

ONE HUNDRED FOURTEENTH CONGRESS  
**Congress of the United States**  
**House of Representatives**

COMMITTEE ON ENERGY AND COMMERCE

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September 15, 2016

The Honorable Daniel Levinson  
Inspector General  
Office of Inspector General  
U.S. Department of Health and Human Services  
200 Independence Avenue, S.W.  
Washington, DC 20201

Dear Mr. Levinson:

In September 2012, the National Football League (NFL or the League) provided a donation of \$30 million to the Foundation for National Institutes of Health (FNIH) for the Sports and Health Research Program (SHRP) – a public-private partnership with the National Institutes of Health (NIH). The SHRP was established for the purpose of supporting “research on serious medical conditions prominent in athletes and relevant to the general population.”<sup>1</sup> Consistent with other FNIH programs, SHRP has policies and procedures to ensure the integrity and objectivity of NIH research funded through the public-private partnership.

In December 2015, ESPN’s Outside the Lines published the first of a series of reports alleging that the NFL attempted to influence NIH decision-making for a research grant to be funded through SHRP.<sup>2</sup> In response to the initial ESPN report, Democratic Members of this Committee launched an investigation into the NFL’s actions and the effect on the independence of NIH decisions related to the grant. In May 2016, the Democratic staff released a report which

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<sup>1</sup> Press Release, Foundation of the National Institutes of Health, “NFL Commits \$30 Million Donation to FNIH to Support Medical Research (Sept. 5, 2012) *available at* <http://www.fnih.org/news/press-releases/national-football-league-commits-30-million-donation>

<sup>2</sup> Steve Fainaru et. al., ESPN, “NFL backs away from funding BU brain study; NIH to fund instead” (December 22, 2015) *available at* <http://espn.go.com/espn/print?id=14417386#>.

concluded that the NFL had attempted to inappropriately influence NIH decision-making, but that “NIH leadership maintained the integrity of the science and the grant review process.”<sup>3</sup>

Based on the information available to the Republican staff, however, there appear to be important questions and concerns related to these events that have not been adequately vetted or addressed. The FNIH was established by Congress in 1990 to allow the NIH to secure the benefits of public-private partnerships.<sup>4</sup> These public-private partnerships through FNIH are carefully structured to prevent donors from improperly influencing NIH use of funds in the execution of its inherently governmental responsibilities. In this case, however, it appears that NIH’s actions may have contributed to the breakdown of the structures and processes that exist to preserve the integrity of NIH research. Specifically, if the conduct of the NFL or its advisors was, in fact, inappropriate, NIH not only failed to identify and address this behavior, but rather encouraged ongoing discussion, thus creating a perception that the League had input on the use of SHRP funds. This grant award has become the source of tremendous public debate and, therefore, clear answers and lessons are necessary. For these reasons, the Committee refers this matter to your attention and requests a thorough and objective review by the Office of Inspector General to assess whether the policies and procedures concerning public-private partnerships under the authority of FNIH were followed, and if not, what revisions or reforms should be considered. This will help SHRP, and other public-private partnerships, avoid similar distractions in the future so all parties can focus on what matters most – the science.

### **Background**

The Sports and Health Research Program (SHRP) was created in September 2012 for the purpose of accelerating “research on serious medical conditions prominent in athletes and relevant to the general population.”<sup>5</sup> The program was established in response to interest from the NFL, and the League provided a founding donation of \$30 million. While the program is designed to address health concerns across all sports, to date, the NFL remains the only donor to the program.

The SHRP is administered through interparty agreements among the donor (NFL), FNIH, and NIH. There is a Memorandum of Understanding (MOU) between FNIH and NIH which outlines the responsibilities of NIH and FNIH for administration of the SHRP. In addition, there is a Letter of Agreement (LOA) between the FNIH and the NFL which establishes the terms of

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<sup>3</sup> Democratic Staff Report, Committee on Energy and Commerce, “The National Football League’s Attempt to Influence Funding Decisions at the National Institutes of Health,” (May 23, 2016), at 3 (Hereinafter “Democratic Staff Report”).

<sup>4</sup> The NIH is prohibited from soliciting private donations so Congress authorized the establishment of the Foundation in 1990 as a not-for-profit 501(c)(3) to facilitate public-private partnerships that support NIH’s mission.

<sup>5</sup> Press Release, Foundation of the National Institutes of Health, “NFL Commits \$30 Million Donation to FNIH to Support Medical Research (Sept. 5, 2012) available at <http://www.fnih.org/news/press-releases/national-football-league-commits-30-million-donation>

the NFL's donation to SHRP. There are several key aspects of these agreements relevant to this referral:

- 1) Research Plans – The LOA between the NFL and FNIH outlines 11 areas of research interest for SHRP, three related to head trauma, six discrete health concerns (e.g. cardiac death in young athletes, heat and hydration illness, the effects of drugs and performance enhancing substances, etc.), and two related to third party or donor proposals.<sup>6</sup> Specific research priorities within or related to these areas of interest are identified through collaborative discussions between the NFL, FNIH, and NIH. Once a research priority of mutual interest is identified, the NIH is responsible for developing a Research Plan, which FNIH then provides to the NFL. There may be additional discussions between all three parties about the specifics of the Research Plan. Once there is agreement and the Research Plan is executed by all three parties, all responsibility for execution of the Research Plan transfers to NIH. The LOA specifically states that the “DONOR acknowledges and agrees that NIH will have responsibility for and control over the scientific and administrative aspects of the Research Plans it manages under the program, including but not limited to holding workshops, developing and posting calls for applications, reviewing applications, determining grantees, awarding grants, overseeing the grants, including the scientific and financial progress of grantees, monitoring data sharing plans, and publication of research results related to the program.”<sup>7</sup> This is consistent with NIH policy regarding donor influence.<sup>8</sup>
- 2) Donor Communications – FNIH is responsible for all interactions with the donor, the NFL. In addition to providing required scientific progress and financial reports, and coordinating public communications, they are also responsible for responding to “reasonable requests for information regarding the program,” and using “reasonable efforts to facilitate resolution of any Donor related issues that arise with respect to the applicable project.”<sup>9</sup>
- 3) Responsibility for Payment – Under the terms of the LOA, once a Research Plan is executed by all parties, the donor, in this case the NFL, is responsible for payments set forth in the Research Plan. Section 9(b) of the LOA specifically notes that even if the NFL terminated the Agreement with FNIH – which they may do “for any reason or for no reason upon providing FNIH thirty (30) days’ advance written notice” – that would not

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<sup>6</sup> Master Letter of Agreement between National Football League and Foundation for the National Institutes of Health, The Sports Health and Research Program (Sept. 1, 2012), at 1-2 (Hereinafter “LOA”).

<sup>7</sup> *Id.*, at 3.

