

# Congress of the United States House of Representatives

COMMITTEE ON SCIENCE, SPACE, AND TECHNOLOGY

2321 RAYBURN HOUSE OFFICE BUILDING

WASHINGTON, DC 20515-6301

(202) 225-6371

[www.science.house.gov](http://www.science.house.gov)

October 23, 2013

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

Dear Director Collins,

On September 18, we wrote you in response to a July 30<sup>th</sup> letter from Dr. Lawrence A. Tabak regarding our concerns about an article published by 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).

As noted in our prior correspondence, we have concerns about Dr. Birnbaum's article titled, "When Environmental Chemicals Act Like Uncontrolled Medicine," which was published in the journal *Trends in Endocrinology and Metabolism*.<sup>1</sup> Specifically, Dr. Birnbaum's article does not include an explicit disclaimer stating whether the views expressed in the article represent the views of the Administration or her own. This appears to be a departure from NIH policy for peer-reviewed publication because according to NIH's Policy Manual:

*Normally, the need for a disclaimer in relation to official materials, presentations, or publications is eliminated through the clearance process. However, a disclaimer may still be needed even after official clearance to make clear that the presentation should not be construed as necessarily representing the NIH view.*<sup>2</sup>

As you know, in his July letter to us, Dr. Tabak acknowledged that the "review did not occur in this instance,"<sup>3</sup> and that Dr. Birnbaum's article "should have undergone an internal NIH

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<sup>1</sup> 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).

<sup>2</sup> NIH Policy Manual: 1184 – "Scientific, Technical, and Other Professional Information Presented by NIH Employees: Review, Approval, and Distribution," available at: <http://oma1.od.nih.gov/manualchapters/management/1184/main.html>.

<sup>3</sup> Letter from Dr. Lawrence A. Tabak, Deputy Director, National Institutes of Health, to Chairmen Paul Broun and Larry Bucshon, July 30, 2013.

review before submission.”<sup>4</sup> Yet a September 20<sup>th</sup> news article reported Dr. Birnbaum allegedly saying that, “NIH scientists do not have to use disclaimers when publishing papers.”<sup>5</sup>

Dr. Birnbaum’s personal views aside, the Code of Federal Regulations, which is legally binding by statutory law, has clear language regarding the clearance process. As noted in NIH’s Guidelines for Ensuring the Quality of Information Disseminated to the Public:

*Consistent with HHS Standards of Conduct (45 CFR 73.735-705 Writing and Editing)....If the writing or editing activity is related to the employee’s official duties or other responsibilities and programs of the Federal Government, the employee must*

- (i) make no mention of his or her official title or affiliation with the Department, or*
- (ii) use his or her official title or affiliation with the Department and a disclaimer, or*
- (iii) submit the material for clearance within the operating component, under procedures established by the component.*<sup>6</sup>

Further:

*The Department’s regulations (Standards of Conduct) to which the NIH subscribes, require that disclaimers be used in all unofficial writing and editing related to the employee’s official duties and/or affiliation with programs of the Federal Government in which the employee’s identification with NIH is to be shown, can be inferred, or is well-known.*<sup>7</sup>

NIH Guidelines note that, “NIH employees are responsible for the statements they make, regardless of whether they have been cleared.”<sup>8</sup> While we await your reply to our September 18<sup>th</sup> letter, we submit the following additional questions based on our concerns over Dr. Birnbaum’s alleged interpretation of federal law relative to HHS Standards of Conduct:

1. Is the September 20<sup>th</sup> article accurate in its representation of Dr. Birnbaum’s views that “NIH scientists do not have to use disclaimers when publishing papers?” If there is a discrepancy between what Dr. Birnbaum said and what the article’s author inferred, please explain the discrepancy.
2. If the article is accurate in its depiction of Dr. Birnbaum’s interpretation of the law, then please explain whether Dr. Birnbaum’s interpretation reflects the official policy

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<sup>4</sup> Ibid.

<sup>5</sup> “Republicans Continue Criticism of NIH Article Linking Chemical Use to Disease,” *Environment & Energy*, September 20, 2013; available at: <http://www.eenews.net/eedaily/stories/1059987581/search?keyword=birnbaum>.

<sup>6</sup> Department of Health & Human Services: Guidelines for Ensuring the Quality of Information Disseminated to the Public: I. National Institutes of Health, available at: <http://aspe.hhs.gov/infoquality/Guidelines/NIHinfo2.shtml>.

