

Congress of the United States

House of Representatives

COMMITTEE ON SCIENCE, SPACE, AND TECHNOLOGY

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June 13, 2013

Dr. Francis Collins
Director
National Institutes of Health
9000 Rockville Pike
Bethesda, MD 20892

Dear Director Collins,

Recently, Dr. Linda Birnbaum, Director of the National Institute of Environmental Health Sciences (NIEHS) of the National Institutes of Health (NIH), and the National Toxicology Program (NTP), published an article titled "When Environmental Chemicals Act Like Uncontrolled Medicine," in the journal *Trends in Endocrinology and Metabolism*.¹ We encourage government scientists to continue their research and publish their work. However, to avoid confusion, government scientists must clearly distinguish when they are speaking on their own behalf, or as a government official. In her article, Dr. Birnbaum makes statements that either lack scientific citations, or draw conclusions not supported by the citation referenced. Without an explicit disclaimer, it is unclear whether the article represents Dr. Birnbaum's personal views or reflects Administration policy.

While the Office of Government Ethics regulations allow an employee to use his or her title or position in connection with an article published in a scientific journal, the article must include "a reasonably prominent disclaimer satisfactory to the agency stating that the views expressed in the article do not necessarily represent the views of the agency or the United States."²

Absent the disclaimer, it is difficult to ascertain whether this article went through an appropriate clearance process within NIH. According to NIH policy for non-peer-reviewed publication, "[i]n general, any writing by an NIH employee on a work-related subject, whether intended for electronic or print publication, or for oral delivery, must be prepared according to accepted NIH standards, reviewed for substantive content, and administratively approved."³ Further, NIH policy states that "[a] clear distinction must be made between the presentation of

¹ Birnbaum, L.S., "When Environmental Chemicals Act Like Uncontrolled Medicine," *Trends in Endocrinology and Metabolism*, May 7, 2013; available at: [http://www.cell.com/trends/endocrinology-metabolism/fulltext/S1043-2760\(12\)00225-1](http://www.cell.com/trends/endocrinology-metabolism/fulltext/S1043-2760(12)00225-1). (Hereinafter Birnbaum Article).

² Code of Federal Regulations, Administrative Personnel; See 5 C.F.R. § 2635.807(b)(2); available at: <http://www.gpo.gov/fdsys/pkg/CFR-2009-title5-vol3/xml/CFR-2009-title5-vol3-sec2635-807.xml>.

³ NIH Employee Procedures for Complying with NIH Publication Policy (for non-peer-reviewed publications), available at: <http://sourcebook.od.nih.gov/oversight/non-peer-reviewed-instruct.htm>. (Hereinafter NIH Policy).

scientific data and the presentation of opinion that may be construed as the position of NIH.”⁴ As discussed below, some of Dr. Birnbaum’s statements sound less like a presentation of scientific data and more like an opinion - which may be construed as a position of NIH.

In one example, during a discussion on breast cancer, Dr. Birnbaum discusses the use of DDT (dichloro-diphenyl-trichloroethane), which has been banned in the U.S. since the early 1970s.⁵ Dr. Birnbaum states that high levels of DDT are associated with increased breast cancer risk, and women who were exposed to DDT before the age of four exhibited the highest risk, citing a paper by Cohn *et al.*⁶ However, while Cohn *et al* examine risks for those exposed before fourteen years of age, there is no discussion of children exposed before the age of four.⁷ Further, the conclusions of this study clearly state that exposure to DDT “early in life may increase breast cancer risk” (emphasis added).⁸ Dr. Birnbaum’s interchangeable use of the words “may” and “are” as though they have the same meaning, which they do not, raise concerns about the validity of some of her claims in her article, and reinforce concerns about her opinion versus a presentation of scientific facts.

Dr. Birnbaum additionally makes broad and general statements in the article that appear to represent both her viewpoint as well as that of HHS. For example, Dr. Birnbaum states:

- “The proliferation of inadequately tested chemicals in commerce may be contributing to the skyrocketing rates of disease.”⁹ Considering the number of chemicals in commerce that go through an EPA approval process, this statement implies that HHS does not believe that EPA is adequately protecting public health.
- “In fact, environmental chemicals can act like *bona fide* medicines on endocrine pathways, and should thus be considered likewise. In the same way as physicians endeavor to understand and monitor the effect of medicines on endocrine pathways, we ought to achieve the same understanding and control of the effects of environmental chemicals.”¹⁰

⁴ NIH Policies and Procedures for Promoting Scientific Integrity, November 2012, at 16; available at: <http://www.nih.gov/about/director/sci-int-nov2012.pdf>.

