths the tobacco industry is willing to go to distort evidence, manipulate science and suppress information to ensure the economic viability of the industry. Equally as significant, the evidence demonstrates that the tobacco industry has gone to extraordinary lengths to associate its work with well-respected institutions and then abused that relationship.

### ***Distortion and Manipulation of Science***

Internal tobacco industry documents provide substantial evidence of a highly organized and sophisticated campaign by the tobacco industry to distort and manipulate science. The tobacco industry established national and international organizations and committees that it claimed would conduct independent scientific research on the issue of tobacco and health and recruited a cadre of scientific experts to counter the growing scientific evidence of an association between smoking and environmental tobacco smoke (ETS) and disease. While these organizations and committees were ostensibly created to support independent scientific research, analysis of tobacco industry documents demonstrate the real purpose of these organizations was to support industry favorable research, create scientific controversy where there was none and discredit scientific research viewed as threatening to the industry.<sup>i</sup> In a number of cases the work of these organizations appeared to be that of a legitimate, scientific grantmaking entity with distinguished scientists involved. In fact the research projects were often directed by tobacco industry lawyers or the research grants were carefully constructed to either divert attention away from the major health issues or to produce results the tobacco industry already understood would create scientific doubt where none really existed.<sup>ii</sup>

A few examples:

#### ***Tobacco Industry Research Committee/ Council for Tobacco Research***

The tobacco industry created the "Tobacco Industry Research Committee," [later renamed the Council for Tobacco Research (CTR)], that it said would support independent scientific research and was to be comprised of "a group of distinguished scientists from the fields of medicine, research and education whose integrity is beyond question."<sup>iii</sup> However, internal company documents reveal the real purpose of the CTR was to counter the growing scientific evidence of the harms of smoking and to reassure the public about the risks of smoking.

CTR funded research attacked scientific studies that linked smoking and disease and CTR only supported scientists who generated data that supported the industry's interests.<sup>iv</sup> As one tobacco industry document noted, "doubt is our product"<sup>v</sup> and CTR furthered that agenda.

### *Center for Indoor Air Research*

Later, the tobacco industry created the Center for Indoor Air Research (CIAR). Similar to the CTR, the CIAR was promoted as an independent scientific entity created to support research on indoor air quality issues. Instead, CIAR projects were designed to undermine and discredit the research on ETS and disease.

Similar to the work of the CTR, this program was meant to create the illusion of a scientific controversy surrounding ETS and health and influence public opinion, all under the auspices of independent science.<sup>vi</sup>

### *Project Mix*

In 1997, Philip conducted Project MIX, a series of studies that purported to examine the potential chemical and biological effects of 333 cigarette additives. Three different groupings of additives were tested against a control cigarette containing only tobacco. Project Mix researchers concluded that the addition of the additives did not affect the toxicity of cigarette smoke. The results of Project Mix were summarized in four papers accepted for publication in *Food and Chemical Toxicology* in 2001 and 2002, have been cited by other tobacco industry scientists and have been promoted to the broader scientific community, the general public and the Institute of Medicine. A recently published scientific critique<sup>vii</sup> of the methodology of these studies by researchers at the University of California San Francisco (UCSF) called into question the validity of all of Project Mix's scientific conclusions and found that industry researchers manipulated the study protocol to produce results more favorable to the tobacco industry than were justified by sound science.

### ***Suppression of Information***

Judge Kessler summarized how the industry treats data that produces results that it deems harmful to its bottom line:

“in order to protect themselves from smoking and health related claims in litigation, and in order to avoid regulation which they viewed as harmful: they suppressed, concealed, and terminated scientific research; they destroyed documents including scientific reports and studies; and they repeatedly and intentionally improperly asserted the attorney-client and work product privileges over many thousands of documents (not just pages) to thwart disclosure to plaintiffs in smoking and health related litigation and to federal regulatory agencies, and to shield those documents from the harsh light of day.”<sup>viii</sup>

The examples are legion. A couple of specific examples:

- R.J. Reynolds' "Mouse House" is probably one of the best known examples of industry suppression on information. RJR established a facility nicknamed "Mouse House" because researchers used mice to research the health effects of smoking. Research done at the Mouse House was routinely withheld from the scientific community – scientists were forbidden to discuss or publish their findings. When researchers started producing results detrimental to the company - specifically it is believed they came close to the underlying biological mechanism to cause emphysema - the entire project was shut down. Scientists were told to hand over their notebooks and lost their jobs.<sup>ix</sup>
- As we learned only a decade later, in 1984 Philip Morris shut down its Program to develop a Nicotine analogue after early results provided solid proof that nicotine in its products causes addiction because senior executives were afraid that the research could be used to prove that they knew and understood the addictive power of nicotine.<sup>x</sup>

Testimony provided in *U.S. v. Philip Morris* demonstrates that the Philip Morris incident was not unique. The evidence demonstrated that tobacco companies suppressed their extensive research findings related to the addictiveness of nicotine and intentionally withheld this data from government authorities<sup>xi</sup>.