<sup>7</sup> Ibid.

<sup>8</sup> Ibid.

Dr. Collins  
October 23, 2013  
Page 3

at NIH and HHS. If not, please explain how Dr. Birnbaum came to interpret the federal law differently and whether her interpretation contradicts the law.

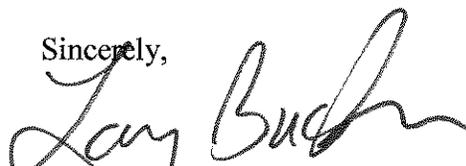
We have attached our September 18<sup>th</sup> letter to remind you of the now-outstanding questions we posed in that letter with an initial deadline to reply by October 4th. Understanding that the government shutdown may have impacted your staff's ability to address our concerns in a timely manner, we are extending that deadline and request you respond to all questions in this and our September 18<sup>th</sup> letter by November 8, 2013.

If you have any questions about these requests, 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 & Technology

Cc:

Rep. Dan Maffei  
Ranking Member  
Subcommittee on Oversight

Rep. Dan Lipinski  
Ranking Member  
Subcommittee on Research & Technology

Dr. Lawrence Tabak  
NIH Deputy Ethics Counselor

Dr. Linda Birnbaum  
Director, NIEHS and NTP

Attachment

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September 18, 2013

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

Dear Director Collins:

On July 30, 2013, we received a letter from Dr. Lawrence A. Tabak in response to our June 13, 2013 letter regarding a recently published article by 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). Our letter raised questions about Dr. Birnbaum's accuracy in the presentation of scientific data and in describing peer reviewed studies in her article titled, "When Environmental Chemicals Act Like Uncontrolled Medicine," in the journal *Trends in Endocrinology and Metabolism*.<sup>1</sup> In addition, we highlighted our concerns about a lack of transparency as, given the absence of a disclaimer, it was unclear whether the article represented Dr. Birnbaum's personal views or Administration policy. While we appreciated Dr. Tabak's reply, it did not address all our concerns, and in fact, his letter has raised more questions.

As mentioned, Dr. Birnbaum's article does not include an explicit disclaimer stating whether the views expressed represent the views of the Administration or her own. It is not clear how we should interpret the response we were provided. On one hand, Dr. Tabak seems to imply that the article represents the views of the agency "[b]ecause the article was published in a peer-reviewed journal and...Dr. Birnbaum's scientific views cannot be separated from her role as an institute director..."<sup>2</sup> On the other hand, the article did not undergo "an internal NIH review before submission,"<sup>3</sup> as required under NIH policy for peer reviewed publications. Nor was there a reason provided in Dr. Tabak's letter for this oversight on the agency's part.

Further, according to NIH policy for peer-reviewed publication, "In 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."<sup>4</sup> In light of Dr. Tabak's cryptic letter, which fails to address one of our

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<sup>1</sup> 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/abstract/S1043-2760%2812%2900225-1>; (Hereinafter Birnbaum Article).

<sup>2</sup> Letter from Dr. Lawrence A. Tabak, Deputy Director, National Institutes of Health, to Chairmen Paul Broun and Larry Bucshon, July 30, 2013; (Hereinafter Tabak Letter).

<sup>3</sup> Ibid.

<sup>4</sup> NIH Employee Procedures for Complying with NIH Public Access Policy (for peer-reviewed publications), available at: [http://publicaccess.nih.gov/nih\\_employee\\_procedures.htm](http://publicaccess.nih.gov/nih_employee_procedures.htm); (Hereinafter NIH Peer-Reviewed Publications Policy).

central concerns, we remain unsure as to whether the article reflects official policy or Dr. Birnbaum's personal views.

Additionally, regarding submissions for publication, according to the guidance provided by the journal that published Dr. Birnbaum's article, "[m]anuscripts may be peer reviewed,"<sup>5</sup> (emphasis added). Dr. Tabak's reply states that the Birnbaum article was "peer-reviewed according to the policies of the journal with the reviewers' comments accommodated by the author."<sup>6</sup> Despite this assurance, and given the paucity of information provided in his letter, we have concerns about the quality and extent of the peer review conducted, and how extensively reviewers' comments were accommodated by Dr. Birnbaum.