⁵ EPA Press Release: “DDT Ban Takes Effect,” December 31, 1972, available at: <http://www.epa.gov/history/topics/ddt/01.html>.

⁶ Birnbaum Article, *supra*, note 1.

⁷ Cohn, B.A., Wolf, M.S., Cirillo, P.M., Scholtz, R.I., “DDT and Breast Cancer in Young Women: New Data on the Significance of Age at Exposure,” *Environmental Health Perspectives*, Volume 115, Issue 10, October 2007, Pp. 1406-1414; available at: <http://www.scopus.com/record/display.url?eid=2-s2.0-35448960505&origin=inward&txGid=C1037D1A6427B7FB9F7F82DE870896ED.CnvcAmOODVwpVrjSeqQ%3a2>. [We note that the study authors do not mention in their discussion or conclusions the findings in Table 4 of their report as they relate to children < 4 yrs old. This is likely because the odds ratio for children <4 yrs old was not statistically significant at P<0.05. This lack of statistical significance was not mentioned by Dr. Birnbaum in her article.]

⁸ Ibid.

⁹ Birnbaum Article, *supra*, note 1.

¹⁰ Ibid.

“If these associations are real, given the exposure of the general population to environmental chemicals...it only makes sense that we control these exposures to reverse the dramatic increase in chronic, non-communicable diseases that we have observed over the past 40 years. Because patients do not take medications that affect their health without significant safety testing and marketing regulations, their exposure to environmental chemicals should be similarly controlled.”¹¹ These statements imply that HHS believes that the “dramatic increase in chronic non-communicable diseases” is due to environmental chemicals and thus controlling the exposures is the solution to reversing increases.

The confusing nature of Dr. Birnbaum’s authorship of her article - whether the views in the article are her own or those of NIH, HHS, or the Administration - raise questions about the NIH commitment to transparency. These are not new concerns, because as of the date of this letter, the Committee has yet to receive answers to questions for the record posed to Dr. Birnbaum following a hearing on the Report on Carcinogens over a year ago.¹² The lack of a response to these formal questions by Congress is particularly egregious in light of the President’s claimed dedication to transparency, highlighted in one of his first memos during his first term.¹³

As a senior-level employee at HHS, we hold Dr. Birnbaum to an appropriately high standard. We expect Dr. Birnbaum to be accurate and transparent in the presentation of scientific data and in describing peer reviewed studies. We also expect her to respond to questions from Members of Congress that are part of an official hearing record. Her failure to comply with these expectations compels us to request the following information and documents:

1. Please confirm whether the statements in the Birnbaum article represent NIH, HHS, or Administration policy. If they do not, please ensure that an appropriate disclaimer is added to this article and included in all similar articles by HHS employees.
2. Please confirm whether Dr. Birnbaum’s article was subject to NIH procedures for non-peer-reviewed publications.¹⁴ In doing so, please provide all procedural documents, approval forms, cover sheets, etc., that are required for review and clearance relative to publication of a non-peer-reviewed work. Please ensure that these documents include all those required to be filed by Dr. Birnbaum, as well those generated by NIH regarding the Birnbaum article.

¹¹ Ibid.

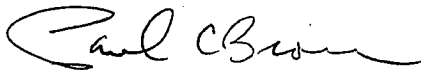
¹² “How the Report on Carcinogens Uses Science to Meet its Statutory Obligations, and its Impact on Small Business Jobs,” Committee on Science, Space, & Technology, Subcommittee on Investigations & Oversight and Committee on Small Business, Subcommittee on Healthcare & Technology - Joint Hearing, April 25, 2012, available at: <http://science.house.gov/hearing/committee-science-space-technology-subcommittee-investigations-oversight-and-committee-small>.

¹³ Memorandum from President Obama, “Transparency and Open Government,” January 21, 2009, available at: http://www.whitehouse.gov/the_press_office/TransparencyandOpenGovernment.

¹⁴ NIH Policy, *supra*, note 3.

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Please provide the requested information by June 27, 2013. If you have any questions about this request, please feel free to have your staff contact Raj Bharwani with the Committee at (202) 225-6371.



Rep. Paul Broun, M.D.
Chairman
Subcommittee on Oversight

Sincerely,



Rep. Larry Bucshon, M.D.
Chairman
Subcommittee on Research

Cc:

Rep. Dan Maffei
Ranking Member
Subcommittee on Oversight

Rep. Dan Lipinski
Ranking Member
Subcommittee on Research

Dr. Lawrence Tabak
NIH Deputy Ethics Counselor

Dr. Linda Birnbaum
Director, NIEHS and NTP