### **The Tobacco Industry has a long history of Misusing Independent Credible Institutions and co-opting credible individual Scientists**

In discussing whether “independent third parties” should be approved “by the FDA in advance of research” to evaluate MRTP applications, the history of the tobacco industry with credible independent third parties becomes relevant. A core concept of the recommendation to approve of third parties in advance is to provide those institutions and the science they produce with a stamp of credibility.

In other situations this may be a good idea, but if the goal here is to provide a stamp of approval in advance to institutions and research conducted by those institutions to be used in support of individual product applications under Section 911, it is an idea fraught with danger.

The unfortunate reality is that long ago the tobacco industry developed a strategy of hiding behind the credibility of “independent third” parties of unquestionable credibility to further its scientific deception and has demonstrated repeatedly its mastery of manipulating our faith in organizations that we otherwise have every reason to respect – from respected governmental institutions like the National Cancer Institute, to our nation’s respected medical organizations, the American Medical Association, to our nation’s most prestigious universities and some of their most well-known faculty.

This history and a large body of evidence supports the view that the tobacco industry will always find a way to undermine credible science and corrupt entities - even those entities whose integrity and mission seem incorruptible. A few examples of the industry’s actions in this area are described below.

#### *The Tobacco Working Group (TWG)*

Early in the effort to deal with the problem of tobacco and health, the National Cancer Institute was persuaded to create The Tobacco Working Group, a multidisciplinary advisory group to its Smoking and Health program. The TWG was chaired by Dr. Gio Gori, then Deputy Director of NCI’s Division of Cancer Cause and Prevention, and included scientists, researchers, physicians and tobacco company representatives. The tobacco industry convinced NCI that tobacco industry participation was essential so industry could share what it knew and so that it could stay abreast of government activity with regard to smoking and health issues. The result: an agenda skewed towards harm reduction and away from growing the body of evidence related to smoking and lung cancer and little of scientific value

There is evidence that the tobacco industry was able to stop at least one press NIH press release regarding research to develop a less hazardous cigarette.<sup>xii</sup> Industry representatives also worked to block the TWG from replicating and expanding upon research performed by Oscar Auerbach which found that cigarette smoke caused lung cancer in dogs. Auerbach and his colleagues also wanted to conduct follow-up studies on the effects of nicotine on cardiovascular disease in dogs.<sup>xiii</sup>

The net result: the tobacco industry was able to use the NCI funding to establish its credibility, give the false impression that it was supporting a legitimate scientific agenda and divert the scientific agenda away from the most important research.

#### *The American Medical Association*

The impact of the tobacco industry's funding of research had an even greater impact on the actions of the American Medical Association. R.J. Reynolds provided the American Medical Association (AMA) \$15 million in funding over a span of 14 years (1964 – 1978), which paid for the Association's Education and Research Fund (ERF) project. The ERF was supposed to support independent research on smoking and health. Not coincidentally, the grant produced nothing more than a collection of unrelated studies and too few results that added nothing to the field.

In retrospect the tobacco industry got just what it wanted. Instead of leading the charge for strong governmental action, the AMA took the position that there was still an open controversy as Congress debated what to do after the publication of the 1964 Surgeon General's Report and for most of the 1970's and during that time the industry continued to point to AMA as proof of its dedication to finding answers to the cigarette debate.<sup>xiv</sup>

#### *Damon Runyon Memorial Fund for Cancer Research*

The American Tobacco Company and other cigarette manufacturers financed a cancer research effort conducted at New York University (NYU) and Sloan-Kettering Institute (SKI). The tobacco companies funded this research secretly through the Damon Runyan Memorial Fund for Cancer Research, which was established to fight cancer. Although the tobacco companies hid their role in organizing the research, the principal investigators from NYU and SKI knew that part of their role was to help the tobacco industry clean up its image. Runyon Fund officials agreed to tobacco industry instructions to keep the funding source secret and were cited in the press as "refusing to accept as a fact any relationship between smoking and lung cancer." A similar collaboration was established Duke University with funding secretly channeled through the Runyon Fund.<sup>xv</sup>

