



**PETA**

PEOPLE FOR THE ETHICAL  
TREATMENT OF ANIMALS

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March 3, 2011

Jonathan Michael Samet, M.D., M.S.  
Chair  
Tobacco Products Scientific Advisory Committee  
Center for Tobacco Products  
U.S. Food and Drug Administration  
10903 New Hampshire Ave.  
Silver Spring, MD 20993

Via e-mail: [jsamet@usc.edu](mailto:jsamet@usc.edu)

Dear Dr. Samet,

People for the Ethical Treatment of Animals (PETA) and the cosigners of this letter are writing to respectfully request the Tobacco Products Scientific Advisory Committee (TPSAC) to use its influence to end a U.S. Department of Health & Human Services' (DHHS) practice that is a conflict of interest with the agency's aggressive mission to curb tobacco use and at odds with the letter and spirit of ethical guidelines regarding animal experimentation. Specifically, we have recently learned that the National Institutes of Health's National Cancer Institute (NCI) has sold mice to R.J. Reynolds Tobacco Company, Philip Morris International (Altria), and Lorillard Tobacco for use in painful and deadly studies aimed at testing new cigarette ingredients and developing new tobacco products. By allowing the NCI to sell animals to tobacco companies, DHHS is facilitating and profiting from the development and sale of inherently dangerous products whose use the agency itself has deemed "the leading cause of preventable illness and death in the United States."<sup>1</sup> As TPSAC is charged with advising the government on issues related to the marketing, production and use of tobacco products, we urge it to use its authority to permanently end DHHS's sale of animals to tobacco companies. We have unsuccessfully attempted to resolve this with the NCI directly.

In numerous studies published between 1999 and 2010 (see the appendix), tobacco companies have identified the NCI's Frederick Cancer Research and Development Center as the source of thousands of mice who were used in cruel tests to compare the risks of cigarettes made with various flavoring ingredients, cigarettes made using different tobacco-curing techniques, and the harms of conventional tobacco-burning cigarettes versus cigarettes that heat tobacco. **Documents obtained by PETA on December 22, 2010, through a Freedom of Information Act request to the NCI indicate that from May 2005 to July 2008, NCI sold 6,256 mice to R.J. Reynolds for a total of \$30,389.75.**

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<sup>1</sup>National Cancer Institute, "Cancer Topics: Smoking," accessed 2 March 2011  
<<http://www.cancer.gov/cancertopics/tobacco/smoking>>.

Philip Morris, R.J. Reynolds, and Lorillard used mice from NCI for tests in which the mice had tar-like concentrated cigarette smoke particles spread onto their bare skin three times a week for up to seven months in order to intentionally cause the animals to develop skin tumors. Many of the animals in these studies developed multiple tumors and also suffered from impaired limb function, emaciation, hair loss, and skin lesions and ulcers and were then killed and had their organs dissected.

The authors of these papers implicitly and explicitly acknowledge that the purpose of the animal tests is to guide the development of new tobacco products.

In one study that used mice purchased from NCI, R.J. Reynolds concluded that the results would help "to evaluate changes in cigarette design, new materials used in the manufacture of cigarettes, changes in tobacco processing, or the development of new technologies to increase or reduce the biological activity that results from burning tobacco."<sup>2</sup>

Although we have contacted the NCI about this matter, we have not received any assurance that this practice will not commence.

As you are likely aware, the NCI's evidence-based position on this matter is that "[t]here is no safe tobacco product."<sup>3</sup> If the tobacco industry wishes to continue developing and marketing products that addict and kill people, it should do so without the help of the government and without harming animals. Indeed, in 1997, the U.K. government enacted a nationwide prohibition on the use of animals for developing and testing tobacco products.<sup>4</sup> The Home Office stated that in making a cost-benefit analysis, it could not justify the use of animals, classifying these experiments as "morally or ethically objectionable."<sup>5</sup> Germany and Austria specifically prohibit the use of animals for this purpose as well.<sup>6</sup> PETA urged the FDA to adopt a similar prohibition in September 2009 in a public comment submitted on Docket No. FDA-2009-N-0294-0001.

