## ONE HUNDRED FOURTEENTH CONGRESS

## Congress of the United States

## House of Representatives

COMMITTEE ON ENERGY AND COMMERCE

2125 RAYBURN HOUSE OFFICE BUILDING WASHINGTON, DC 20515-6115

Majority (202) 225-2927 Minority (202) 225-3641

January 7, 2016

The Honorable Francis Collins, M.D. Director
National Institutes of Health
9000 Rockville Pike
Bethesda, MD 20892

Dear Dr. Collins:

Last month, ESPN published a detailed article alleging that the National Football League (NFL) "backed out" of funding a seven year, \$16 million National Institutes of Health (NIH) study to attempt to diagnose chronic traumatic encephalopathy (CTE) in living patients. The study was originally to have been funded by a \$30 million donation from the NFL to the NIH, which the NFL described as an "unrestricted" gift to the agency. The NFL allegedly pulled funding for the CTE research when it learned that NIH had awarded the grant to Dr. Robert Stern, a Boston University (BU) researcher who has been critical of the NFL in the past.

The NIH is the world's leading biomedical agency. The NIH's independent peer review process forms the cornerstone of the NIH research mission and ensures that applications submitted to the NIH are evaluated by scientific experts in a manner free of inappropriate influences or bias.<sup>4</sup> We are concerned about the potential implications of outside entities

<sup>&</sup>lt;sup>1</sup> NFL Backs Away from Funding BU Brain Study; NIH to Fund it Instead, ESPN (Dec. 22, 2015) (online at espn.go.com/espn/otl/story/\_/id/14417386/nfl-pulls-funding-boston-university-head-trauma-study-concerns-researcher).

<sup>&</sup>lt;sup>2</sup> National Football League, *National Football League Grants \$30 Million in Unrestricted Funding to the Foundation for the National Institutes of Health for Medical Research* (Sept. 5, 2012) (online at www.nfl.com/news/story/0ap100000058447/article/nfl-donates-30-million-to-national-institutes-of-health).

<sup>&</sup>lt;sup>3</sup> NFL Backs Away from Funding BU Brain Study; NIH to Fund it Instead, ESPN (Dec. 22, 2015) (online at espn.go.com/espn/otl/story/\_/id/14417386/nfl-pulls-funding-boston-university-head-trauma-study-concerns-researcher).

<sup>&</sup>lt;sup>4</sup> National Institutes of Health, *NIH Peer Review: Grants and Cooperative Agreements* (2013) (online at grants.nih.gov/grants/peerreview22713webv2.pdf).

attempting to exercise "veto power" or other influence over the selection of NIH research applicants, and we therefore seek to better understand the role the NFL has played in the allocation and administration of its \$30 million "unrestricted" donation.

The NFL originally made the \$30 million "unrestricted" donation to the NIH in 2012, to advance the science and medical understanding of brain injuries. The Foundation for the NIH (FNIH), a non-profit organization that solicits donations for NIH research, administers the grant through the Sports Health Research Program (SHRP), a partnership among the NFL, the NIH, and the FNIH. According to the NFL, research supported through the SHRP is conducted under the direction of the NIH, "in accordance with federal law and policy applicable to NIH-funded research."

However, according to ESPN, despite the NFL's characterization of the \$30 million gift as "unrestricted," and "with no strings attached," the league actually retained veto power over projects it funded. Dr. Walter Koroshetz, the director of the NIH's National Institute for Neurological Disorders and Stroke, affirmed this understanding to ESPN.<sup>8</sup>

The NFL allegedly exercised this veto power when it learned that NIH had awarded the CTE study grant to Dr. Robert Stern at BU. Dr. Stern and his research team were selected through a scientific merit review and a separate review by an NIH Advisory Council. According to ESPN, NIH has ultimately decided to fund the study on its own.

The BU-led study involves 50 researchers at 17 institutions and hundreds of former NFL and college players who will participate as subjects. The study seeks to detect, define, and measure the progression of CTE, which currently can only be diagnosed after death and has been found in 87 former NFL players over the last 10 years. <sup>10</sup> CTE is a neurodegenerative disease

<sup>&</sup>lt;sup>5</sup> National Football League, *National Football League Grants \$30 Million in Unrestricted Funding to the Foundation for the National Institutes of Health for Medical Research* (Sept. 5, 2012) (online at www.nfl.com/news/story/0ap100000058447/article/nfl-donates-30-million-to-national-institutes-of-health).

<sup>&</sup>lt;sup>6</sup> Foundation for the National Institutes of Health, *Sports and Health Research Program* (online at www.fnih.org/what-we-do/current-research-programs/shrp) (accessed Jan. 5, 2016).

<sup>&</sup>lt;sup>7</sup> National Football League, *National Football League Grants \$30 Million in Unrestricted Funding to the Foundation for the National Institutes of Health for Medical Research* (Sept. 5, 2012) (online at www.nfl.com/news/story/0ap100000058447/article/nfl-donates-30-million-to-national-institutes-of-health).