<sup>8</sup> NIH Policy Manual, *1135-Gifts Administration* (October 5, 2011) available at <https://oma1.od.nih.gov/manualchapters/management/1135/>.

<sup>9</sup> Memorandum of Understanding between The Foundation for the National Institutes of Health and Office of the Director, National Institutes of Health, The Sports Health and Research Program, at 4 (Hereinafter “MOU”).

“terminate or otherwise relieve any of NFL’s obligations for payment of any installments that are set forth in any executed Research Plan(s),”<sup>10</sup>

- 4) Request for Payment – The LOA states that “upon agreement by DONOR, the FNIH, and NIH on the Research Plan, the FNIH will transfer DONOR funds to NIH.”<sup>11</sup> FNIH clarified that this is done as needed, based on a general schedule outlined in the Research Plan. FNIH added that the funding schedules in the Research Plan are indicative and therefore, they do not invoice a donor until they receive a specific request from NIH.<sup>12</sup>

Since the inception of the SHRP, the NFL, NIH, and FNIH have executed five Research Plans. The first four Research Plans proceeded without concern or controversy. The events in question center on Research Plan 5, executed by the parties in July 2014. The Research Plan contained three primary components: 1) a longitudinal study to detect early stages and progression of chronic traumatic encephalopathy (CTE); 2) a workshop to plan a longitudinal study on youth and sport health; and (3) semiannual stakeholder meetings.<sup>13</sup> The bulk of the funding under Research Plan 5, approximately \$16 million, was scheduled to go to a grant for the longitudinal study of CTE in high risk adults.

### **The Democratic Staff Investigation**

In response to the December 2015 ESPN report, on January 7, 2016, Democratic members of this Committee opened an investigation. In letters to NIH and FNIH, the Democratic members requested documents and information necessary to inform their understanding of “the agreements between NFL, NIH, and FNIH and the NFL’s involvement in the administration of its \$30 million ‘unrestricted’ donation to NIH.”<sup>14</sup>

The Committee’s Republican staff participated in three initial briefings related to the Democratic staff’s investigation, two with Dr. Walter Koroshetz, Director of the National Institute of Neurological Disorders and Stroke at NIH, and one with Dr. Maria Friere, President and Executive Director of FNIH. The Republican staff received a limited number of documents produced by NIH and email communications provided by FNIH. Further, after the second briefing with Dr. Koroshetz, (on February 10, 2016), the Republican staff was not informed of further briefings or correspondence related to the Democratic staff’s investigation.

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<sup>10</sup> LOA, at 6

<sup>11</sup> LOA, at 4.

<sup>12</sup> Summary provided by the Foundation for the National Institutes of Health, “Sports and Health Research Program – Grant Structure” (on file with Committee Staff).

<sup>13</sup> Sports Health and Research Program, Research Plan, Schedule No. 5 (July 24, 2015).

<sup>14</sup> Letter from Ranking Member Frank Pallone, Jr. et al., Committee on Energy and Commerce, to Dr. Francis Collins, Director, NIH (January 7, 2016); Letter from Ranking Member Frank Pallone, Jr. et al., Committee on Energy and Commerce, to Dr. Maria Freire, President and Executive Director, Foundation for the National Institutes of Health (January 7, 2016).

On May 23, 2016, the Democratic staff released a report summarizing the results of their investigation. The report contained six findings and five recommendations.<sup>15</sup>

Findings:

1. The NFL improperly attempted to influence the grant selection process at NIH.
2. The NFL's Head, Neck and Spine Committee members played an inappropriate role in attempting to influence the outcome of the grant selection process.
3. The NFL's rationalization that the Boston University study did not match their request for a longitudinal study is unfounded.
4. FNIH did not adequately fulfill its role of serving as an intermediary between NIH and the NFL.
5. NIH leadership maintained the integrity of the science and the grant review process.
6. The NFL did not carry out its commitment to respect the science and prioritize health and safety.

Recommendations:

1. FNIH must establish clearer guidelines regarding donor communications with NIH.
2. FNIH must come to a mutual understanding with donors at the beginning of the process regarding their degree of influence over the research they are funding and remind donors that NIH policy prohibits them from exerting influence at any point in the grant decision-making process.
3. FNIH should provide donors with the clear, unambiguous language from the NIH Policy Manual, which states that a donor may not dictate terms that include "any delegation of NIH's inherently governmental responsibilities or decision-making," or "participation in peer review or otherwise exert real or potential influence in grant or contract decision-making."
4. NIH and FNIH should jointly develop a process to address concerns about donors acting improperly.
5. The NFL, FNIH, and NIH should amend their current agreements to ensure that each party has a clear understanding of its role for the remainder of this partnership.

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<sup>15</sup> Democratic Staff Report, at 3-4.

### **Stakeholder Reaction to the Democratic Staff Report**

In response to the Democratic staff report, several members of the NFL's Head, Neck and Spine Committee (HNS) publically voiced concerns about the conclusions regarding their conduct.<sup>16</sup> In addition, these independent medical advisors asserted that they were never contacted by the Democratic committee staff prior to the release of the report.<sup>17</sup> The FNIH also voiced disagreement with the report. In a public response, FNIH stated:

May 23, 2016 — This morning, the Democratic Staff of the Committee on Energy and Commerce issued a report on the Sports and Health Research Program (SHRP), a partnership among the National Institutes of Health (NIH), National Football League (NFL) and the Foundation for the National Institutes of Health (FNIH). The following is the FNIH's response to the report.

**The FNIH acted appropriately, with integrity and transparency, in fulfilling its mandate under SHRP. As acknowledged by the Democratic Staff report, the governing documents among the FNIH, NIH and NFL made clear that the NIH had exclusive control over the scientific and administrative aspects of the program.**

The report makes recommendations regarding communication issues that the FNIH has already identified and taken steps to address. The FNIH has strengthened protocols around communications among NIH, NIH researchers and FNIH donors that will prevent unauthorized contact among parties.

The FNIH has had a long history of successful and productive public-private partnerships in support of the NIH mission. These adjustments to governing agreements will help ensure the success of future scientific partnerships in support of human health.<sup>18</sup>

Based on the limited information available to the Republican staff, as well as the subsequent concerns raised by the Members of the HNS and FNIH, the Republican staff identified several issues regarding the roles and responsibilities of NIH that warrant the attention of the OIG. Resolving these questions will ensure the integrity of NIH grant processes and

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<sup>16</sup> Dr. Hunt Batjer et. at. The Hill, "Committee's NFL concussion report gives wrong impression." (June 15, 2016) available at <http://64.147.104.30/opinion/letters/283654-committees-nfl-concussion-report-gives-wrong-impression>.

