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Grant Administration

The NFL-NIH Research Partnership: Why Congress is Worried



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In “Concussion,” released in theaters this past December, Will Smith plays the crusading forensic pathologist Dr. Bennet Omalu, on a mission to study and expose the risks to professional football players of chronic traumatic encephalopathy (“CTE”), a degenerative brain disease believed to be caused by repeated blows to the head and, as such, a particular risk in professional contact sports. A classic Hollywood tale of David and Goliath, the film chronicles the true story of Dr. Omalu’s struggle to publish the first research on CTE

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despite pressure from the National Football League (“NFL” or the “League”) intended to suppress his work and silence his message.

Based on recent real-life events, fans of the movie may get to enjoy a sequel. On Jan. 7, 2016, Democratic members of Congress¹ sent letters to Francis Collins, director of the National Institutes of Health (“NIH”),² and Maria C. Freire, president and executive director of the Foundation for the National Institutes of Health (“FNIH” or the “Foundation”),³ seeking information and documents related to the recent announcement that the NIH had awarded a \$16 million grant to researchers,⁴ including lead principal investigator Dr. Robert Stern at Boston University, to study CTE and, in par-

¹ The letters were signed by Frank Pauline, Jr., Ranking Member, House Committee on Energy and Commerce; Diana DeGette, Ranking Member, Energy and Commerce Subcommittee on Oversight and Investigations; Jan Schakowsky, Ranking Member, Energy and Commerce Subcommittee on Commerce, Manufacturing and Trade; and Gene Green, Ranking Member, Energy and Commerce Subcommittee on Health.

² <https://democrats-energycommerce.house.gov/sites/democrats.energycommerce.house.gov/files/Collins.NIH%20NFL%20Letter.2016.1.7.pdf>, visited Jan. 12, 2016.

³ <https://democrats-energycommerce.house.gov/sites/democrats.energycommerce.house.gov/files/Freire.FNIH%20NFL%20Letter.2016.1.7.pdf>, visited Jan. 12, 2016.

⁴ The grant is to approximately 50 researchers across 17 institutions.

ticular, how to diagnose the condition in living patients (the “CTE Study”).⁵ The request was driven by concerns that the NFL had inappropriately interfered with the NIH’s funding determination.

In 2012, the NIH announced that the NFL had donated⁶ \$30 million to the FNIH for the study of serious conditions in athletes, including concussions and CTE; this donation helped found the Sports and Health Research Program (“SHRP”). The FNIH website describes the SHRP as a partnership between the NFL, the NIH and the FNIH. However, the NFL is not a signatory to the Memorandum of Understanding (“MOU”) between the NIH and the FNIH outlining the roles and responsibilities in furtherance of the SHRP.⁷ Rather, the MOU defines the potential “Donors” to the SHRP as “many sports leagues and associations and others,” and contemplates that the FNIH will raise funds from Donors to support the SHRP. According to the NIH’s news release, the NFL’s donation to the FNIH is the “largest philanthropic gift the NFL has given in the league’s 92-year history.”⁸ The donation in part responded to public criticism of the NFL’s management of the concussion debate, including during congressional hearings in 2009.⁹ ESPN recently reported that the NFL objected to the NIH using the \$30 million grant to fund the CTE Study.¹⁰ According to ESPN’s reporting, although the \$30 million provided to the FNIH was allegedly “unrestricted,” and presumably available for the FNIH to disperse, the NFL “vetoed” the use of the money for the CTE Study, primarily because Dr. Stern has been a vocal critic of the NFL’s management of player concussions.

In the wake of the ESPN article, the FNIH issued a statement clarifying that “[t]he 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 early next year to support an additional study on CTE using funds from SHRP, which will double the support for re-

search in this area.”¹¹ The NIH may have valid reasons for funding the CTE Study without FNIH/SHRP money; however, the decision is in tension with the original Request for Application (“RFA”) issued by the NIH on July 29, 2014—the RFA in response to which Dr. Stern and others applied to fund the CTE Study—which states: “Publications and oral presentations of work conducted under this Cooperative Agreement are the responsibility of the PD(s)/PI(s) and appropriate Project Leaders and will require appropriate acknowledgement of the FNIH Sports Health Research Program and NIH Institutes support. Timely publication of major findings is required.” (Emphasis added.)¹² This requirement that the FNIH and the SHRP be acknowledged is consistent with the terms of the MOU, and suggests that, at the very least, the NIH anticipated contribution of SHRP money to the CTE Study when the original RFA was issued.