Modern, human-relevant *in vitro* tests<sup>7</sup> and human molecular biomarker methods<sup>8</sup> are available and already employed by tobacco companies for assessing the harm of new and existing tobacco products, ingredients, and additives. Indeed, all the tobacco-product toxicity tests required by the

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<sup>2</sup>D. Meckley, J.R. Hayes, K.R. Van Kampen, A.T. Mosberg, and J.E Swauger, "A Responsive, Sensitive, and Reproducible Dermal Tumor Promotion Assay for the Comparative Evaluation of Cigarette Smoke Condensates," *Regulatory Toxicology and Pharmacology* 39 (2004): 135-49.

<sup>3</sup>National Cancer Institute, "National Cancer Institute Fact Sheet," accessed 2 March 2011 <<http://www.cancer.gov/cancertopics/factsheet/Tobacco/cessation>>.

<sup>4</sup>Home Office, "Guidance on the Operation of the Animals (Scientific Procedures) Act 1986," Ch. 5, Sec. 5.23, accessed 2 March 2011 <http://www.archive.official-documents.co.uk/document/hoc/321/321-05.htm>.

<sup>5</sup>Home Office, "The Cost/Benefit Assessment," *Report of the Animal Procedures Committee for 1997* (London: TSO, 2000) Ch. 2, Ann. 1-3, App. F <<http://www.apc.gov.uk/reference/ar97.pdf>>.

<sup>6</sup>H.J. Hedrich and G.R Bullock, eds., *The Laboratory Mouse* (London: Academic Press, 2004).

<sup>7</sup>C. Andreoli, D. Gigante, and A. Nunziata. "A Review of In Vitro Methods to Assess the Biological Activity of Tobacco Smoke With the Aim of Reducing the Toxicity of Smoke," *Toxicology In Vitro* 17.5-6 (2003): 587-94.

<sup>8</sup>*cf.* Frost-Pineda *et al.* "12-Week Clinical Exposure Evaluation of a Third-Generation Electrically Heated Cigarette Smoking System (EHCS) in Adult Smokers," *Regulatory Toxicology and Pharmacology* 52 (2008): 111-17.

Canadian government—which has regulated tobacco since 1997—are *in vitro*, non-animal tests,<sup>9</sup> and some major tobacco manufacturers—including Imperial Tobacco<sup>10</sup>—have policies against animal testing.

In 2002, the Karolinska Institute in Stockholm, which each year awards the Nobel Prize in Physiology or Medicine, cut all its ties with the tobacco industry, stating that "[i]t is incredibly important that we who are supposed to work to improve people's health are in no way associated with the tobacco industry."<sup>11</sup> Esteemed organizations such as the Johns Hopkins School of Public Health, University of Arizona School of Public Health, Emory University School of Medicine, Harvard School of Public Health, Harvard Medical School, and Ohio State University School of Public Health have also severed financial ties with the tobacco industry for the same reason.<sup>12</sup>

Like these other organizations, agencies of the DHHS should in no way promote or profit from the tobacco industry's devious schemes to take advantage of the public and lead children and adults into addiction and disease. Sadly, it appears that NCI is providing tobacco companies the tools to continue doing so and is making money in the process. Conflicts of interest like those raised by the relationship between NCI and big tobacco erode the public's trust in government agencies that are supposed to protect public health and call into question the government's decision making skills and commitment to actually extinguishing tobacco use and reducing the use of animals in experiments.

The passage of the Family Smoking Prevention and Tobacco Control Act, the formation of TPSAC, the FDA's proposed bolder health warnings on cigarettes and advertisements and other measures make clear the government's serious commitment to discouraging tobacco use. We ask that you ensure that the message of this admirable strategy is implemented consistently across all agencies of the DHHS by using your authority to permanently end the NCI's inappropriate relationship as a supplier of animals to the tobacco industry.

Sincerely,



Kathy Guillermo  
Vice President, Laboratory Investigations Department  
People for the Ethical Treatment of Animals  
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<sup>9</sup>Health Canada, "Toxicity Test Methods," accessed 2 March 2011 <<http://www.hc-sc.gc.ca/hc-ps/tobac-tabac/legislation/reg/indust/method/tox-eng.php>>.

