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Director, Office of Investigative Oversight  
Office of Research Integrity  
Department of Health and Human Services  
1101 Wootton Parkway, Suite 750  
Rockville, MD 20852

May 15, 2008

Your reference: 3808

Dear Dr. Dahlberg,

Thank you for your letter of Nov 19, 2007 concerning our request that the ORI investigate the June 27, 2006 Surgeon General Report entitled "The Health Consequences of Involuntary Exposure to Tobacco Smoke: A Report of the Surgeon General". In your letter you state that ORI was not able to address our concerns because the Office was unable to identify specific allegations of misconduct in our early submission. Although we believe we identified specific allegations of research misconduct that meet the definition of research misconduct at 42 C.F.R. Part 93.103, we would like to take this opportunity to clarify those allegations. We again request that the ORI investigate our allegations pursuant to 42 C.F.R. Part 93.103.

Our present complaint of misconduct is directed at the U.S. Surgeon General's Office, author of the report: "The health Consequences of Involuntary Exposure to Tobacco Smoke: A Report of the Surgeon General" of June 26, 2006, which has been knowingly and intentionally based "*on a series of epidemiologic studies...whose essential data about individual exposures to environmental tobacco smoke are intentionally fabricated*", as your letter quotes from our initial submission.

Our present complaint fits precisely the line at 42 C.F.R. Part 93.103 that you letter provides as a definition of research misconduct:

*(a) Fabrication is making up data or results and recording or reporting them.*

To restate our points, the U.S. Surgeon General and others have stated that the best documented evidence is offered by the epidemiologic studies of lung cancer and involuntary exposure to environmental tobacco smoke (ETS). Thus, focusing on these studies provides the best evidence for our complaint.

It should be clear that prospective epidemiologic studies have been out of the question, leaving only the possibility of retrospective studies. Because lung cancer incidence peaks at ages beyond 55, by necessity the subjects of retrospective epidemiologic studies of lung cancer and ETS exposure are of advanced age. In fact, virtually all epidemiologic studies of lung cancer and ETS exposure have dealt with aged non-smoking spouses of smoking husbands or wives.

The U.S. Surgeon General report in question notes that a legitimate risk assessment requires a summary measure of the infinitely variable momentary doses of ETS that were internalized over the prior lifetime of each study subject. It also recognizes that such summary measure is impossible to obtain.<sup>1</sup> The logical corollary is that a legitimate risk assessment is not possible, but the U.S. Surgeon General report and all epidemiologic studies intentionally ignored this insurmountable obstacle, and arbitrarily decided that instead of dose, exposure alone is sufficient in assessing risk. In fact, however, the retrospective determination of lifetime exposures is also impossible, and for essentially the same reasons that have induced the Surgeon General to conclude that a summary determination of lifetime doses is impossible.

Even assuming the sufficiency of exposure alone in assessing risk, how would exposure be *measured*? Studies claiming to have calculated lifetime risks must have done so by obtaining retrospectively the summaries of all measurements of each distinct and ever changing momentary exposures to ETS over the prior lifetimes of each study subject. As a point of reference, the lifetime of a 55 year old person amounts to some 480,000 hours, or 20,000 days, or 2,800 weeks, or 660 months... With this in mind, even the most naïve observer can tell that retrospective measures of ETS exposure are utterly impossible, that any claim to have done so would be farcical, and that any normative conclusions from such an exercise would be deceiving and fraudulent.

Yet, all studies of lung cancer and ETS claim to have performed the impossible task of determining retrospectively the summary “measures” of innumerable momentary ETS exposures over lifetimes. Typically, aged self-declared non-smokers were asked to state how many cigarettes, cigars or pipes might have been smoked in their presence during their lifetime since birth, how thick the smoke might have been in the rooms, were the windows open, and similar vagaries.<sup>2</sup> The resulting answers, casually elicited in a few minutes usually over the phone - or by proxy recalls provided by relatives of deceased

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<sup>1</sup> The Health Consequences of Involuntary Exposure to Tobacco Smoke: A Report of the Surgeon General. June 27, 2006. <http://www.surgeongeneral.gov/library/secondhandsmoke/> See page 18.

<sup>2</sup> See the typical questionnaire at [http://www.data-yard.net/who\\_quest/quest\\_iarc\\_98.pdf](http://www.data-yard.net/who_quest/quest_iarc_98.pdf) .

persons – have been recorded by all studies as precise summation measures of individual lifetime exposures, as if myriad momentary exposures had been physically measured with identical metrics day by day of previous individual lives, and error and bias free. Studies have then entered such illusory numbers into statistical elaborations to fabricate risks with two decimal points of precision, and such legerdemain has been enthusiastically endorsed by the U.S. Surgeon General and report in question, with full awareness of the deception involved.

Our original complaint lists corollary instances of misconduct, the analysis of which may or not require specific epidemiologic expertise, but the above considerations should be sufficient in their own right to qualify a plainly manifest and deplorable act of scientific misconduct on the part of the U.S. Surgeon General, and of the authors of all epidemiologic studies of ETS and lung cancer. Similar charges are equally valid for studies of ETS and cardiovascular and other diseases, which depend on identical sham “measurements” of ETS exposures.

Incidentally, we do not claim any discrepancy - as you suggest - between the epidemiologic studies and the U.S. Surgeon General report in question: they are all equally responsible of the identical misconduct. Our present complaint is limited specifically to the Surgeon General report on ETS, as the central example of calculated misconduct. To further prove our point, we shall soon begin to submit to your office individual analyses of each of the lung cancer and ETS studies that have been taken to support the Surgeon General report on ETS.

Many of those studies have been fully or partially funded by the Public Health Service and its institutions, but we find it immaterial that the US Government may not have funded some studies. Our present complaint relates specifically to misconduct perpetrated by the Office of the Surgeon General, fully funded by the Public Health Service of the US Government. The misconduct we claim refers to the conscious use of fraudulent epidemiologic studies by that Office, with the intent of sustaining statements and policies that are just as fraudulent as the underlying epidemiologic studies adduced as justification.

Regards

Maryetta Ables  
FORCES, Inc.

<sup>1</sup>The Health Consequences of Involuntary Exposure to Tobacco Smoke: A Report of the Surgeon General. June 27, 2006.

<http://www.surgeongeneral.gov/library/secondhandsmoke/> See page 18.



cc:

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