It is difficult to draw any firm conclusions about whether anything inappropriate has occurred without knowing (1) the actual terms of the NFL’s funding to the FNIH and (2) the specific facts behind the NIH’s recent decision to support the CTE Study with funds other than those managed by the FNIH. Although the MOU between the NIH and the FNIH suggests an active role for financial contributors to play in developing research concepts under the SHRP, as well as the opportunity for input into individual research plans funded through the SHRP, how that active role was described in the funding award executed by the NFL is a key question.¹³ Depending on the facts, it is conceivable that what occurred was entirely legal—within the scope of the FNIH’s authority and supported by the terms of the funding agreement, or simply a change in funding direction for the CTE Study appropriately within the discretion of the NIH. However, regardless of the law, the case raises other public policy and ethics questions that may need further evaluation. Answers to the fundamental ambiguities in the facts reported thus far, including the nature and the form of the NFL funding, may help uncover whether any missteps occurred. The information and documentation requested by Congress appear, not surprisingly, to be geared at trying to resolve the discrepancies.

The FNIH—What Role Does it Play?

The entity that received the \$30 million from the NFL in this case was the FNIH, a non-profit 501(c)(3) corporation established by Congress in 1990.¹⁴ The FNIH is not “an agency or instrumentality of the United States

⁵ At present, CTE can only be diagnosed post-mortem.

⁶ The original NIH press release used the terms “donation” and “gift”; however, subsequent media coverage has referred to the funding as a “grant.” The terms of the Memorandum of Understanding between the NIH and the FNIH, discussed herein, suggest that “private donations and sponsorships” will support the program. Because it is not yet known whether the specific funding transfer from the NFL was documented as a gift or a grant—and because the distinction of form is immaterial to this discussion—the terms are used herein interchangeably in reference to the NFL funding, with an effort to use the term most consistent with the context in which it appears.

⁷ The MOU, obtained by a reporter from STAT through a request under the Freedom of Information Act and made publicly available on-line (www.statnews.com), was executed by the NIH and the FNIH on Sept. 4, 2012, a day before the press release announcing the NFL funding to the FNIH.

⁸ <http://www.nih.gov/news-events/news-releases/national-football-league-commits-30-million-donation-foundation-national-institutes-health-support-medical-research>, visited Jan. 12, 2016.

⁹ http://www.nytimes.com/2009/10/29/sports/football/29hearing.html?_r=0, visited Jan. 12, 2016.

¹⁰ http://espn.go.com/espn/otl/story/_id/14417386/nfl-pulls-funding-boston-university-head-trauma-study-concerns-researcher, visited Jan. 12, 2016.

¹¹ <http://fnih.org/news/announcements/statement-on-shrp-funding>, visited Jan. 12, 2016.

¹² See National Institutes of Health/National Institute of Neurological Disorders and Stroke, RFA-NS-14-012, *Detect, Define and Measure the Progression of Chronic Traumatic Encephalopathy (U01)*, July 29, 2014.

¹³ Of note, the MOU contemplates that if the private-public partnership contemplated by the SHRP is completed or the MOU is terminated before completion, the FNIH retains control of donations that it has received under the MOU that were not disbursed prior to completion or termination. Unless the funding agreement with the NFL contains inconsistent and superseding terms, this would suggest that the NFL would not retain the right to “claw back” funds donated to the FNIH in support of the SHRP, even if the program terminates.

¹⁴ 42 U.S.C. § 290b.

Government”¹⁵ and is distinct from the NIH itself. It was established to support the work of the NIH, as well as “to advance collaboration with biomedical researchers from universities, industry, and nonprofit organizations.”¹⁶ The NIH transfers between \$500,000 and \$1.25 million to the FNIH each year from its own funds.¹⁷ Like other nonprofit recipients of funding awards—such as academic medical centers, hospitals and other research institutions—the FNIH is authorized to “accept gifts, grants, and other donations, establish accounts, and invest and expend funds in support of” certain permitted activities, including “the conduct and support of studies, projects, and research, which may include stipends, travel and other support for personnel in collaboration with national and international nonprofit and for-profit organizations.”¹⁸ It may “solicit, accept, hold, administer, invest, and spend any gift, devise, or bequest of real or personal property made to the Foundation”¹⁹ and is authorized to enter into the agreements and other transactions deemed appropriate by the FNIH’s executive director.²⁰ Nothing in the FNIH’s authorizing legislation requires that the monies it receives be unrestricted. The FNIH may “transfer funds to the National Institutes of Health and the National Institutes of Health may accept transfers of funds from the Foundation,” which funds then become “subject to all Federal limitations relating to federally-funded research.”²¹