<sup>10</sup>Imperial Tobacco, "Product Testing Using Animals," accessed 16 Nov. 2010 <<http://www.imperial-tobacco.com/index.asp?page=471>>.

<sup>11</sup>University of California San Francisco, "Tobacco Research Fund Policies," accessed 16 Nov. 2010 <<http://senate.ucsf.edu/townhallmeeting/TobaccoResearchFundPolicies.pdf>>.

<sup>12</sup>University of California San Francisco, "Some Existing Policies Regarding Tobacco Industry Funding," accessed 16 Nov. 2010 <<http://senate.ucsf.edu/townhallmeeting/dctobaccopolicies.pdf>>.

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Enc. Summary of published tobacco company experiments on mice obtained from NCI  
Letter, dated December 22, 2010, from NCI to PETA, documenting sales of mice to R.J.  
Reynolds

cc: Neal L. Benowitz, M.D.  
Mark Stuart Clanton, M.D., M.P.H.  
Karen L. DeLeeuw, M.S.W.  
Dorothy K. Hatsukami, Ph.D.  
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## **Smoking product and ingredient experiments on animals conducted by tobacco companies using mice purchased from the National Cancer Institute<sup>13</sup>**

Prepared and submitted by  
People for the Ethical Treatment of Animals  
March 2011

### R.J. Reynolds (Winston-Salem, NC)

- 400 female mice, purchased from the National Cancer Institute (NCI), were killed after having tar-like concentrated cigarette smoke particles spread on to their bare skin three times per week for 29 weeks to assess the tumor-promoting potential of an experimental cigarette (Meckley and others 2004)
- 270 mice, purchased from NCI, were killed after having cigarette tar painted onto their bare skin three times per week for 12 weeks in a study designed to assess the tumor-promoting potential of an experimental cigarette (Curtin and others 2004)
- 440 female mice, purchased from NCI, were killed after having cigarette tar painted onto their bare skin three times per week for 30 weeks to assess the tumor-promoting potential of tobacco cured using different methods (Hayes and others 2007)
- 240 female mice, purchased from NCI, were killed after having cigarette tar painted onto their bare skin thrice weekly for 29 weeks. The mice's responses to three different cigarettes—a conventional reference cigarette and two experimental cigarettes—and data was collected on tumor development (Kathman and others 2010)

### Philip Morris International (Neuchâtel, Switzerland)

- An unknown number of mice, purchased from NCI, were killed after having cigarette tar painted onto their bare skin five times per week for 26 weeks. The study was designed to compare the tumor incidence associated with smoking three different cigarettes: “ultra-low tar,” “low-tar,” and “full-flavor” (Roemer and others 2009)

### Lorillard (Greensboro, NC)

- More than 210 mice, purchased from NCI, were killed after having cigarette tar painted onto their bare skin thrice weekly for 26 weeks to examine the effects of tobacco flavoring ingredients on cigarette toxicity (Gaworski and others 1999)

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<sup>13</sup> These studies represent a sample of those published or cited in peer-reviewed journal articles. Many more are conducted privately at the facilities mentioned in this document and remain unpublished and unavailable to the public.

## References

Curtin, G.M., Hanausek, M., Walaszek, Z., Mosberg, A.T., Slaga, T.J. Short-Term *In Vitro* and *In Vivo* Analyses for Assessing the Tumor-Promoting Potentials of Cigarette Smoke Condensates. *Toxicological Sciences* 2004: 81, 14-25.

Gaworski, C.L., Heck, J.D., Bennett, M.B., Wenk, M.L. Toxicologic evaluation of flavor ingredients added to cigarette tobacco: skin painting bioassay of cigarette smoke condensate in SENCAR mice. *Toxicology* 1999: 139, 1-17.

Hayes, J.R., Meckley, D.R., Stavanja, M.S., Nelson, P.R., Van Kampen, K.R., Swauger, J.E. Effect of a flue-curing process that reduces tobacco specific nitrosamines on the tumor production in SENCAR mice by cigarette smoke condensate. *Food and Chemical Toxicology* 2007: 45, 419-430.