<sup>&</sup>lt;sup>8</sup> NFL Backs Away from Funding BU Brain Study; NIH to Fund it Instead, ESPN (Dec. 22, 2015) (online at espn.go.com/espn/otl/story/\_/id/14417386/nfl-pulls-funding-boston-university-head-trauma-study-concerns-researcher).

<sup>&</sup>lt;sup>9</sup> *Id.* 

<sup>10</sup> Id.

associated with repetitive head impacts. It is associated with memory loss, impaired judgement, impulse control problems, aggression, depression, suicidal ideation, and progressive dementia similar to Alzheimer's disease.<sup>11</sup>

The NFL has disputed ESPN's account of the funding dispute, stating that "The NFL did not pull funding from the BU study." Furthermore, NFL spokesman Brian McCarthy wrote that "The NIH makes all funding decisions. The NFL has no 'veto power' as part of its unrestricted \$30 million grant to NIH." 12

Additionally, the FNIH released a statement that "The NFL funding commitment to SHRP remains intact. NFL was willing to contribute to the Boston University CTE study headed by Dr. Stern. NIH made the decision to fund this study in its entirety and to issue a Request for Applications (RFA) early next year to support an additional study on CTE using funds from SHRP, which will double the support for research in this area." <sup>13</sup>

Given the various conflicting accounts, we seek to better understand the nature of the agreement(s) between NFL, NIH, and FNIH, and the NFL's involvement in the administration of its \$30 million "unrestricted" donation to NIH. To assist our inquiry, please provide the following documents and information by February 1, 2016:

- 1. Any and all agreements between the NFL and the NIH, the NFL and the FNIH, and the NIH and FNIH related to the \$30 million NFL donation, including all contract addendums, additions, clarifications, and modifications, formal or informal.
- 2. All documents and communications between any employees, contractors, and affiliates of the NFL and any employees of the NIH pertaining to the \$30 million donation, including any terms or conditions.
- 3. All documents and communications between any employees of the NIH and any employees of the FNIH pertaining to the \$30 million donation, including any terms or conditions.

Please also provide the following information and respond to the following questions by February 1, 2016:

<sup>&</sup>lt;sup>11</sup> Christine M. Baugh et. al., *Chronic Traumatic Encephalopathy: Neurodegeneration Following Repetitive Concussive and Subconcussive Brain Trauma*, Brain Imaging and Behavior (June 2012).

<sup>&</sup>lt;sup>12</sup> NFL Disputes ESPN Report on Brain Study Funding; NIH Says no NFL Veto, Washington Post (Dec. 22, 2015).

<sup>&</sup>lt;sup>13</sup> Foundation for the National Institutes of Health, *The FNIH's Statement on SHRP Funding* (online at http://fnih.org/news/announcements/statement-on-shrp-funding) (accessed Jan. 5, 2016).

- 1. What is the protocol that apply when NIH receives donations from an outside entity through the FNIH? Please provide copies of any applicable rules, guidance, regulations, or laws governing the relationship between NIH, FNIH, and any outside donors.
- 2. What is the nature of the agreement between FNIH, NFL, and NIH with respect to decisions around research solicited and selected to be supported by NIH?
- 3. How does the NIH plan to fund the Boston University CTE study led by Dr. Robert Stern? Would NIH support the study in the absence of the gift?
- 4. Dr. Walter Koreshetz, was quoted as confirming that the NFL "retained veto power over projects that it funds." Did the NFL maintain "veto power" over any aspect of the research projects funded through the SHRP, including the identity of researchers associated with grant applications, scope or subject of the proposed research, or publication of research results? Was this understanding memorialized in writing? If so, please provide a copy. Please also provide any other documents and communications related to this understanding, including internal communications within NIH, as well as any communications between employees, contractors, or affiliates of the NFL and employees of NIH.
- 5. Has any employee, contractor, or affiliate of the NFL exercised veto power, threatened to exercise veto power, or threatened to withdraw funding from the SHRP at any point in time, for any reason? If so, please provide an explanation of these circumstances, and any related documents and communications, including internal communications within NIH, as well as any communications between employees, contractors, or affiliates of the NFL and employees of NIH.
- 6. At this time, how much of the NFL's \$30 million donation has been committed to research studies focused on brain injuries? Please provide details on the studies that have received grants derived from this donation and the conditions of those grants. Please provide details on the NIH's future plans for investment in concussion research.

Your assistance in this matter is greatly appreciated. If you have any questions, please contact Una Lee of the minority committee staff at (202) 225-3641.

<sup>&</sup>lt;sup>14</sup> NFL Backs Away from Funding BU Brain Study; NIH to Fund it Instead, ESPN (Dec. 22, 2015) (online at espn.go.com/espn/otl/story/\_/id/14417386/nfl-pulls-funding-boston-university-head-trauma-study-concerns-researcher).

Sincerely,

Frank Pallone, Jr., Ranking Member Committee on Energy and Commerce Diana DeGette, Ranking Member Subcommittee on Oversight and Investigations

Jan Schakowsky, Ranking Member Subcommittee on Commerce,

Manufacturing and Trade

Gene Green, Ranking Member Subcommittee on Health