The FNIH is given sole authority to carry out the activities described in its authorizing legislation.²² Although the director of the NIH serves as an *ex officio* member of the FNIH’s Board of Directors, no employee of the NIH may serve as an appointed, voting member.²³ The FNIH’s board is required to ensure the integrity of its operations, “through the development and enforcement of criteria and procedures relating to standards of conduct, financial disclosure statements, conflict of interest rules, recusal and waiver rules, audits and other matter determined appropriate by the Board.”²⁴ Furthermore, no FNIH officer, employee or board member may participate in any consideration or determination by the FNIH that would impact a financial interest held by the individual.²⁵ The FNIH is required to publish a financial report for each fiscal year, including information about “the source and amount of all gifts or grants to the Foundation of money” with “specification of any restrictions on the purposes for which gifts or grants to the Foundation may be used.”²⁶

¹⁵ 42 U.S.C. § 290b(a).

¹⁶ 42 U.S.C. § 290b(b).

¹⁷ 42 U.S.C. § 290b(l).

¹⁸ 42 U.S.C. § 290b(c).

¹⁹ 42 U.S.C. § 290b(h)(11).

²⁰ 42 U.S.C. § 290b(h)(12).

²¹ 42 U.S.C. § 290b(j)(10). The MOU provides that the FNIH will support the SHRP with donated funds “either directly or through contributions to the NIH OD Conditional Gift Fund or Conditional Gift Funds of appropriate Institutes and Centers. The FNIH will hold payments from the Donor(s) and disburse funds according to the schedule specified in the Research Plan mutually agreed upon with NIH, FNIH and the applicable Donor(s).”

²² 42 U.S.C. § 290b(c)(3).

²³ 42 U.S.C. § 290b(d)(1)(F).

²⁴ 42 U.S.C. § 290b(j)(1).

²⁵ 42 U.S.C. § 290b(j)(2).

²⁶ 42 U.S.C. § 290b(j)(4).

The FNIH’s 2012 Annual Report notes the NFL’s “donation” of \$30 million, and lists the NFL as one of two donors providing in excess of \$5 million to the FNIH. However, any contractual restrictions attendant to that donation are not apparent from the report itself, other than to acknowledge that its purposes, while not yet finalized, include brain injury as potential areas of study, among others.²⁷ ESPN has reported that certain audited financial statements for the FNIH “describe the league’s gift as a ‘conditional contribution’ that allows the NFL to cancel the funding. The previously unreported statements, posted on the organization’s website, list the NFL’s donation under contributions ‘subject to donor conditions.’ Although those conditions are not specified, the NFL grant is one of several described as ‘conditioned upon meeting certain milestones and/or the funder not canceling.’”²⁸

Although the full picture has yet to emerge in this case, it appears that, for whatever reason, the FNIH did not transfer any SHRP money to the NIH in support of the CTE Study.

Research Gifts, Grants and Contracts—Distinctions With a Difference?

As previously discussed, the exact form and any terms of the funding provided by the NFL to the FNIH are not yet clear. Research funding from both private and public sources can take various forms and come unrestricted (i.e., “no strings attached”) or with very specific terms and conditions. When the NIH itself funds research grants and contracts in response to requests for proposals, those monies also come to the grantees and contractors with various terms and conditions, many prescribed by law. When an institution receives money from an industry partner such as a pharmaceutical company or a private foundation (i.e., a 501(c)(3) organization similar to the FNIH), the degree of control retained by the funder can fall along a fairly wide continuum and depend on the negotiated agreement.

Industry sponsors may convey financial support to research projects through very specific services contracts with research sites (for example, a clinical trial agreement through which the company hires a site to carry out a specific trial, pursuant to a specific protocol, under the specific terms of the agreement), in which case the sponsor exercises a great degree of control over how the research budget is spent. Alternatively, industry sponsors and private nonprofit foundations may support institution- or investigator-initiated research projects, sometimes in response to institutional requests for funding, in the form of sponsored research agreements. The use of funds provided through sponsored research agreements is also subject to the negotiated terms of the agreement, but sites may enjoy greater rights and discretion as a result of playing a larger role in developing the project. Institutions also may receive general funding support for certain areas of research (i.e., a research grant to support “oncology

²⁷ Foundation for the National Institutes of Health, *Collaboration for Innovation: 2012 Annual Report*.