Kathman, S.J., Potts, R.J., Ayres, P.H., Harp, P.R., Wilson, C.L., Garner, C.D. A Bayesian statistical analysis of mouse dermal tumor promotion assay data for evaluating cigarette smoke condensate. *Regulatory Toxicology and Pharmacology* 2010: 58, 106-113.

Meckley, D.R., Hayes, J.R., Van Kampen, K.R., Ayres, P.H., Mosberg, A.T., Swauger, J.E. Comparative study of smoke condensates from 1R4F cigarettes that burn tobacco versus ECLIPSE cigarettes that primarily heat tobacco in the SENCAR mouse dermal promotion assay. *Food and Chemical Toxicology* 2004: 42, 851-863.

Roemer, E., Ottmueller, T.H., Zenzen, V., Wittke, S., Radtke, F., Blanco, I., Carchman, R.A. Cytotoxicity, mutagenicity, and tumorigenicity of mainstream smoke from three reference cigarettes machine-smoked to the same yields of total particulate matter per cigarette. *Food and Chemical Toxicology* 2009: 47, 1810-1818.

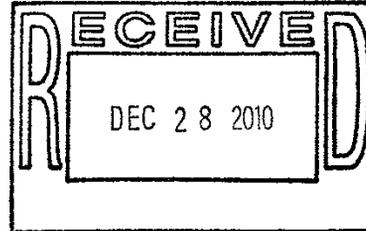


DEPARTMENT OF HEALTH & HUMAN SERVICES

National Institutes of Health  
National Cancer Institute  
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9000 Rockville Pike, MSC 2580  
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December 22, 2010

Alka Chandna, Ph.D.  
People for the Ethical Treatment of Animals  
501 Front Street  
Norfolk, VA 23510



**Re: NCI 11-020; FOIA Case No. 38271**

Dear Dr. Chandna:

This is a final response to your November 18, 2010 Freedom of Information Act (FOIA) request addressed to Suzy Milliard. You requested a copy of documentation related to the National Cancer Institute's (NCI) sales of mice to tobacco companies, for the period of January 1, 2005 to the present.

We searched the files of the Division of Cancer Treatment and Diagnosis for records responsive to your request. NCI did not profit from the sale of any mice. Mice were "surplus" animals, in excess of animals requested by federal research institutions. In the spirit of the FOIA, we are providing the following 1 page spreadsheet relating to mice provided to RJ Reynolds for recovered costs. That search produced 1 page releasable to you in full.

In certain circumstances provisions of the FOIA and Department of Health and Human Services FOIA Regulations allow us to recover part of the cost of responding to your request. Because the cost is below the \$25 minimum, there is no charge for the enclosed materials.

Sincerely,

Suzanne Milliard  
Freedom of Information Coordinator  
NCI/OGCR/FOIA

Enclosures: 1 page

Ship Date	Recipient	ORL SENCAR	recovered cost
May 2, 2005	DM/RJ Reynolds Tobacco Co.	780	\$ 3,510.00
May 23, 2005	DM/RJ Reynolds Tobacco Co.	460	\$ 2,070.00
March 27, 2006	DM/RJ Reynolds Tobacco Co.	500	\$ 2,375.00
April 24, 2006	DM/RJ Reynolds Tobacco Co.	620	\$ 2,945.00
May 15, 2006	DM/RJ Reynolds Tobacco Co.	620	\$ 2,945.00
October 16, 2006	GC/RJ Reynolds Tobacco Co.	636	\$ 3,021.00
February 26, 2007	DM/RJ Reynolds Tobacco Co.	620	\$ 3,100.00
May 28, 2007	DM/RJ Reynolds Tobacco Co.	725	\$ 3,625.00
February 4, 2008	DM/RJ Reynolds Tobacco Co.	645	\$ 3,386.25
June 30, 2008	DM/RJ Reynolds Tobacco Co.	375	\$ 1,968.75
July 21, 2008	DM/RJ Reynolds Tobacco Co.	275	\$ 1,443.75
	total	6256	\$ 30,389.75