#### *University-based Research Funded by the Tobacco Industry*

Soliciting university-based researchers was a critical component of the tobacco companies' public relations efforts to help make the case that tobacco companies were really acting in the best interest of the public. According to Dr. Allan Brandt, a medical historian at Harvard University who testified in *U.S. v. Philip Morris*, "the tobacco industry took advantage of university-industry connections in a complex scheme to undermine and distort scientific knowledge of tobacco's harms." Further, Brandt found that "the tobacco industry uses such funding programs to burnish a deservedly tarnished image, to claim its social legitimacy while aggressively selling a deadly product, the universities accepting tobacco money have been co-opted to support activities that sharply conflict with their own missions."<sup>xvi</sup>

Dozens of world class universities have received funding from the industry, including Harvard, Yale, Stanford and the University of California Los Angeles (UCLA). Scholars, who receive funding from the industry conduct research, publish articles and books, serve as expert witnesses in court and provide testimony before Congress.<sup>xvii</sup>

Industry funded research grants and studies based out of universities were not designed to evaluate the extent to which smoking was harmful. Instead, research was designed to undermine the scientific evidence base associating smoking and adverse health effects and to distract attention away from the issue of smoking's effect on health. Thousands of articles were published by industry-funded scientists. None of these articles answered the questions related to how and to what extent cigarettes cause disease, but they created the illusion that the tobacco industry was seriously examining the issue.

A few examples:<sup>xviii</sup>

- Tobacco and Health Research Program, established in the 1960s, at the University of Kentucky, was supposed to examine the relationship between smoking and health.
- Harvard's Tobacco and Health Research Program was established in 1972 to investigate a number of topics, including human smoking behavior and smoke chemistry.
- UCLA's School of Medicine received a multi-million dollar grant to establish a "Program on Tobacco and Health". UCLA's Professor of Medical Oncology, Dr. Martin Cline announced the grant as follows:

"Such support is critical in the exploration of novel approaches to human disease and essential for promising young medical scientists in an atmosphere of intellectual freedom ."

Subsequently, Dr. Cline appeared as an expert witness for the industry, testifying that smoking was not a definitive causal factor for certain diseases or addictive.

- Washington University received millions of dollars in grants to explore lung cancer treatment and prevention. Once again, this grant produced nothing of value.
- R.J. Reynolds provided funds to Harvard Medical School for teaching and research. Not coincidentally, a medical school professor then testified before a congressional committee about smoking on the industry's behalf.
- Dr. Carl Seltzer was a professor of Public Health at Harvard University until 1976. With tobacco industry funding he conducted research related to the constitutional and genetic hypothesis favored by the industry. He then criticized studies that found an association between smoking and adverse health effects.
- Dr. Henry Rothschild at Louisiana State University received about \$250,000 to study the role of genetic and environmental factors and the development of lung cancer. This work too shifted attention away from tobacco as a cause of disease. The tobacco industry relied on Dr. Rothschild's work in congressional testimony in 1983 in response to the Smoking Prevention, Health and Education Act of 1983. Rothschild testified that his work "indicates that genetic factors may play a significant role in excess mortality from lung cancer".

The purpose in citing these examples is not necessarily to criticize the institutions and individuals named, but to point out the manner in which the tobacco industry has misused its funding of America's most credible scientific institutions as a caution to the FDA in giving credibility to research based on the fact that it comes from a particular institution or in assuming that it can easily prevent the tobacco companies from abusing even the most prestigious institutions.

## CONCLUDING DISCUSSION

1) The FDA should proceed carefully in its implementation of Section 911 in light of the tobacco industry's long history of attempting to keep consumers using its products by making unsubstantiated claims of reduced harm and

by misusing the scientific process and scientific institutions to carry out its agenda. Section 911's greatest impact may well be in preventing unsubstantiated claims or claims that have an overall negative impact on public health.

2) No one should be fooled by the tobacco industry's claims today that it is genuinely interested in promoting good science and finding and promoting products that will benefit the public health. We have heard the same claims before on multiple occasions.

3) FDA's top priority should be to establish rigorous scientific standards that all applications under Section 911 should meet, including openness and transparency so that all tobacco industry funded research and all conditions placed on that research can be scrutinized by FDA and by independent experts whose priority is to protect the public health. Transparency and openness are critical. Yet, so far the tobacco industry will not even allow FDA to disclose what applications have been filed so that research decisions are being made behind closed doors.

4) The tobacco industry has extraordinary financial resources. It has the ability to fund research to support any Section 911 application if it so chooses. Until now, it has used those resources to undermine the public health and challenge sound science rather than build a reputation of trust or a credible science base. Institutions that have chosen not to work with the tobacco industry have done so to protect their own integrity.