<sup>17</sup> *Id.*

<sup>18</sup> Statement, Foundation for the National Institutes of Health, "The FNIH's Statement on the Democratic Staff Report of the Committee on Energy and Commerce," (May 23, 2016) available at <http://www.fnih.org/news/announcements/the-fnihs-statement-on-the-democratic-staff-report-of-the-committee-on-energy-and-commerce>. (Emphasis added)

decisions, strengthen SHRP, and enable all parties to eliminate the distraction and focus on what matters most – advancing critical research related to head trauma and sports related injuries.

### **Sequence of Events**

As described above, the current controversy centers on the fifth Research Plan executed under SHRP. The primary component of Research Plan 5 was a \$16 million grant for a longitudinal study of CTE in high risk adults. While the NFL has expressed interest in a true longitudinal study on brain trauma, the research grant agreed to by the parties – including the NFL - under Research Plan 5 had a more limited scope and duration. The document stated:

Although a large, natural history longitudinal study of young athletes over many years would be a powerful approach to identify the population incidence and prevalence of neurological deficits caused by brain trauma, it would require several decades to complete the study. Given the urgency of the problem, an alternative approach is to focus on high risk individuals with symptoms and medical history suggestive of CTE. In such individuals it may be possible to detect progression over the 3-5 year time span of this study. Therefore, this initiative aims to support a 7-year longitudinal, hypothesis-driven study to detect, define and monitor the progression of CTE in high-risk middle-aged adults, along with appropriate control studies.<sup>19</sup>

Research Plan 5 was executed by all three parties in July 2014. Upon execution, NIH assumed responsibility for issuing the Request for Applications (RFA), reviewing submissions, and making a funding decision. The National Institute of Neurological Disorders and Stroke (NINDS) Council met in May 2015 and recommended awarding the grant to a multi-center group led by Dr. Robert Stern from Boston University (BU).

Dr. Stern and a number of his colleagues at BU are among the most recognized experts and researchers on neurodegenerative diseases and Traumatic Brain Injury (TBI). Based on their research, they have been vocal about the link between football and long-term cognitive impairment, including CTE. This has, at times, created tension with the NFL. There is not, however, a complete lack of engagement between the League and BU. For example, Dr. Robert Cantu, a respected brain trauma expert from the Boston University School of Medicine is a medical advisor for the League. In addition, Dr. Ann Mckee – a nationally recognized neuropathologist from BU --received a grant award from an earlier SHRP Research Plan – without controversy or opposition. .

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<sup>19</sup> *Id.*, at 1-2. The NFL has raised concerns that the grant award for Research Plan 5 was inconsistent with their understanding of the research to be conducted. However, as noted in the Democratic Staff report (pp.28-30), the grant does appear consistent with the research agreed to by all parties in Research Plan 5.

Following the Council meeting in May 2015, the BU group was informed that they would receive the grant award. Normally, this information is closely held until NIH publicizes the Notice of Grant Award (NGA). However, prior to the NGA, one of the NFL's medical advisors, Dr. Elliot Pellman, contacted the President and Executive Director of FNIH, Dr. Maria Freire about the award. In a June 17, 2015 email, Dr. Pellman shared concerns that he and other NFL medical advisors had about the rumored award decision.<sup>20</sup> According to Dr. Freire, award decisions are supposed to be confidential and she could not recall a previous example of a donor learning this information before it was made public.<sup>21</sup> In fact, prior to Dr. Pellman's email, Dr. Freire indicated that FNIH was unaware of NIH's award decision.<sup>22</sup>

Dr. Pellman's email raises questions about how the NFL or its advisors learned of NINDS' grant award recommendation. The Democratic staff report suggests the awardee, Dr. Stern, informed the NFL directly.<sup>23</sup> It is unclear, however, whether Dr. Stern's outreach occurred before or after Dr. Pellman's email to FNIH.<sup>24</sup> Regardless, the fact that a donor was made aware of an award decision before it was made public raises questions regarding NIH rules or guidance regarding confidentiality prior to the public NGA.

After receiving Dr. Pellman's note, Dr. Freire forwarded the message to Dr. Koroshetz, Director of NINDS. He responded to her email the next evening, stating:

Yes we knew this was coming. Lot of history here. But our process was not tainted and all above board. The grant will go to a multisite group around the country. NINDS will manage it. The data will be believable and unbiased. Trouble is of course is [sic] that the group is led by the people who first broke the science open and NFL owners and leadership think of them as the creators of the problem. I think we need to go to Betsy Nabel first and get her on board (Betsy is their chief medical officer). We spoke this week.<sup>25</sup>

It is worth noting that the email from Dr. Pellman made no reference to concerns about the NIH process, only the group selected to receive the award and its ability to be "unbiased and collaborative."<sup>26</sup> In fact, the day before, June 17, 2015 – the same day Dr. Pellman contacted FNIH – Dr. Koroshetz emailed Dr. Nabel, the NFL's chief medical adviser, in response to a number of issues related to brain injury research he had discussed with her earlier that day. The

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<sup>20</sup> Email from Dr. Elliot Pellman to Dr. Maria Freire, FNIH (June 17, 2015) (On file with Committee Staff).

<sup>21</sup> Briefing by Dr. Maria Freire, President and Executive Director, Foundation for the National Institutes of Health to staff of the Committee on Energy and Commerce (January 28, 2016).

<sup>22</sup> *Id.*

<sup>23</sup> Democratic Staff Report, at 15.

<sup>24</sup> Email from Jeff Miller, Exec. VP for Player Health and Safety, NFL to Republican Staff, Committee on Energy and Commerce (June 1, 2016) (On file with Committee Staff).

<sup>25</sup> Email from Dr. Walter Koroshetz, NIH to Dr. Maria Freire, FNIH (June 18, 2015) (On File with Committee Staff).

<sup>26</sup> Email from Dr. Elliot Pellman to Dr. Maria Freire, FNIH (June 17, 2015) (On file with Committee Staff).

first bullet in his email notes, “[y]es the longitudinal trial that will launch soon is very multi center. Will get you details as soon as NGA is out.”<sup>27</sup> He also noted that an individual at Brigham and Women’s Hospital – where Dr. Nabel serves as President – “is tied in to most of our activities.”<sup>28</sup> While Dr. Koroshetz denied discussing the grant with Dr. Nabel at that time, his email suggests they had addressed the study to some degree.<sup>29</sup>

Shortly after responding to Dr. Freire’s email on June 18, 2015, Dr. Koroshetz emailed Dr. Nabel to inform her about the outreach from Dr. Pellman to FNIH. He stated:

Got message from fNIH that NFL questioning NIH funding decision of the longitudinal study and asking fNIH to slow down the process.

So legally I don’t think NIH can talk about a study [until] NGA is out. And as you know we can’t allow outside parties to influence NIH funding decisions, which we made clear to NFL going in.

I am certain that the study will be high level science and unbiased. It is a cooperative agreement so NINDS sets milestones and are involved in oversight.