²⁸ <http://espn.go.com/espn/print?id=14526955>, visited on Jan. 12, 2016.

research” at an institution, or the research endeavors of a specific laboratory, without many details as to the specific projects that will be pursued), or the money may be received as a “gift,” as opposed to a sponsored research grant or contract. Gifts are generally processed differently than research grants and contracts, through an institution’s development office as opposed to its grants and contracts office and subject to different standards for overhead. Although gifts may be broad and unrestricted in nature—such as those provided in support of an institution’s general missions of education, research and patient care—they can also have terms and conditions, which may restrict the use of the funds accordingly. In sum, no matter what form research funding takes (i.e., contract, grant or gift), it may be truly unrestricted—in which case the funder cannot direct future use—or it can come with terms, conditions or other parameters. If a funding agreement or document of gift provides the funder with certain approval rights, it would generally be legally permissible for the funder to exercise those in the form of an objection to the recipient using the funds in a manner that would violate the parties’ agreement.

Here, it is the FNIH (a 501(c)(3) nonprofit organization) that received funding from the NFL (a private organization) ostensibly to support certain work that would be pursued in collaboration with the NIH (a government agency), presumably through the normal procedures by which the FNIH transfers resources to the NIH in accordance with the terms of the MOU between the FNIH and the NIH. In essence, the FNIH sits as a management and disbursement entity for the NFL’s funds, responsible for allocating those funds to projects pursued by the SHRP in collaboration with the NIH and any other collaborating academic sites. Under its authorizing statute, the FNIH is explicitly prohibited from using the funds it receives to conduct its own research in a way that would compete with the NIH.²⁹ Although it is not the entity conducting the funded research, the FNIH would nonetheless be obligated to allocate the funds in accordance with the terms of any agreement with the NFL, including any rights of control the NFL negotiated. Knowing the terms of that agreement is critical to understanding what type of input, if any, the NFL was permitted to have with respect to the ways in which the money was used, and whether the FNIH—or the NIH for that matter—was in a position to trump those rights. If the NFL had certain residual rights, exercising them may not be a legal problem per se, but it certainly could be a public relations concern given the type of media coverage this has garnered.

Although it has been reported and acknowledged in the letters from Congress that Dr. Stern and the other recipients of the recent \$16 million grant were selected through the NIH’s scientific merit review process, with the implication that the NFL should not be able to override this independent merit determination, these are really separate issues. That the NIH’s access to the funds managed by the FNIH may be subject to any associated

²⁹ 42 U.S.C. § 290b(j)(9)(A) (“The Foundation shall exist solely as an entity to work in collaboration with the research programs of the National Institutes of Health. The Foundation may not undertake activities (such as the operation of independent laboratories or competing for Federal research funds) that are independent of those of the National Institutes of Health research programs.”)

terms and conditions is not necessarily inconsistent with, or violative of, the NIH’s own scientific merit review process. They are cumulative requirements, as one can easily envision a research grant agreement between the NFL and the FNIH through which the NFL agrees to make this money available to fund certain areas of research pursued by the SHRP that both pass the NIH’s internal scientific merit review process—a necessary pre-condition—and also meet the approval of the NFL in certain regards (or otherwise meet certain criteria that the parties have agreed to in advance through the negotiated funding contract). More troubling would be a scenario where the NFL was able to require that the NIH fund certain research using the NFL’s donated funds *whether or not* the research passed the NIH’s standard merit review (an allegation not at issue in this case).

As noted above, the FNIH is the sole entity responsible for the management and distribution of the funds it receives; however, its stated purpose is to raise “private-sector funds for a broad portfolio of unique programs that complement and enhance the NIH priorities and activities.”³⁰ ESPN reported, based on an anonymous source, that upon seeking support from the FNIH in connection with its decision to fund Dr. Stern’s study, the NIH encountered “delays,” resulting in an ultimate decision by the NIH to fund the study without contribution from SHRP funds.³¹ If the NIH in fact encountered “delays” when it sought access to SHRP funds for the CTE Study, it will be crucial to understand *why* that occurred in order to identify anything untoward. If the FNIH was, in fact, reluctant to contribute SHRP funding to this particular NIH grant, it will be material whether such reluctance was driven by funding terms and conditions appropriately negotiated with the NFL or, if the funds were truly unrestricted, a more troubling exercise of influence or pressure by the NFL. The facts have simply not yet been sufficiently developed and substantiated to answer these questions. The production of information by the NIH and the FNIH in response to Congress’s request—due by Feb. 1, 2016—will hopefully bring much needed clarity.

Do Conditional Grants Offend Academic Freedom?

A larger issue highlighted by this case is whether, as a policy matter, we should tolerate certain types of conditional funding, particularly in the quasi-public realm of an entity such as the FNIH. Comparing the arguably permissible restrictions or conditions that often attach to a funding grant at the time it is made with the impermissible restrictions on the dissemination of results once a funded project has occurred provides an illuminating contrast. It is arguably acceptable, if supported by the terms of the funding agreement, that the funder retains the ability to approve the selection of the projects to which the money will go and the responsible

³⁰ <http://www.nih.gov/news-events/news-releases/national-football-league-commits-30-million-donation-foundation-national-institutes-health-support-medical-research>, visited Jan. 12, 2016.