The confusing nature of Dr. Birnbaum's article regarding whose views it represents is compounded by the non-transparent reply from Dr. Tabak to our letter – which posed two straightforward questions. Both Dr. Birnbaum's article and Dr. Tabak's reply appear to contradict the sentiment expressed in the Concluding Statement in NIH's Policies and Procedures for Promoting Scientific Integrity, which states in part, "NIH has an unwavering commitment to scientific integrity, transparency, and public accountability that serves at the core of its mission."<sup>7</sup>

To that end, we once again request the following information and documents: In your response, please reference the numbers below so it is clear which questions are being answered:

1. Please state 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 explain why Dr. Birnbaum's article was not subject to NIH procedures for peer-reviewed publications.<sup>8</sup> In doing so, please provide any procedural documents, approval forms, cover sheets, etc., that may have been filed by Dr. Birnbaum that were overlooked. In addition, please state whether Dr. Birnbaum has published articles in the past that have also failed to undergo internal NIH reviews for both peer-reviewed and non-peer-reviewed publications. If so, please identify the articles, when and where they were published, and the reasons for the lack of a NIH review.
3. Please describe precisely the peer review process for Dr. Birnbaum's article including: who selected the peer reviewers and how were they selected? Please also provide the peer reviewers comments, and evidence of how they were "accommodated by the author."<sup>9</sup>
4. Have there been other instances within the agency where publications by senior-level employees failed to undergo internal NIH reviews for both peer-reviewed and non-peer-reviewed publications? If so, please provide a list of the employees, the articles they published, including when and where, and the reasons for the lack of a NIH review.

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<sup>5</sup> "Instructions for Authors: Science & Society Article," *Trends in Endocrinology & Metabolism*, available at: [http://download.cell.com/images/edimages/Trends/Endometabolism/2011-12%20guidelines/TEM%20Science%20Society%20Author%20Guidelines\\_2013.pdf](http://download.cell.com/images/edimages/Trends/Endometabolism/2011-12%20guidelines/TEM%20Science%20Society%20Author%20Guidelines_2013.pdf).

<sup>6</sup> Tabak Letter, *supra*, note 2.

<sup>7</sup> NIH Policies and Procedures for Promoting Scientific Integrity, November 2012, at 16; available at: <http://www.nih.gov/about/director/sci-int-nov2012.pdf>.

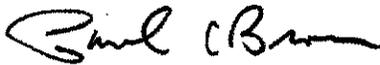
<sup>8</sup> NIH Peer-Reviewed Publications Policy, *supra*, note 4.

<sup>9</sup> Tabak Letter, *supra*, note 2.

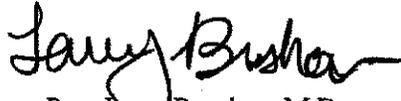
5. Dr. Tabak's letter states that NIH restated the "clearance process with all Institute and Center Directors to ensure that the NIH Office of the Director clears all manuscripts written by Institute and Center Directors and OD Deputy Directors."<sup>10</sup> Please explain how specifically, with supporting documents, this restatement was issued. Is there a training or re-training component to this? Is there an explanation of the potential consequences to future violations of the clearance process? What are the consequences?
6. We understand that Dr. Birnbaum will be on a panel to discuss, "Environmental Exposure and Cancer: Asking Questions and Taking Action," which will be followed by the D.C. premier of the film "Unacceptable Levels."<sup>11</sup> According to promotional materials, this film is "about the chemicals in our body, how they got there and what we can do about it."<sup>12</sup> Will Dr. Birnbaum be serving in her official capacity during her panel appearance and remarks? What approval, if any, did Dr. Birnbaum obtain from the NIH Office of the Director to participate on this panel? Please provide all supporting documents regarding her participation on this panel, including her prepared remarks. If Dr. Birnbaum is not appearing in her official capacity, what steps will be taken to ensure that her remarks and participation are not interpreted as official NIH policy?

Please provide the requested information by October 4, 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.

Sincerely,



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



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

Cc: Rep. Dan Maffei  
Ranking Member  
Subcommittee on Oversight

Rep. Dan Lipinski  
Ranking Member  
Subcommittee on Research & Technology

Dr. Lawrence Tabak  
NIH Deputy Ethics Counselor

Dr. Linda Birnbaum  
Director, NIEHS and NTP

<sup>10</sup> Ibid.

<sup>11</sup> *Unacceptable Levels* – D.C. Premier at the Capitol Visitor Center – Eventbrite at: <https://unacceptablelevelsdcc.eventbrite.com>.

<sup>12</sup> Ibid.