I understand very well the emotion around this and the complicated history. We would be happy to sit down with you, go through the study in detail and get your input once public.

Sorry to get you in the middle of this but you’re the perfect position to ensure that the science advances.

Will be happy to allay concerns with NFL folks when we can publicly discuss.<sup>30</sup>

The Democratic staff report states that Dr. Nabel “emailed Dr. Koroshetz the day after Dr. Pellman emailed Dr. Koroshetz to express her own concerns.”<sup>31</sup> The Republican staff is unaware of any email from Dr. Pellman to Dr. Koroshetz. Further, the email cited in the Democratic staff report is dated June 23, 2015, six days after Dr. Pellman contacted FNIH.<sup>32</sup> It is important to clarify that Dr. Nabel’s email was in response to the email Dr. Koroshetz sent to her on June 18, 2015. In her initial response she passed along a pdf she received from the NFL,

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<sup>27</sup> Email from Dr. Walter Koroshetz, NIH to Dr. Betsy Nabel (June 17, 2015) (On file with Committee Staff).

<sup>28</sup> *Id.* [This individual was one of the recipients of the grant in question].

<sup>29</sup> Briefing by Dr. Walter Koroshetz, Director of NINDS, NIH to Energy and Commerce Committee Staff (Feb 10, 2016) (On file with Committee Staff).

<sup>30</sup> Email from Dr. Walter Koroshetz, NIH to Dr. Betsy Nabel (June 17, 2015) (On file with Committee Staff).

[Despite his note that they could not discuss the grant until NGA was public, as noted in footnote 12, he had already hinted at one of the recipients in correspondence with Dr. Nabel].

<sup>31</sup> Democratic Staff Report, at 15.

<sup>32</sup> *Id.*

who may have received it from a grant applicant, and shared concerns that were raised to her by the League or its advisors. She stated:

I am taking a neutral stance here, but I believe the concern is that members of the study section had published within the past two years with Dr. McKee or Dr. Cantu, who the grant applicant believes will receive the [Notice of Grant Award]. Obviously, my goal is to make sure the science goes forward.<sup>33</sup>

Dr. Koroshetz responded that he would follow up with his review staff when he returned from overseas travel.<sup>34</sup> Shortly thereafter, Dr. Nabel responded with her appreciation and an additional concern that “[a]pparently a Dr. Stern, who may also be with this group, has filed independent testimony in the NFL/Players Association settlement. I hope this group is able to approach their research in an unbiased manner.”<sup>35</sup>

Two days later, on June 25, 2015, Dr. Koroshetz responded to Dr. Nabel’s note to inform her “NINDS can certainly try to enforce strict objectivity in the study and work the group dynamic as there are four Principal investigators.”<sup>36</sup> He shared the names and institutions of the three other principal investigators involved in the study, as well as a clinical site, and suggested a meeting with the principal investigators to inform the NFL medical team about the study and discuss concerns.<sup>37</sup> The NGA was still not public at this time. Therefore, this offer appears to contradict his message on June 18, 2015, where he explained that NIH could not discuss the grant until the NGA was public. It is unclear what changed between June 18, 2015 and June 25, 2015 that enabled NIH to discuss a non-public grant decision, as well as why NIH did not proceed with announcing the NGA, as planned.

During the same time period, on June 22, 2015, Jeff Miller, Executive Vice President of Health and Safety for the NFL, emailed Dr. Freire to request a time to discuss the grant.<sup>38</sup> At that time, Dr. Freire was under the impression that Dr. Koroshetz was reaching out to Dr. Nabel but had not heard anything about the outcome of those discussions.<sup>39</sup> Mr. Miller responded, “If you want to wait for them to connect, I understand but we would like to discuss the grant with

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<sup>33</sup> Email from Dr. Betsy Nabel to Dr. Walter Koroshetz (June 23, 2015) (On file with Committee Staff). [As noted in the Democratic staff report, neither Dr. McKee nor Dr. Cantu are listed as primary investigators on the Notice of Award announcement. However, they are affiliated with primary institution – Boston University – and the Republican staff has not reviewed the complete grant to know if they are listed as advisors or will otherwise contribute to the work affiliated with the grant. Dr. McKee has previously received funding for CTE research through SHRP and Dr. Cantu is a medical advisor to the NFL]

<sup>34</sup> Email from Dr. Walter Koroshetz, NIH to Dr. Betsy Nabel (June 22, 2015) (On file with Committee Staff).

<sup>35</sup> Email from Dr. Betsy Nabel to Dr. Walter Koroshetz, NIH (June 23, 2015) (On file with Committee Staff).

<sup>36</sup> Email from Dr. Walter Koroshetz, NIH to Dr. Betsy Nabel (June 25, 2015) (On file with Committee Staff).

<sup>37</sup> *Id.*

<sup>38</sup> Email from Jeff Miller, NFL to Dr. Maria Freire, FNIH (June 22, 2015) (On file with Committee Staff).

<sup>39</sup> Based on email records available to the Committee, FNIH was unaware of the back-and-forth between Dr. Koroshetz and Dr. Nabel until he forwarded the exchange to Dr. Freire on the evening of June 25, 2015. This appears to contradict the terms of the MOU which placed responsibility for donor communications with FNIH.

the FNIH as well.”<sup>40</sup> This led to a phone call between Mr. Miller and representatives of FNIH on June 26, 2015.<sup>41</sup>

In advance of that conversation, in a series of emails between the evening of June 25, 2015, and early afternoon June 26, 2015, Dr. Koroshetz updated Dr. Freire on his conversations with Dr. Nabel and provided his suggestions for next steps. He initially recommended the offer he gave to Dr. Nabel – to set up a phone call with the principal investigators of the grant.<sup>42</sup> Dr. Freire responded that FNIH felt it was best to see what the NFL wanted and offer a follow-up with him.<sup>43</sup> In response, Dr. Koroshetz agreed and asked FNIH to emphasize that the grant award involved multiple groups and would have NIH oversight. He also mentioned the concerns about the review process raised by Dr. Nabel and that his program directors had examined those concerns. They found that some panel members “were recused from discussing this grant due to conflicts” but overall the “[p]rogram did think there was a high level of integrity in the review process.”<sup>44</sup> He added, “of course NIH is going to fund it with or without NFL support. So in fact it is high risk for the NFL to drop out.”<sup>45</sup> He also raised the idea of offering a potential compromise – expanding the study to include additional locations and investigators or fund related work.<sup>46</sup> Dr. Freire decided to proceed with the strategy of hearing what NFL had to say on the call and then determining appropriate next steps, likely a call with Dr. Koroshetz.<sup>47</sup>

On the June 26, 2015 phone call, FNIH offered to arrange a phone call with Dr. Koroshetz. As described in the Democratic staff report, this call occurred on June 29, 2015, and involved NIH, FNIH, and the representatives from the NFL and the League’s HNS committee.<sup>48</sup> Based on Dr. Freire’s recollection – and email exchanges discussed above – the NFL and its advisers raised three main concerns with the grant award:

- 1) The NIH peer review process – The League’s independent medical advisors, many who have extensive experience with NIH, were concerned that members of the review panel had ties or had coauthored research with individuals tied to the grant award.
- 2) Dr. Stern’s declaration – In 2014, Dr. Stern filed a declaration in opposition to the NFL’s proposed settlement of a class action lawsuit between the League and its players. He argued that the settlement would exclude a large number of players deserving of compensation. The League wanted to know if the declaration was included in the review process to evaluate whether it was indicative of bias.