The answer is not to create another system the tobacco industry can manipulate. It is to set out clearly as the IOM has done in Recommendations One through Nine the criteria and type of science that will be necessary to support any application and then to also require any funder to meet the governance criteria set out in Recommendations Eleven and Twelve. If third parties are allowed to determine what research to conduct and are guaranteed freedom and the right to publish whatever they find unencumbered by tobacco industry lawyers, it is highly likely that credible third parties may do so.

There is no reason for FDA to establish a special set of rules for the tobacco industry. The reality is that whenever a new regulatory structure is created there is always a transition period. As Daniel Carpenter points out in his book, "Reputation and Power: Organizational Image and Pharmaceutical Regulation at the FDA", when FDA first required pre-market approval of new drugs, every pharmaceutical company had to build their in-house research capacity. Some did; others did not succeed in doing so.<sup>xx</sup> The hurdle facing the tobacco industry is no greater and no different.

There are important distinctions, however, between the tobacco industry and the pharmaceutical industry that are important and argue against a system of pre-approving third party institutions doing work funded by a particular MRTP sponsor. Whatever the tension between the FDA and the pharmaceutical industry, the pharmaceutical industry knows that it cannot survive if it loses credibility with the public or the FDA.<sup>xx</sup> Thus, it has a great deal at stake in producing science the FDA and the public perceives as honest and credible. The tobacco industry, on the other hand, is able to sell its product to the public even though it is held in low esteem and has little credibility because virtually all new users are children and its product is highly addictive.

In addition, the tobacco industry has already set a very different tone for how it is going to deal with the FDA. Every time the FDA takes a regulatory action it can expect to be sued by a member of the tobacco industry. Therefore, whatever the industry says, it has made clear that it will not depend upon building a trusting relationship with the FDA; it will challenge every action FDA takes. Fear not rust, therefore, is the basis of the tobacco industry's



relationship with FDA. Thus, the tobacco industry doesn't have the incentive to produce the kind of science necessary for a long term trusting relationship.

To date, the tobacco industry has always placed short term profits over reducing harm or protecting the public's health. If it is necessary to distort science or undermine credible institutions to do so, it has proven that it is prepared to do so

We believe independent third parties may help the FDA to consider broad scientific questions unrelated to individual product applications. Both examples of third party entities cited by the IOM are very different than the use of a third party to do the research related to a specific product application. The Reagan-Udall Foundation is a public private partnership to broadly advance regulatory science at FDA that is still in its early stages. The EPA model cited by IOM also focuses on broad issues of scientific conflict over research on health and air quality. But, most importantly, until now the tobacco industry has behaved as if their financial interests and the public health are inherently in conflict.

We agree that third parties can play a role in helping develop more fully IOM Recommendations One through Nine as particular scientific issues arise to examine specific scientific issues, but it should be the FDA, not an MRTP sponsor that determines what research is necessary so that there is no conflict involved and so that the tobacco industry doesn't drive the agenda in a way that is contrary to the FDA's priorities.

In reality, pre-approval could have the opposite effect of its intention. The IOM report posits that if the FDA does not look at industry data with proper skepticism, it could hurt the FDA's and CTP's reputation and credibility, given the industry's long history. We believe giving pre-approval to third parties could create the same risk. The tobacco companies have an interest in influencing the results produced even by credible third parties. pre-approval will allow the tobacco companies to make the argument the research that comes out of pre-approved third parties is inherently reliable, even if they have successfully influenced outcomes.

While it might seem unlikely that revered institutions serving as third parties might be unduly influenced by tobacco companies, one need only look at the historical record to see how this has happened.

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- <sup>i</sup> Glantz, Stanton A., et al., *The Cigarette Papers*, University of California Press, 1996. Proctor, Robert N., *Golden Holocaust*, University of California Press, 2011. *U.S. V. Philip Morris USA, Inc., et al.*, No. 99-CV-02496GK, Final Opinion, August 17, 2006, <http://www.tobaccofreekids.org/reports/doj/FinalOpinion.pdf>.
- <sup>ii</sup> Glantz, Stanton A., et al., *The Cigarette Papers*, University of California Press, 1996.
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- <sup>v</sup> Brandt, Allan M., "A Not-So-Slippery Slope," *Academe*, November-December 2010.
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- <sup>vii</sup> Wertz SM, et al., The Toxic Effects of Cigarette Additives. Philip Morris' Project Mix Reconsidered: An Analysis of Documents Released Through Litigation. *PLoS Medicine*, Vol. 8, Issue 12, December 2011.
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- <sup>xvii</sup> Proctor, Robert N., *Golden Holocaust*, University of California Press, 2011.
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- <sup>xix</sup> Carpenter, Daniel, Reputation and Power, at 641-642.
- <sup>xx</sup> Carpenter at 637