³¹ http://www.nytimes.com/2015/12/23/sports/football/grant-of-nearly-16-million-for-cte-researchers.html?hp&action=click&pgtype=Homepage&clickSource=story-heading&module=first-column-region®ion=top-news&WT.nav=top-news&_r=0, visited Jan. 12, 2016.

principal investigators (those would simply be negotiated terms of an award). However, it would be inconsistent with research ethics and acceptable standards (including those of the International Committee of Medical Journal Editors) for the terms of a research grant to provide the research funder veto rights over the publication or presentation of research results once the research has begun. That's a fairly blurry line, because it contemplates a world where research funders can say, "we do not permit you to direct money to investigators that we think are unfriendly to our agenda"—the lurking allegation in the press coverage of this case—but they could *not* say, "we will give you this money and see what your findings are, and only if we agree with the results may you put it out for public consumption."

Concerns about undue influence by private parties on the NIH's allocation of funding awards are driving this story in both Congress and the media. The congressional authors of the Jan. 7, 2016, letters cite the "NIH's independent peer review process" as a "cornerstone of the NIH research mission" that protects against bias in funding decisions, and note concern "about the potential implications of outside entities attempting to exercise 'veto power' or other influence over the selection of NIH research applicants." This concern may conflate the roles of the NIH and the FNIH; as noted above, a failure by the FNIH to provide funds to the NIH in support of a project the NIH has identified as meritorious (even if allegedly based on inappropriate pressure being brought to bear on the FNIH) is not necessarily the same thing as third-party interfering with the NIH's independent merit review process. In the end, the CTE Study was in fact funded by the NIH, just without support from the FNIH. As this case is further unpacked, it may prompt critical thinking of how the FNIH functions in relation to the NIH.

In 2005, in the wake of scandal and public outcry, the HHS instituted more stringent ethics rules designed to reduce conflicts of interest in HHS employees, including those employed by the NIH. Notwithstanding the regulatory overhaul, Congress held hearings in 2006 to explore what was described by the then chairman of the House Energy and Commerce's Subcommittee on Oversight and Investigations as "the largest scandal in all of NIH's existence."³² Notably, the NIH ethics rules do not speak to potential conflicts of interest at the organizational level, or whether funding to the NIH, as an

agency, from a private entity through the FNIH should be subject to similar protections and limitations.³³

The potential vulnerability for the NIH and the FNIH will be if this was, in fact, an unrestricted gift and the investigation ultimately demonstrates that the reason the FNIH declined to provide the NIH with the NFL grant money for the CTE Study was because of pressure exerted by the NFL in response to the selection of Dr. Stern as the principal investigator. If the funds came to the FNIH without restriction, then their disbursement would presumably be subject only to the FNIH's authorizing legislation, its applicable policies and procedures for how funds are allocated—including any operating principles for the SHRP—and the terms of the MOU. A decision by the FNIH not to provide the NIH with access to the NFL funds, or a decision by the NIH to use other public monies in lieu of the NFL funds, could garner criticism, and potential legal action, if unsupported by the NFL/FNIH agreement and done as a result of the NFL's disagreement with who will serve as the principal investigator. Even assuming the FNIH declined to apportion these funds to the CTE Study out of respect for legitimately and appropriately negotiated funding conditions, this case may cause Congress to examine whether the FNIH, as an entity legally authorized to solicit private funds to support the mission of the NIH, should be permitted to accept certain types of restrictions from private donors.

Conclusion: What's Next?

It will be interesting to watch what comes of Congress's factual investigation. What we do know is that Congress has good reason to be invested in this issue. One can only assume that the NFL's commitment to fund research into player injury has in part been motivated by the prior congressional hearings and widespread public criticism around the League's management of CTE and concussion concerns. When the full range of facts is known, a nuanced legal analysis may reveal whether the FNIH should have committed—and the NIH should have accepted—the SHRP funding to the CTE Study. However, regardless of that legal analysis, the potential threat to public trust raised by this case is unavoidable. Congress has a strong interest in exploring whether the NIH's partnerships with private organizations such as the NFL risk undermining the public's trust in the NIH's independence, and for that reason one can expect a thorough congressional review and continued media coverage for the foreseeable future.

³² http://www.pharmatimes.com/Article/06-09-15/Ethics_failures_“the_worst_scandal_in_NIH_history_”_says_US_legislator.aspx, visited Jan. 15, 2016.

³³ See 5 C.F.R. Parts 5501 and 5502.