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<sup>40</sup> Email from Jeff Miller, NFL to Dr. Maria Freire, FNIH (June 23, 2015) (On file with Committee Staff).

<sup>41</sup> Email from Dr. Maria Freire, FNIH to Jeff Miller, NFL (June 23, 2015) (On file with Committee Staff).

<sup>42</sup> Email from Dr. Walter Koroshetz, NIH to Dr. Maria Freire, FNIH (June 25, 2015) (On file with Committee Staff).

<sup>43</sup> Email from Dr. Maria Freire, FNIH, to Dr. Walter Koroshetz, NIH (June 26, 2015) (On file with Committee Staff).

<sup>44</sup> Email from Dr. Walter Koroshetz, NIH to Dr. Maria Freire, FNIH (June 26, 2016) (On file with Committee Staff).

<sup>45</sup> *Id.*

<sup>46</sup> *Id.*

<sup>47</sup> Email from Dr. Maria Freire, FNIH to Dr. Walter Koroshetz, NIH (June 26, 2015) (On file with Committee Staff).

<sup>48</sup> Democratic Report, at 16.

- 3) Majority of SHRP funds going to a single institution – According to Dr. Freire, the NFL was concerned about a large percentage of SHRP funds going to one institution.<sup>49</sup> Dr. Ann McKee, another BU researcher, previously received a grant through an earlier SHRP Research Plan. Dr. Freire told Committee staff that part of the goal of the SHRP was to seed multiple research programs.<sup>50</sup>

It is unclear to what extent these concerns were addressed during the June 29, 2015 phone call. On the call, however, Dr. Koroshetz raised the potential compromise of funding multiple groups and he suggested revisiting the grant that received the second highest score during the NIH review.<sup>51</sup> As noted in the Democratic staff report, this was a University of North Carolina (UNC)-led project which included two members of the NFL HNS Committee as principal investigators.<sup>52</sup>

While the NFL and its advisors certainly raised concerns about the NIH review process and award decision, it does not appear that anyone affiliated with the League had requested or expressed interest in an alternative path forward prior to this proposal being suggested by NIH. Further, there is nothing in the record available to Republican staff to suggest that the NFL advocated for consideration of this specific study prior to this suggestion by NIH or in subsequent discussions related to this grant.

Subsequent media reports disclosed that Dr. Richard Ellenbogen, Professor and Chairman of the Department of Neurological Surgery at the University of Washington School of Medicine, and Co-Chair of the NFL's HNS Committee, was listed as a “minor consultant” on the UNC grant application.<sup>53</sup> According to Dr. Ellenbogen, he had never seen the grant application and did not know he was named as an advisor.<sup>54</sup> He was, however, among the members of the HNS Committee that had concerns about the award decision process and he was a participant for at least a portion of the June 29, 2015 conference call with Dr. Koroshetz.<sup>55</sup>

Several days after the June 29, 2015 phone call, Dr. Ellenbogen sent an email to Dr. Koroshetz. He stated:

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<sup>49</sup> Briefing by Dr. Maria Freire, President and Executive Director, Foundation for the National Institutes of Health to staff of the Committee on Energy and Commerce (January 28, 2016).

<sup>50</sup> *Id.*

<sup>51</sup> Democratic Report, at 17.

<sup>52</sup> *Id.* Based on the information available to Republican staff, these individuals were not involved in the dialogue with NIH and FNIH.

<sup>53</sup> Steve Fainaru et al., ESPN, *NFL donations to brain research benefit league-linked doctors, raise worries about influence on science* (Feb. 4, 2016) available at [http://espn.go.com/espn/otl/story/\\_/id/14711203/nfl-donations-brain-research-benefit-league-linked-doctors-raise-worries-influence-science-lines](http://espn.go.com/espn/otl/story/_/id/14711203/nfl-donations-brain-research-benefit-league-linked-doctors-raise-worries-influence-science-lines).

<sup>54</sup> Briefing by Dr. Richard Ellenbogen et al. to the Republican staff of the Committee on Energy and Commerce (May 31, 2015).

<sup>55</sup> *Id.* Dr. Ellenbogen informed the Republican staff that he was only on the call for a few minutes before he had to drop off.

This is just a note to thank you for your time and listening to the concerns of your academic team who has long believed in the gravitas and importance of supporting NIH. I am not writing [as] the leader of the HNS committee albeit, that is a job I do without financial compensation and from that platform we have gotten 50 states to pass the Zack Lystedt Law and money put aside for important research. I am writing you as a person who has been very grateful for all the NINDS support my department in particular and the UW has received over the years. I am a solution oriented person. I very much like your suggestion that the route out of this issue will be awarding the grant to two discrete groups and splitting the money equally with an oversight committee. At the end of the day, it would be the right decision even if there were no concerns raised about the reviewer's bias or the Stern statement. It is both 100% in keeping with the successful 1<sup>st</sup> phase of the NIH/fNIH grants and it is in the spirit of "we need to follow the science by many research teams in an unbiased manner." Your solutions bring "equipoise" to the question and to the potential controversy down the line, and is simply the right thing to do. [T]hanks for suggesting it...As a surgeon/scientist laboring in the TBI world for years, I see the gift in it...<sup>56</sup>

The Democratic staff report does not acknowledge or address this correspondence. It does, however, describe Dr. Koroshetz's recollection of a subsequent phone call with Dr. Ellenbogen. According to Dr. Koroshetz, Dr. Ellenbogen reiterated his opposition to awarding the grant to the group from Boston University and suggested that he could not recommend the NFL fund the study.<sup>57</sup>

In a conversation with the Republican staff, Dr. Ellenbogen acknowledged a phone call with Dr. Koroshetz but strongly disagreed with the account of this conversation in the Democratic staff report. He does not recall expressing any opposition to funding the BU study.<sup>58</sup> Based on his recollection, he did not want to prevent Boston University from receiving funds, but supported Dr. Koroshetz's suggestion of incorporating multiple research teams.<sup>59</sup> He added that it would only harm a fellow NFL medical advisor if Boston University did not receive the grant because he understood or assumed that Dr. Robert Cantu would be involved in the research led by Dr. Stern.<sup>60</sup>

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<sup>56</sup> Email from Dr. Richard Ellenbogen to Dr. Walter Koroshetz (July 1, 2015) (On File with Committee Staff).

<sup>57</sup> Democratic Staff report, at 18.

<sup>58</sup> Briefing by Dr. Richard Ellenbogen et al. with the Republican staff of the Committee on Energy and Commerce (May 31, 2016).

<sup>59</sup> *Id.*

<sup>60</sup> *Id.* [It is unclear if Dr. Cantu was, in fact, involved in Dr. Stern's research. He is not listed as a Principal Investigator but he is affiliated with Boston University and his research has focused on similar concerns.

According to Dr. Ellenbogen, the phone call with Dr. Koroshetz occurred after Dr. Koroshetz reached out to him to discuss the proposal for funding two studies.<sup>61</sup> He recalls being informed that in order to fund two studies, NIH would need an additional \$15 million from the NFL.<sup>62</sup> Otherwise, NINDS may have to reallocate money, placing other NINDS research in jeopardy. At the time, Dr. Ellenbogen had a grant proposal, completely separate and unrelated to SHRP, under review at NINDS and he came away from the conversation with the impression that if the NFL could not provide the additional funds, NINDS would have to reallocate resources and his unaffiliated proposal would be at risk.<sup>63</sup> Jeff Miller informed the Republican staff that he assumed the two studies would split the existing \$16 million in SHRP funding until Dr. Ellenbogen informed him of the conversation with Dr. Koroshetz.<sup>64</sup>

The Republican staff has not reconciled the differing accounts of this phone call. However, both versions raise questions and concerns. If Dr. Koroshetz's account is accurate, it raises questions not only about the propriety of Dr. Ellenbogen's involvement, as suggested in the Democratic staff report, but also about Dr. Koroshetz and why he continued to engage Dr. Ellenbogen, as discussed below. If Dr. Ellenbogen's account is accurate, it raises concern about the propriety of an NIH employee discussing a funding request with an individual affiliated with a donor.

Based on the documents and information available to the Republican staff, there was no further contact among the parties until July 7, 2015, when Dr. Nabel reached out to Dr. Freire to introduce herself and request a phone call to discuss next steps.<sup>65</sup> It is unclear whether the two communicated before Dr. Freire had to leave the country; however, on July 10, 2015, Dr. Koroshetz contacted Dr. Nabel. He explained that he spoke to Dr. Freire and requested a time to talk with Dr. Nabel. He also provided additional information on the NIH's conflict of interest (COI) rules and the bottom line assessment that there were no conflicts between the peer review panel and the grant awardees for the SHRP grant.<sup>66</sup> On July 10, 2015, Dr. Nabel emailed Dr. Freire and stated, "Let's connect when you return. No rush. Walter and I had a good conversation. I am hopeful we will find a path through this."<sup>67</sup> The Republican staff is unaware of the substance of the discussion that took place between Dr. Koroshetz and Dr. Nabel.

In early August 2015, there were further discussions between FNIH and representatives from the NFL. At the time, there was a general understanding that Dr. Koroshetz would propose the idea of two studies; however, it was unclear how they would be funded. After a discussion

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<sup>61</sup> *Id.* [The Committee staff has not confirmed the exact date of this conversation].

<sup>62</sup> *Id.*

<sup>63</sup> *Id.*

<sup>64</sup> *Id.*

<sup>65</sup> Email from Dr. Betsy Nabel to Dr. Maria Freire, FNIH (July 7, 2015) (On File with Committee Staff).

<sup>66</sup> Email from Dr. Walter Koroshetz to Dr. Betsy Nabel (July 10, 2015) (On File with Committee Staff). [This conflicts with a previous email to Dr. Freire where he noted that some reviewers were barred from discussing due to conflict – see e.g. footnote 23]

<sup>67</sup> Email from Dr. Betsy Nabel to Dr. Maria Freire, FNIH (July 10, 2015) (On File with Committee Staff).

between FNIH and Dr. Nabel, on August 12, 2015, Dr. Freire emailed Dr. Nabel to provide an update on the situation. She stated:

I spoke to Walter; he is ready to go to Council (September 9<sup>th</sup>!) with the proposal we discussed. He will make the case that having more sites and broader range of investigators will make for a much stronger study. That said, he doubts Council will agree to fund the second grant if the monies have to come entirely from NINDS, if he can find the funds. I am pretty sure we could move the needle substantially if we could get the \$10M we discussed from NFL – Walter would have to find \$4M.<sup>68</sup>

Dr. Nabel responded, adding Jeff Miller to the discussion. She noted “I’m not sure the NFL will have incremental funds. Jeff will contract [sic] you both directly to discuss further... In the interest of supporting the best science and the health of current and former players, I hope we can find a resolution.”<sup>69</sup> After another discussion with FNIH, on August 17, 2015, Jeff Miller emailed Dr. Koroshetz, cc’ing FNIH. He stated “After a conversation with Dr. Freire and some understanding of the request for further NFL investment, I am hoping we can schedule a time to meet with in the next few days.”<sup>70</sup> While the parties attempted to find a time for this discussion, on August 19, 2015, Dr. Freire emailed Jeff Miller to relay the outcome of a conversation with Dr. Koroshetz. She stated:

I had a very good conversation with Walter. It is my understanding that he will present his proposal to fund the top 2 projects to the NINDS Council on September 9/10. He understands that there may not be any additional fund for this from you. Nevertheless, he is willing to go to Council with the proposal because he realizes that this strategy is scientifically very solid. Having said this, Walter is realistic and knows that it will be a long-shot to get the funds from his budget. He is open to finding alternative funding structures that might make the funding of the 2 proposals possible...<sup>71</sup>

There is evidence to suggest there was an additional phone call between all parties at the end of August 2015, likely in response to Jeff Miller’s request on August 17, 2015. Email records indicate there was a call scheduled on August 27, 2015, for “the follow-up discussion about the request for further NFL investment.”<sup>72</sup> The call was to include NIH, FNIH, and the NFL, as well as several medical advisors from the League’s HNS Committee.

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<sup>68</sup> Email from Dr. Maria Freire, FNIH to Dr. Betsy Nabel (August 12, 2015) (On File with Committee Staff).

<sup>69</sup> Email from Dr. Betsy Nabel to Dr. Maria Freire, FNIH (August 12, 2015) (On File with Committee Staff).

<sup>70</sup> Email from Jeff Miller, NFL to Dr. Walter Koroshetz, NIH (August 17, 2015) (On File with Committee Staff).

<sup>71</sup> Email from Dr. Maria Freire, FNIH to Jeff Miller, NFL (August 19, 2015) (On File with Committee Staff).

<sup>72</sup> Meeting Invite from Dr. Walter Koroshetz

Dr. Ellenbogen was unavailable to participate in the August 27<sup>th</sup> call, which prompted Dr. Koroshetz to contact Jeff Miller and ask “thoughts on how best to include Rich?”<sup>73</sup> Dr. Koroshetz also reached out to Dr. Ellenbogen directly to explain the purpose of the call. He stated: “Jeff called the meeting. I will take his lead. Definitely time is key as council is Sept 10. I am working off the last plan which seemed agreeable to all – to propose funding two studies. How council will vote is hard to say given price tag. But that’s the plan.”<sup>74</sup> Shortly thereafter Dr. Ellenbogen responded:

Thank-you Walter! I think the science will have bigger impact with two groups and especially if one has no history. This is an important question for people like myself who have a lab but also see the TBI patients whose parents are very conflicted about sports.<sup>75</sup>

The correspondence in advance of the August 27, 2015 call further illuminates the concerns raised by these events. The fact that Dr. Koroshetz reached out to the NFL to try to find a way to include Dr. Ellenbogen – who, based on Dr. Koroshetz’s account, was highlighted in the Democratic staff report for his inappropriate involvement and communication with NIH – suggests NIH either did not consider these communications to be inappropriate or failed to adhere to its own rules regarding donor influence<sup>76</sup>.

The NINDS Council met on September 9-10, 2015, and Dr. Koroshetz presented the concept of funding two studies. The Council rejected the idea and maintained support for the original Boston University proposal. Given the importance of the study, the Council also recommended that NINDS should fund the research, if necessary.<sup>77</sup>

The Democratic staff report concluded that after the Council decision, “the NFL should have committed to funding the CTE study in full.”<sup>78</sup> The report also concluded that “FNIH should have been clearer with the NFL about their obligation to fund the study.”<sup>79</sup> However, the feedback to the NFL from both FNIH and NIH shortly after the September Council meeting suggests a different set of expectations.

Shortly after the Council decision, on September 12, 2015, Dr. Freire emailed Jeff Miller regarding a conversation she had with Dr. Koroshetz. She reported: “Spoke with Walter. All good. He will look at other needs/options and propose times for a meeting. And a glad yes on potentially having joint/overarching governance if more than one group get [sic] funded for the

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<sup>73</sup> Email from Dr. Walter Koroshetz, NIH to Jeff Miller, NFL (August 25, 2015) (On File with Committee Staff).

<sup>74</sup> Email from Dr. Walter Koroshetz, NIH to Dr. Richard Ellenbogen (August 25, 2015) (On File with Committee Staff).

<sup>75</sup> Email from Dr. Richard Ellenbogen to Dr. Walter Koroshetz, NIH (August 25, 2015) (On File with Committee Staff).

<sup>76</sup> Democratic Staff Report, at 27.

<sup>77</sup> Democratic Staff Report, at 19.

<sup>78</sup> *Id.* at 26.

<sup>79</sup> *Id.* at 30.

longitudinal study.”<sup>80</sup> Jeff Miller responded, “how quickly can we move this along?”<sup>81</sup> Shortly thereafter, Dr. Freire emailed Jeff Miller and Dr. Koroshetz. She wrote:

Thank you both for your flexibility and willingness to work to achieve a path forward that will benefit patients and science. To this end, it would be beneficial to find a time in the next week or so to meet to discuss options for projects that achieve this goal. An in-person meeting would be best, although it might difficult to achieve; a phone conversation is the next best option (but a second-best from my perspective). Jeff, I understand that you would like to ask [Dr. Nabel] and perhaps one or two members of your Head, Neck and Spine Committee to join the discussion. Walter, I know you are looking at possible grants or topics that would nicely fit the purpose.<sup>82</sup>

Due to scheduling issues, this phone call did not occur until October 2, 2015. Based on these emails, however, it appears that the immediate response by NIH and FNIH after the Council meeting was to begin identifying additional research projects to be funded by the NFL. As documented in the Democratic staff report, when FNIH approached the NFL in mid-October about funding at least a portion of the BU grant, it appears the expectations had changed.<sup>83</sup> Further, even at that point, the request was presented as if the NFL had a choice in the use of SHRP funds.

If it was clear from the Council’s recommendation that NIH preferred for this study to be funded by SHRP, it is unclear why the initial feedback to the NFL focused on identifying additional funding opportunities. Directly or indirectly, this created a perception that NIH would fund the Boston University study and SHRP funds would go towards additional research.

If and when expectations changed, both NIH and FNIH failed to provide clear guidance on what was expected from the NFL. If NIH was concerned about having to use NINDS funds, they did not need to seek or wait for the NFL approval. Under the terms of the LOA, they could have requested FNIH invoice the NFL for the first year of that grant.

This narrative is not intended as a complete or definitive account of these events. Nor is it intended to assign blame or culpability. This grant award has created substantial public debate and controversy. Unfortunately, to date, there has not been a thorough and objective examination of these events. Therefore, this narrative highlights the areas of concern Republican staff believe must be incorporated in such a review to ensure that appropriate lessons are learned and applied to avoid similar outcomes in the future.

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<sup>80</sup> Email from Dr. Maria Freire, FNIH to Jeff Miller, NFL (September 12, 2015) (On File with Committee Staff).

<sup>81</sup> Email from Jeff Miller, NFL to Dr. Maria Freire, FNIH (September 15, 2015) (On File with Committee Staff).

<sup>82</sup> Email from Dr. Maria Freire, FNIH to Dr. Walter Koroshetz, NIH and Jeff Miller, NFL (September 15, 2015) (On File with Committee Staff).

<sup>83</sup> Democratic Staff Report, at 20-22.

### Areas for Review

This grant has already received tremendous public scrutiny. Much of that attention, to date, has focused on the actions of the NFL and its independent advisors – and to a certain extent, FNIH. However, as documented in this letter, there are additional questions and concerns about NIH's role in these events. These include, but are not limited to:

- 1) Why didn't the NIH require the NFL to pay pursuant to the terms of the agreement?

Under the terms of the LOA, the NFL was responsible for payments included in any executed Research Plan. Research Plan 5 was signed by all parties in July 2014. Therefore, when the NFL raised concerns about the grant decision in June 2015, NIH had no formal obligation to delay the award. While the NFL certainly could have resisted providing the annual installments required under Research Plan 5, the LOA contained an arbitration provision for “any controversy, claim or dispute arising out of or relating to this Agreement or concerning the respective rights or obligations of the parties hereto, including breach thereof...”<sup>84</sup> While this course of action may have undermined the relationship between the parties and thus compromised any potential future donations to SHRP, if FNIH and NIH were uncomfortable with the NFL's actions or concerned about the use of limited federal resources, it was an option for consideration at any point in the six months of discussion over this grant. Further, there is no evidence to suggest that the NFL would not have funded the study if so requested by NIH and FNIH. The months of collaborative discussion, however, created a situation where the use of SHRP funds apparently became more of a choice than a requirement.

- 2) If the actions of the NFL or its advisors were clearly inappropriate, as the Democratic staff report concludes, why did NIH and FNIH engage with representatives of the League and perpetuate the impression that the dialogue was appropriate? If confronted with inappropriate conduct by a donor, what are NIH's responsibilities to flag and address such behavior?

The Democratic staff report concludes that “[t]he NFL improperly attempted to influence the grant selection process at NIH.”<sup>85</sup> In the explanation of that finding, the report suggests that Dr. Koroshetz disagreed with the NFL's perception that their actions were proper and their concerns were raised in an appropriate manner.<sup>86</sup> The report adds:

“[Dr. Koroshetz] expressed that the stipulations in funding agreements have consistently expressed that the NIH scientific process is out of bounds for donors. Dr. Koroshetz was aware of no other instance where a

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<sup>84</sup> LOA, at 7.

<sup>85</sup> Democratic Staff Report, at 25.

<sup>86</sup> *Id.*, at 26.

donor raised objections to a grantee prior to the issuance of a notice of grant award (NGA).”<sup>87</sup>

Under the terms of the SHRP and NIH policy, a donor – in this case the NFL – should not be able to influence grant funding decisions after a research plan is executed. Therefore, if Dr. Koroshetz, or anyone at NIH or FNIH, felt that the NFL’s actions were inappropriate, they could have asserted their authority under the terms of the SHRP and proceeded with the NGA. There is nothing in the sequence of events – as they are currently understood – that suggests anyone from NIH or FNIH pushed back or attempted to correct the NFL. Instead, the NIH and FNIH engaged in a months-long collaborative dialogue with the League, thus reinforcing the perception that there was nothing improper about these interactions.

3) Did NIH adhere to the terms of the MOU regarding donor communications?

Under the terms of the MOU between NIH and FNIH for the SHRP, FNIH is responsible for all donor communications. This includes responding to “reasonable requests for information regarding the program,” and using “reasonable efforts to facilitate resolution of any Donor related issues that arise with respect to the applicable project.”<sup>88</sup> The majority of the NFL’s outreach, including the initial email from Dr. Pellman, was directed through FNIH. There were a number of examples, however, of NIH – specifically the Director of NINDS, Dr. Koroshetz – communicating directly with the League’s medical advisers. The evidence suggests that in many, if not most cases, NIH initiated these exchanges. While it appears that FNIH and NIH have taken steps to clarify roles and responsibilities for donor communications, it is important to ensure these measures will protect the integrity of the grant process going forward.

4) What are NIH policies for the control of non-public information, including information related to Notice of Grant Awards, as well as non-funded grant proposals? Were they followed in this series of events?

This entire episode has been complicated by apparent breakdowns in the control of non-public or confidential information. For example, if the NFL had not learned of the selected grantee prior to the announcement of the NGA, it is unlikely this would be an ongoing source of controversy or concern. In addition, NIH is not permitted to discuss non-public award decisions. Yet, at some point in this series of events, that no longer became a concern. Finally, NIH does not release non-funded grant applications. In this case, however, there appears to be extensive public knowledge about the details of specific grant applications that did not receive this award.

The control of confidential information is critical to the integrity of NIH’s mission and decision-making process. It is important to understand the circumstances of these disclosures to

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<sup>87</sup> Democratic Staff Report, at 26

<sup>88</sup> MOU, at 4.

ensure that NIH possesses and enforces appropriate rules, policies, or procedures to prevent unauthorized disclosures of confidential information.

- 5) How does NIH evaluate conflicts of interest between applicants and donors in public-private partnership grant programs such as SHRP?

There has been much speculation about whether individuals involved in these events had a clear conflict of interest due to their affiliation with the NFL and inclusion on a grant proposal to be funded by the League. There is little evidence to suggest anyone from or affiliated with the League advocated on behalf of a specific research team or grant application, especially in the events leading up to the Council meeting in September. Further, it does not appear that anyone from NIH – which, unlike FNIH, would have access to the details of the grant applications – raised concerns about conflict of interest. In fact, there is evidence to suggest that individuals from NIH reached out to some of the individuals in question to discuss this grant process.

It does, however, raise an important question about how NIH evaluates conflicts of interest between applicants and donors for grants funded through public-private partnerships. For example, the two Principle Investigators on the UNC grant were researchers who also serve as medical advisors to the NFL. While they did not ultimately receive the award, it does not appear that they were specifically excluded from the review due to their affiliation with the League.

While NIH may have clear rules and processes for evaluating these types of potential conflicts, given the controversy ignited by these events it is important to clarify how the Institutes evaluate these situations.

### **Conclusion:**

It is possible the NIH acted appropriately. Perhaps the same can be argued for other parties involved. In the opinion of the Republican staff, the Committee does not have all the facts necessary to reach those conclusions. However, the questions and concerns raised by these events are vital to the integrity of research and the grant award decision-making process. While this grant award has become an unfortunate distraction from the greater issue of improving the science of traumatic brain injury (TBI), given the significant public attention to these events, it is clear that a thorough and objective review by the HHS OIG is necessary. This review is important to the strength and integrity of the SHRP, as well as the independence of NIH decision-making. Further, this controversy has tarnished the reputations of some of the leading TBI researchers and medical experts in the nation. In the interest of the millions of Americans that suffer from these injuries every year, it is critical that any judgement about their conduct be based on a complete assessment of these events.

Thank you for your prompt attention to this referral. If you or your staff has any questions, please contact John Ohly or Brittany Havens of the Committee's Republican staff at (202) 225-2927.

Sincerely,



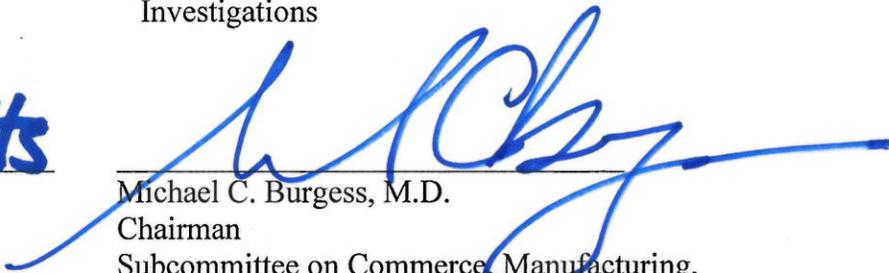
Fred Upton  
Chairman



Tim Murphy  
Chairman  
Subcommittee on Oversight and  
Investigations



Joseph R. Pitts  
Chairman  
Subcommittee on Health



Michael C. Burgess, M.D.  
Chairman  
Subcommittee on Commerce, Manufacturing,  
and Trade